

## Methodologic Issues in Health Informatics Trials – Today's Decisions for Tomorrow's Improvements

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### Abstract

### Background

The Canadian healthcare system is in the midst of employing electronic clinical information and communication technologies. Decision support systems, electronic medical records and other health information systems are increasingly produced, evaluated, and applied in different clinical settings with high hopes of improving the quality of patient care. While the number of high quality studies in health informatics has been growing, many interventions lack positive effects on important patient outcomes or these effects are short-term. In addition, trials evaluating health information technologies experience a number of common problems related to design, organization, and methodologic decisions made throughout different stages of clinical intervention (e.g., recruitment, randomization, data collection and analysis, follow-up). These methodologic decisions can influence the results and conclusions of studies, and thus directly affect the willingness of healthcare providers and payers to adopt and use health information technologies. Therefore, valid methods are essential for accurate assessment of benefits and cost-effectiveness of health information systems in clinical trials. E-health studies tend to be complex interventions that involve a range of active components and multiple targets (e.g., patients, healthcare providers). Part of the complexity is establishing which factors in the intervention determine success or can explain variation in effectiveness across different settings. Unlike regular randomized trials, methodologic guidelines for conducting such multifaceted health informatics studies virtually do not exist.

### Methods

We describe methodologic, logistic, and statistical issues that have to be considered when planning and implementing controlled clinical trials of complex interventions in health informatics. Some of these issues (e.g., choice of randomization, blinding, intention-to-treat, sample size determination, follow-up) are common to clinical trials in other areas. Other challenges, such as use of process outcome measures, validation of composite scores, problem of contamination, participant's compliance, missing data, cost-effectiveness analysis, and generalizability of findings, might be particularly prevalent among health informatics studies due to their complexity, expensiveness, use of multiple data sources, and lack of clearly described "good clinical practices". These issues will be discussed within the framework of COMPETE III project (Computerization Of Medical Practices for the Enhancement of Therapeutic Effectiveness), which investigates the impact of electronic medical records linked to clinical decision-support systems on quality and efficiency of patient vascular care in Ontario. The COMPETE III clinical trial launched in January 2005 and is now near its completion.

## **Findings and Conclusions**

Presented key methodologic and implementation decisions that were made at different stages of the COMPETE III trial as well as some alternative solutions could be generalized to other practice-based clinical studies involving electronic medical technologies and the quality and cost-effectiveness of patient's care.