AN INTERVIEW WITH GLORIA CORONADO AND BEVERLY GREEN

Principal Investigators of Strategies and Opportunities to Stop Colorectal Cancer in Priority Populations (STOP CRC)

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At the April 2015 NIH Collaboratory Steering Committee Meeting, Drs. Coronado and Green presented an update of the STOP CRC UH3 activities (PDF slides). STOP CRC is a large-scale, cluster-randomized, pragmatic trial testing an automated mail approach to raising rates of colorectal cancer screening. It encompasses 40,000 patients at 26 participating community health centers in Oregon and California. In this intervention, the colorectal cancer screening involves mailing a fecal immunochemical test (FIT), or "FIT Kit," to the homes of eligible patients.

In the first phase of the trial, the electronic medical record (EMR) tools needed for the intervention were customized through consultation with EMR specialists and an advisory board of clinicians, policymakers, and payers. The intervention was introduced to participating clinics in the second phase, followed by refinement of the EMR tools. A major accomplishment of this phase has been the implementation of a well-validated quality improvement approach called Plan-Do-Study-Act, or PDSA. The use of PDSA has helped to identify implementation issues and unintended consequences and has empowered clinics to actively address local conditions.

> Plan-Do-Study-Act encourages adaptation of the intervention at local settings and helps with patient engagement at the clinics

Challenges During the UH3 Phase

The PIs described two major challenges of the STOP CRC trial. The first was how to maintain a high level of engagement among participating clinics in the face of leadership turnover at both the medical director and provider levels. The study team addressed this challenge by meeting regularly with leadership teams and by establishing an advisory board and other infrastructure to help leaders stay fully engaged despite performance pressures existing at community clinics.

The second challenge was how to design an analytic plan that is flexible enough to account for the use of real-time EMR tools and adaptable enough for community health care settings. Updates in real-time meant that the lists of eligible and active patients at the clinics were continuously changing, which caused discordance between the lists viewed by clinic staff monthly or quarterly and the back-end reports gathered for research. The team remained transparent about these pragmatic design issues and consulted with an expert panel as well as the Collaboratory's Biostatistics and Study Design Core for advice. These consultations were especially helpful in showing the importance of secondary

analysis using screening rates calculated via Uniform Data Systems, or UDS, which is of great interest to the clinics. UDS scores measure performance on a range of health care issues including colorectal cancer screening.

In the coming year, the STOP CRC intervention will be rolled out to participating usual care sites, where the study team will adapt the EMR tools with a focus on maintenance and sustainability of the program. The PIs expect that additional research questions will emerge in the coming phase. They observed that, while their UH2 pilot was as comprehensive as possible and provided a useful way to begin the research, important learning has continued throughout the UH3 phase.

Overall, findings from the STOP CRC trial support the idea that screening with home-based FIT is highly effective, inexpensive, and easy to deliver. Further results from this pragmatic trial will likely provide evidence to support broad adoption of a direct-mail approach, long-term sustainability of the intervention, improvements in program efficiency via PDSA cycles, and data to drive policy changes that support the use of FIT for colorectal cancer screening.

For more information on STOP CRC, visit the Collaboratory website.

> A big challenge is whether the analytic plan is flexible enough for pragmatic study with real-time tools

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