

Electronic Decision Support System to Reduce Vascular Risk Improved Processes But Not Outcomes

Holbrook A, Pullenayegum E, Thabane L, et al. Shared electronic vascular risk decision support in primary care: Computerization of Medical Practices for the Enhancement of Therapeutic Effectiveness (COMPETE III) randomized trial. Arch Intern Med 2011;171:1736-44.

Study Overview

Objective. To determine whether the use of computerized decision support software for patients at high risk for vascular disease improved care and clinical outcomes.

Design. Randomized controlled trial.

Setting and participants. Community-based primary care practices in Ontario, Canada, using electronic medical records (EMRs). Researchers contacted patients within the practices aged 55 and older who had previously been diagnosed with diabetes mellitus, hypertension, hypercholesterolemia, MI/angina/coronary artery disease, stroke/TIA, or peripheral vascular disease. Patients had to have been seen by their primary physician within the previous 12 months, and nursing home patients and those with cognitive impairments or limited English proficiency were excluded. Consenting patients were then stratified by physician ID and block randomized in groups of 6 to the intervention or control arm.

Intervention. Patients and their providers were given a

web-based risk factor management system to use during and between office visits. The system identified 8 key areas: blood pressure, LDL level, BMI, aspirin use, smoking status, physical exercise, fruit and vegetable intake, and psychosocial well-being (plus, for diabetics, HbA1c and urinary albumin). The website allowed patients and physicians to see the patient's progress on each of the risk factors, and offered advice on how to improve. Patients and providers were asked to review the status of these risk factors at each visit, and patients could also independently access the web page from home. Further, patients were sent a paper copy of their risk factor profile before each scheduled doctor's visit. They were encouraged to schedule quarterly visits with their primary physician. Control patients received usual care. Total follow-up lasted 12 months.

Main outcome measures. The primary outcome was a change in the "process composite score." This score denoted how well a physician achieved frequency targets for checking on the risk factors (eg, LDL should

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be checked every 6 months). The main secondary outcome was a change in the “clinical composite score,” which tracked attainment of clinical outcome goals. Researchers calculated the mean number of risk factors that were on-target (eg, LDL < 96.5 mg/dL) and the percentage of patients with improvement in their clinical variables. Patients were also followed for vascular adverse events such as stroke or MI.

Main results. Of 6877 patients contacted regarding the study, 1179 consented and met eligibility criteria to be randomized to the intervention (n = 545) or control (n = 557) group. All analyses were intention-to-treat. Overall, the group was made up of 53.4% women, with a mean (SD) age of 69.3 (8.6) years. The intervention and control groups were similar with respect to baseline covariates including educational level and relevant comorbidities. The provider group was a relatively seasoned one, with a mean of 20.8 years in practice at the time of the study. Also of note, despite the web-based nature of the intervention in this study, 27.8% of participants noted that they never used the internet. Although patients found the information on the web interface useful, 86.7% of them stated that they preferred the paper mailings because they were not interested in, or did not like using, computers.

Generalized estimating equations were used to evaluate the outcomes of process composite score and clinical composite score. Intervention patients had a significantly greater improvement in the process measures score (4.7 points, max score 27; 95% confidence interval [CI], 3.6–5.7) than control patients, and were more likely to rate their continuity of care as improved (odds ratio [OR], 4.2; 95% CI, 3.0–5.8), as well as their perceived ability to improve their vascular health (OR 3.1; 95% CI, 2.4–4.0). Despite this, there were no differences between the intervention and control groups with respect to clinical outcomes of BP, LDL levels, BMI, physical activity, diet or psychosocial scores. ASA use was minimally improved in the intervention arm, relative to the control group (OR, 1.44; 95% CI, 1.07–1.94). The researchers also used chi-square testing to compare the rate of vascular events between groups and found no difference ($P = 0.75$) during the 1-year follow-up period.

Conclusion. In this large, primary-care based RCT of a computerized shared decision support system for

vascular risk factors, the researchers found that, while process measures were improved by years’ end, there was no change in clinical outcomes as a result of the intervention.

Commentary

EMRs and their associated technologies have been widely publicized as a means of improving patient care. They are believed to do this through reducing costs by avoiding duplicate or unnecessary testing and prescribing, helping prevent errors and facilitating the practice of evidence-based medicine through decision support [1]. Despite these theoretical benefits, systems are costly to implement and maintain, and uptake of the technology has been somewhat limited in the United States. A 2007 survey estimated that only about a third of office-based physician practices in the United States were using some form of EMR [2].

Many practices with EMR technology are attempting to involve patients in their own care by providing internet portals through which they can view components of their medical records. These sites and other interventions like them are a form of shared decision support, in theory guiding both patient and provider toward better care and better outcomes. Previous studies of shared decision support technology have been limited by lack of testing in the “real world” of community practice settings [3] and have predominantly shown no difference in clinical outcomes as a result of the technology [4]. Because chronic disease accounts for up to three-quarters of cost in US health, and vascular disease in particular has extremely high morbidity and mortality, effective interventions with these high-risk patients are sorely needed.

In this study, the investigators created a computerized shared decision support system for high-risk patients in an attempt to improve both process measures and clinical outcomes around vascular health. As the authors point out, this study is novel in that it is quite a large randomized trial of a computerized intervention in a setting of small community practices. The findings that process measures, but not clinical outcomes, were improved as a result of the intervention are in keeping with the preceding literature cited by the authors.

While the intervention itself was designed to be user-friendly both for patients and providers, a large percentage of their study population were not internet users and the majority of patients later disclosed that

they didn't really use the internet portal, but instead preferred the paper mailings of information. This is a very important finding and it calls into question the conclusion that online shared decision support software is not effective at improving clinical outcomes. Rather, this kind of technology may be very effective, just in different patient populations such as younger, more computer-savvy groups. This is certainly worth considering given that older patients with multiple chronic illnesses are the target of many clinical outcome interventions.

The finding that process measures were improved indicates that, from the provider side of the equation, decision support software can be helpful. Unfortunately, remembering to check a patient's HbA1c regularly or document blood pressure readings is of limited impact if the results are persistently abnormal. The one clinical outcome that did show improvement in the intervention group was aspirin (or other antiplatelet agent) use. Unfortunately, this outcome is really more of a process measure—dependent on the provider to prescribe, and not actually following compliance by the patient. Measurement of vascular adverse events, while interesting, may have been limited due to only 12 months of follow up. Even in this high-risk group, events were likely rare enough that a real difference between groups would have been hard to spot.

Applications for Clinical Practice

EMRs and associated shared decision support software have the power to dramatically improve and standardize the physician side of care, but their impact on patient outcomes may be limited. When initiating what are supposed to be “patient-centered” programs, we must ensure that the modality of the intervention is truly appropriate for, and accepted by, the target population. Patients ought to be presented with health information in a format they feel comfortable with for them to have a chance at meaningful behavior change and better outcomes.

—Review by Kristina Lewis, MD, MPH

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