Health information technology evaluators need to distinguish between intervention efficacy as assessed in the ideal circumstances of clinical trials and intervention effectiveness as assessed in the real world circumstances of actual practice. We have developed a framework for implementation fidelity evaluation with methods for estimating intervention effectiveness and efficacy. We apply this framework to evaluate an ongoing health information technology clinical trial.

Introduction: Medical researchers have drawn distinctions between two types of tests for medical technologies. Tests of efficacy determine how a medical technology works under ideal circumstances such as those observed in clinical trials; whereas, tests of effectiveness determine how the technology works in usual circumstances such as those found in actual practice. We defined a framework that estimates intervention efficacy and effectiveness, and that may assist researchers in determining whether system failures are due to information interventions or to the methods of their implementation.

Methods: The Oxford Implementation Index identifies the components of implementation fidelity:1 (1) treatment design, (2) treatment delivery, (3) treatment uptake, and (4) context factors. Statisticians have devised methods to determine the impact of non-adherence on clinical trial results.2 The Rubin Causal Model (RCM) provides a method for estimating the average causal effect of a treatment. It is based upon the distinction between compliers (patients who will adhere to their assigned treatment) and never-takers (patients who will not adhere). This distinction allows us to separate an intervention’s efficacy in adherers alone from its effectiveness in both adherers and never-takers.

Results: By combining the Oxford Implementation Index and the Rubin Causal Model,1,2 we created a framework for evaluating implementation fidelity, with the Index defining the evaluation components and the Model providing the evaluation method. We demonstrate the use of this framework using the “Showing Health Information Value in a Community Network” study (HIT Value), a demonstration project that coordinates health care delivery for 17,000 Medicaid beneficiaries in Durham County, North Carolina. The HIT Value study compares three information interventions which are prompted by missed tests and appointments, inappropriate use of the emergency room, and hospital admissions. They include email alerts to case workers, mailings to patients, and periodic reports to outpatient clinics. For each alert type, we specify performance parameters and metrics that permit the estimation of adherence rates for clinicians, case workers and patients, and allow us to determine how non-adherence impacts the study’s outcomes. All analyses are initially performed using the data as collected. These results estimate the relative effectiveness of our three information interventions. Next, the analyses are repeated using the Rubin Causal Model. These results estimate the relative efficacy of our three information interventions.

Conclusion: We have defined a framework for implementation fidelity evaluation which measures the efficacy and effectiveness of information interventions.

Reference List