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Introduction

Computerized decision support systems (CDSS), electronic medical records (EMR), and other health technologies are increasingly produced, applied, and evaluated in clinical study settings. Many of these health informatics trials (HITs) are complex interventions that involve a range of active components and multiple targets (Figure 1), and experience common problems related to design, methodology, and analysis. These issues can influence the results and conclusions of studies, and affect the acceptance of health information technology.

We describe methodologic, logistic, and statistical challenges that should be considered when planning and implementing complex HITs, using the example of the COMPETE III project, a trial investigating the impact of a shared decision-support system on quality of patient care.

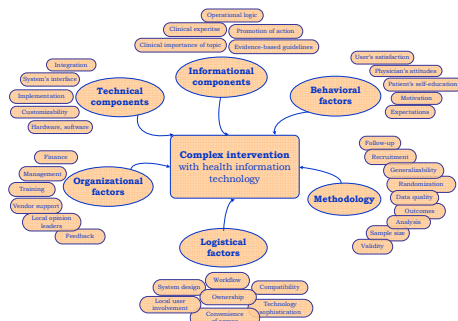


Figure 1. Components of complex interventions

Background

COMPETE III trial (2005–2006) investigated the impact of individual patient-based electronic decision support system integrated with practice EMRs on vascular risk management.

The study recruited 50 EMR-using family physicians from 18 sites in Ontario. Over 1100 patients with vascular risk factors or vascular disease were randomized to two arms – Intervention (complex vascular management program) or Control (usual care). The COMPETE intervention had individualized, web-based monitoring and advice regarding 15 vascular risk variables (blood pressure, cholesterol, smoking, etc.) with the vascular tracker (VT), support from clinical care coordinators, and automated telephone reminder support (Figure 2).

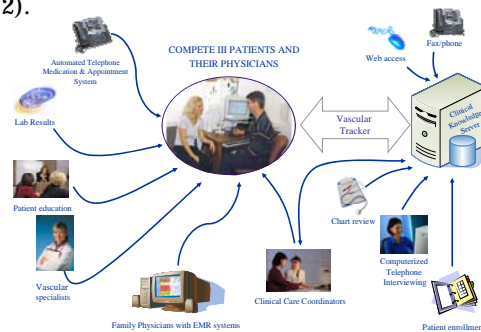


Figure 2. COMPETE III trial overview

Methodologic issues (Figure 3)

Randomization. In our decision we considered the degree of contamination (less than 30%), ability to recruit providers (physicians were unwilling to take a chance to be randomized as controls), and cost-effectiveness of running a cluster RCT (loss of power would not be compensated by the improved precision). COMPETE III used individual-level stratified randomization; sample size and analysis was adjusted for a previously measured (small) clustering effect.

Blinding. In our trial patients, physicians, and clinical care coordinators could not be blinded. The measures to prevent

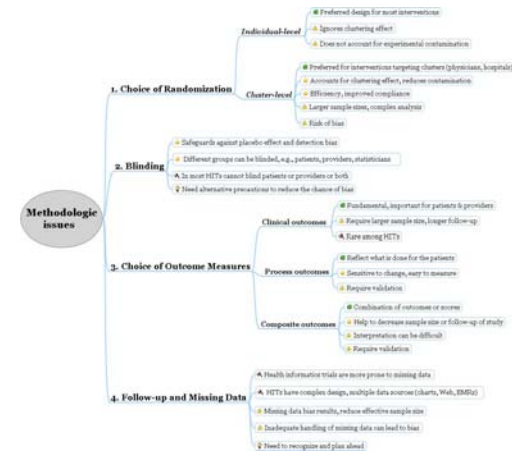


Figure 3. Methodologic issues in COMPETE III

bias included concealed allocation, blinding of trial investigators and statistician, and analysis of data by intention-to-treat principle. The data collection and entry procedures were the same for the both groups.

Outcome measures. Our primary outcome was a process composite score, a sensitive measure made of vascular risk variables that are necessary for the clinical outcomes and supported by high-level evidence. Secondary outcomes were achievement of clinical targets, satisfaction, usability, quality of life, medication adherence, and barriers to implementation.

Missing data. We used a number of strategies to prevent incomplete data or data loss (incentives and feedback to increase compliance, monitoring of data completeness, standardization of data collection, security and on-line safety measures), as well as appropriate statistical techniques for missing data (multiple imputation techniques, sensitivity analysis).