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Short communication

Tailored information increases patient/physician discussion of colon cancer risk and testing: The *Cancer Risk Intake System* trial

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ABSTRACT

Assess whether receipt of tailored printouts generated by the *Cancer Risk Intake System* (*CRIS*) – a touch-screen computer program that collects data from patients and generates printouts for patients and physicians – results in more reported patient-provider discussions about colorectal cancer (CRC) risk and screening than receipt of non-tailored information.

Cluster-randomized trial, randomized by physician, with data collected via *CRIS* prior to visit and 2-week follow-up telephone survey among 623 patients.

Patients aged 25–75 with upcoming primary-care visits and eligible for, but currently non-adherent to CRC screening guidelines.

Patient-reported discussions with providers about CRC risk and testing.

Tailored recipients were more likely to report patient-physician discussions about personal and familial risk, stool testing, and colonoscopy (all $p < 0.05$). Tailored recipients were more likely to report discussions of: chances of getting cancer (+10%); family history (+15%); stool testing (+9%); and colonoscopy (+8%) (all $p < 0.05$).

CRIS is a promising strategy for facilitating discussions about testing in primary-care settings.

1. Introduction

Colorectal cancer (CRC) testing can prevent mortality (U.S. Preventive Services Task Force, 2008) but participation in testing is too low (Smith et al., 2014; Holden et al., 2010). Patients have limited knowledge about need for and benefits of testing (Guerra et al., 2005; Doubeni et al., 2010; Beydoun and Beydoun, 2008). Physicians' recommendations are strong predictors of testing (Sarfaty and Wender, 2007; Wee et al., 2005; Klabunde et al., 2005; O'Malley et al., 2004) but recommendation rates remain suboptimal.

Providers may have difficulty determining what type and schedule of testing is appropriate for patients' particular risk levels, because family and personal risk factors (e.g., number, size, and histology of polyps or family members' ages at diagnosis) (Winawer et al., 2003) are not routinely documented in patients' charts. This may be especially true for patients whose risk levels warrant screening before age 50. There is little information about how many of these younger individuals would benefit from screening, what type they should have, or prevalence of physician recommendations for screening. However, there is reason to believe that screening among younger at-risk individuals is lower than among those over 50. 2010 National Health Interview data showed colonoscopy rate among first-degree relatives ages 40 to 49 (38.3%) was about half of those 50 and older (69.7%) (Tsai et al., 2015). Collecting and evaluating risk information during an office visit can be too time-consuming and complicated (Burke, 2005; Suther and Goodson, 2003) for routine practice.

We developed the *Cancer Risk Intake System* (*CRIS*) — a touch-screen program that collects data prior to office visits and generates printouts

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for patients and physicians tailored on: personal and familial risk factors; guideline-based recommendations for test modality, age at initiation, and schedule; and patient concerns about testing. By providing an individually tailored intervention at the point of care delivery, *CRIS* was meant to be a helpful and unobtrusive adjunct to clinical care.

2. Materials and methods

2.1. Overview

In this cluster-randomized trial, physicians were randomly assigned to receive *CRIS*-tailored printouts outlining patients' specific risk factors, guideline-based testing options, and concerns about testing, or a standard chart prompt for patients ≥50 and not recently screened. Based on assignment of their physicians, patients used *CRIS* and received tailored (n = 329) or non-tailored (n = 322) printouts. To mask the purpose of *CRIS* for the non-tailored comparison group, data collection included questions about multiple cancers, not only CRC. Overall goal of the study was compare screening outcomes between the *CRIS* tailored and non-tailored groups as well as a third group that did not use *CRIS* and received no contact. However, as a mechanism for understanding how the *CRIS* tailored intervention might ultimately increase screening, we also assessed whether it prompted patient-provider discussions. Here we report results from patient telephone surveys conducted with 623 patients from the tailored and non-tailored groups two weeks after the office visit during which they used the *CRIS*. Data were collected by Research Assistants, blinded to participants' random assignment.

2.2. Setting

The study, approved by the University of Texas Southwestern Medical Center Institutional Review Board and registered on clinicaltrials.gov, enrolled insured patients seen in the general internal medicine faculty clinic and the family medicine faculty clinic at the University of Texas Southwestern (UTSW) Medical Center. A UTSW electronic medical records system administrator developed a query to identify potentially eligible patients with upcoming appointments.

2.3. Eligibility criteria

We sought to enroll patients who were eligible for, but not adherent to, CRC testing based on national guidelines (U.S. Preventive Services Task Force, 2008; Smith et al., 2014; Levin et al., 2008). We invited patients younger than 50 because *CRIS* algorithms identify those whose risks warrant early testing due to personal history of polyps or inflammatory bowel diseases, or family history of polyps or cancer. For lower age limit, we selected 25 — the age by which the National Comprehensive Cancer Network at the time of study initiation recommended beginning colonoscopy among carriers of mutations for the Lynch syndrome, the most common hereditary cancer syndrome (Lynch et al., 2004). For patients <50, research assistants (RAs) conducted screening during recruitment calls to identify potentially eligible participants with CRC family history, personal history of inflammatory bowel disease, or adenomatous polyps. We asked about these risk factors during this phone screening process because they are not reliably collected and entered into patients' electronic medical records. We selected 75 as the upper age for inclusion(U.S. Preventive Services Task Force, 2002) and excluded those who had no telephone access and were unable to speak or read English.

2.4. Study design

The study has been explained in detail elsewhere (Skinner et al., 2015a) and is summarized here. Physician was the unit of random assignment. We used the SAS PROC Plan (SAS, 2014) procedure to randomly assign physicians either to *CRIS*-tailored or non-tailored group using permuted-block randomization with varying block sizes; their patients were therefore pre-identified as *CRIS*-tailored or non-tailored group members before they were invited (Those identified as members of a no-contact control group were, by definition, never contacted and are not included in this report of outcomes from the telephone survey). Identified patients with upcoming appointments (n = 10,216) received letters signed by the clinic medical director saying they "might be invited" for participation in a "study of beliefs and practices about cancer prevention and early detection." After one week during which 96 opted out of contact, research assistants (RAs) called patients to explain the study, verify eligibility and, if patients agreed, arrange in-person meetings 30 min before appointments. Of 2989 potentially eligible patients reached and invited, 1032 agreed to participate and 935 arrived in time to use *CRIS*.

Research Assistants (RA) met patients in the clinic waiting room to obtain consent and facilitate use of the *CRIS* program on a touchscreen tablet computer. After completion, patients gave the tablet back to the RA, who connected it with a printer to generate the printouts. RAs handed the patient's printout directly to the patient and placed the physician's printout with the patient's demographic sheet — the only piece of paper used for the clinic encounter.

CRIS collected demographics, personal history including previous testing, detailed family history, and concerns about testing, then used these data to determine first whether any testing was currently needed. Of the 935 who completed the *CRIS*, 651 were in need of testing. For these, *CRIS* determined risk-appropriate testing option(s) and generated the tailored or non-tailored printouts. RAs conducted telephone interviews with 95.7% (623/651) of participants within 2 weeks of the office visit. Participants received a $10 gift card for completing the *CRIS* and $15 for completing the 2-week telephone interview.

2.5. Interventions and measures

Sample *CRIS*-tailored printouts appear in Fig. 1. Each includes: summary of patient's CRC risks, appropriate test(s) based on self-reported risk factors, and concerns about testing. Consistent with health behavior theory (Skinner et al., 2015b), the patient's version portrays elevated risk factors with a graphic, includes a statement about testing benefits along with which type of testing is guideline-based, and includes brief messages designed to address concerns. Physicians' printouts list risk factors, guideline-based testing option(s), and the patient's concerns. Because data entered into the program are only as accurate as users' knowledge and memory, a statement explains the information is based on patient report on the specific date.

Patients in the non-tailored group received text from the *American Cancer Society* brochure (about multiple types of screening) inserted into a format similar to the tailored printouts; their physicians received the UT Southwestern "best practice" electronic prompt for patients 50 and older with no documentation of CRC screening.

To assess topics of discussion during the visit, Research Assistants read: *These next questions are about what you and your doctor talked about during your visit. I'll read a list. You probably didn't talk about all of these, but you may have talked about some. For each please answer yes, no, or you can't remember*. They then read the topics shown in Table 2, which lists percentages answering "yes" to each.

2.6. Statistical analysis

To test differences in reported discussions about cancer risk and testing, baseline variables were analyzed using generalized linear mixed models including physician as a random cluster effect. The final analytical sample was 623 patients (n = 314 tailored and n = 309 non-tailored).