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The Impact of a Novel Computer-Based Decision Aid on Shared Decision-Making for Colorectal Cancer Screening: A Randomized Trial (Running head: SDM for CRC Screening)

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Abstract

Background—Eliciting patients' preferences within a framework of shared decision-making (SDM) has been advocated as a strategy for increasing colorectal cancer (CRC) screening adherence. Our objective was to assess the effectiveness of a novel decision aid on SDM in the primary care setting.

Methods—An interactive, computer-based decision aid for CRC screening was developed and evaluated within the context of a randomized controlled trial. A total of 665 average-risk patients (mean age, 57 years; 60% female; 63% Black, 6% Hispanics) were allocated to one of two intervention arms (decision aid alone, decision aid plus personalized risk assessment) or a control arm. The interventions were delivered just prior to a scheduled primary care visit. Outcome measures (patient preferences, knowledge, satisfaction with the decision making process [SDMP], concordance between patient preference and test ordered, and intentions) were evaluated using pre/post-study visit questionnaires and electronic scheduling.

Results—Overall, 95% of patients in the intervention arms identified a preferred screening option based on values placed on individual test features. Mean cumulative knowledge, SDMP and intention scores were significantly higher for both intervention groups compared with the

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control group. Concordance between patient preference and test ordered was 59%. Patients who preferred colonoscopy were more likely to have a test ordered than those who preferred an alternative option (83% vs. 70%; $P<0.01$). Intention scores were significantly higher when the test ordered reflected patient preferences.

Conclusions—Our interactive computer-based decision aid facilitates SDM but overall effectiveness is determined by the extent to which providers comply with patient preferences.

Introduction

Colorectal cancer (CRC) is the second leading cause of cancer-related death and third most commonly diagnosed cancer among men and women in the United States. Screening has been shown to be a cost-effective strategy for reducing both CRC mortality and incidence[1] and is now widely endorsed by most authoritative groups.[2, 3] Despite this endorsement, however, screening rates remain relatively low, partly due to poor patient acceptance and adherence. Data from the 2005 National Health Interview Survey suggests that while screening rates have improved, approximately 50% of eligible Americans have not had appropriate screening.[4]

Shared decision-making (SDM) has been advocated as a potentially effective strategy for increasing patient acceptance and adherence to CRC screening recommendations.[2, 3] CRC screening is ideally suited for this approach given the availability of multiple strategies with distinct advantages and disadvantages, the lack of consensus regarding an optimal strategy, and historical ineffectiveness of the more traditional paternalistic approach where providers assume full responsibility for the decision-making process. Further support is derived from studies that find that patients have distinct preferences for the different screening strategies,[5–18] that providers often misperceive patient preferences,[9] and that many patients support SDM approach for CRC screening.[16]

SDM is an interactive process in which patients and their health care providers form a partnership to exchange information, clarify values, and negotiate a mutually agreeable medical decision.[19, 20] Unfortunately, SDM has been difficult to implement into routine clinical practice in part due to lack of time, lack of clinician expertise and lack of resources.[21] To circumvent several of these barriers, decision aids have been developed to facilitate informed decision-making (IDM) outside of the clinical encounter.[22] IDM is a process in which patients receive sufficient information about the risks, benefits, limitations, alternatives and uncertainties of a clinical condition or disease to make a value-concordant decision and participate in the decision-making process at a desired level. [23, 24] Thus, it is not as collaborative with the provider as SDM, but still includes a key element of patient empowerment. As with any decision aid, decision aids for CRC screening should provide, at a minimum, sufficient information about the pros and cons of the recommended options to enable users to identify a value-concordant preferred option.[25] Besides facilitating IDM, decision aids also have the potential to facilitate SDM by improving the quality and efficiency of the patient-provider encounter and by empowering users to participate in the decision-making process.[25] Alternatively, enabling patients to identify a preferred screening option outside of the clinical encounter could have a detrimental effect on the decision-

making process in situations where patient and provider preferences differ by inducing decisional conflict and/or dissatisfaction with the provider recommendation.

Studies to date have clearly demonstrated that existing decision aids for CRC screening enable users to identify a preferred screening option,[6–9, 12, 13, 15–18, 26] reduce decisional conflict[26] and increase interest in screening [8, 10, 13, 15]. The extent to which decision aids facilitate effective SDM and increase adherence, which are of critical importance to the utility of such tools in clinical practice, however, is less well-established. To address the former shortcoming, we report herein the interim results of a randomized controlled clinical trial aimed partly at evaluating the impact of a novel, interactive computer-based decision aid on relevant measures of SDM, including patient knowledge, patient preferences, satisfaction with the decision-making process, concordance between patient preference and test ordered, and screening intentions.

Methods

Decision Aid Development, Format and Usability Testing

Development of our decision aid was guided by constructs of the Ottawa Decision Support Framework.[27, 28] The actual content of the tool was derived from systematic reviews of available evidence on the cost-effectiveness and attributes of the different screening strategies,[1, 29, 30] a systematic review of existing decision aids[25] and expert opinion. We also conducted a series of focus groups of racially/ethnically diverse previously screened men (n = 7), previously screened women (n = 10), unscreened men (n = 5) and unscreened women (n = 9) recruited from a convenience sample of primary care patients seen at the target sites to determine key factors (e.g., knowledge, attitudes, beliefs, literacy, numeracy, etc.) that needed to be incorporated in the tool.

The prototype version of the decision aid was built using web-based technology but initially formatted for DVD use on portable computer stations to provide maximum flexibility for use in the ambulatory care setting during the clinical trial. The decision aid uses an audiovisual and touch screen format to simplify use for individuals with limited literacy and/or computer skills. It is comprised of a series of modules, in which professional actors playing the role of a black, Hispanic female moderator and a White, non-Hispanic male physician convey relevant information via on-screen video, animation and/or graphics. The modules (Figure 1) include: (1) an introductory segment that briefly discusses the importance of screening, intended purpose of the tool and instructions in its use; (2) an overview of the epidemiology of CRC, natural history, rationale for screening, benefits of screening, the availability of multiple screening options, and the lack of consensus regarding a best screening method; (3) brief descriptions of the five recommended screening methods (fecal occult blood testing [FOBT], flexible sigmoidoscopy, the combination of FOBT plus flexible sigmoidoscopy, double-contrast barium enema and colonoscopy) endorsed by the American Cancer Society, US Preventive Services Task Force and GI Multi-Society Task Force on Colorectal Cancer at the time [2, 3] ; (4) audio and visual (i.e., traffic light graphic) comparisons of each screening method with respect to individual test features including accuracy, inconvenience, discomfort, recommended frequency of testing, complications, and need (or lack thereof) for further diagnostic studies if the screening test is positive; (5) a

summary of the different test features for each screening strategy with optional links to more detailed information about the preparation or test itself, as well as vignettes from a racially diverse group of patients describing their experience with a particular test; and (6) a decision-making module where users are asked to identify a screening preference or lack thereof, using the discrete choice method, rank order test features influencing their selection, and assess whether out-of-pocket payments (if not covered) would alter their choice; and (7) a concluding segment in which the narrator encourages the user to discuss screening and their screening preferences with their doctor, acknowledging that the best CRC screening test is the test that gets done. Users can navigate forward or backward through the tool using either the touch screen or a mouse; they also have the option of repeating segments and printing out key information. Once developed, the tool was reviewed by the Massachusetts Department of Public Health's Colorectal Cancer Working Group for content validity and cultural sensitivity.

A modified version of the decision aid was also created, which includes the web-based "*Your Disease Risk (YDR)*" CRC risk assessment tool (http://www.yourdiseaserisk.wustl.edu). The risk assessment tool was placed just after the introductory segment. The intent of the tool was to assess the extent to which personalized risk estimates influenced decision-making. Based on the available literature at the time,[31] we postulated that personalized risk information might positively influence adherence among patients deemed to be at above average risk.

Usability testing was performed prior to its implementation, in accordance with recommendations by Nielson,[32, 33] to assess ease of learning, efficiency of use, and user satisfaction. Based on observational data and feedback from two rounds of testing with five different users per test, the prototype was revised to enhance functionality and deemed ready for clinical use without further testing.

Study Design

A randomized controlled trial was initiated in April 2005 to evaluate the impact of our decision aid on SDM and patient adherence to CRC screening recommendations. Eligible patients were instructed to arrive one hour before a prearranged office visit with their primary care provider. After obtaining informed consent, patients were administered a pretest comprised of 28 close-ended questions that assessed knowledge, beliefs, attitudes and behaviors related to CRC screening, as well as level of desire for participating in decision-making related to CRC screening.[34] The pretest was administered by one of three trained research assistants in a private office located in one of the ambulatory care clinics at Boston Medical Center or the South Boston Community Health Center. After completing the pretest, patients were randomized to one of two intervention arms (decision aid plus *YDR* personalized risk assessment tool with feedback or decision aid alone) or a control arm after stratification by provider. Patients randomized to the control arm reviewed a modified version of "9 Ways to Stay Healthy and Prevent Disease", previously posted on the Harvard Center for Cancer Prevention website, which discussed generic lifestyle changes other than screening for minimizing risk of preventable diseases. After completing the interactive computer session, patients then met with their providers to discuss screening and identify a

preferred screening strategy. Providers received written notification in the form of a flyer hand delivered by the patient acknowledging that the patient was participating in the "CRC decision aid" study at the time of the visit to ensure that screening was discussed; no information was provided preferences or factors influencing choice for patients in the intervention arm. Before leaving the clinic, subjects were administered a posttest, which assessed whether CRC screening was discussed, whether a screening strategy was chosen, patient satisfaction with the decision-making process and screening intentions; the posttest also re-assessed knowledge, beliefs and attitudes related to CRC screening.

Setting

The study was conducted at two urban ambulatory care sites. The first, Boston Medical Center, is a private, non-profit academic medical center affiliated with the Boston University School of Medicine, which serves a mostly minority patient population (only 28% White, non-Hispanic). The second, the South Boston Community Health Center, is a community health center affiliated with BMC, which serves a mostly White, non-Hispanic, low income patient population. Both sites use the same electronic medical record system (Logician). The study protocols were approved by the Boston University Medical Campus Institutional Review Board, which was responsible for overseeing human studies research at both participating institutions.

Study Population and Recruitment Process

The study sample was comprised of average-risk patients under the care of one of the primary care providers at Boston Medical Center or the South Boston Community Health Center. Patients were deemed eligible if they were 50 to 75 years of age and had had no prior structural CRC screening examinations. Potential subjects meeting any of the following criteria were excluded: (1) prior CRC screening by any method other than FOBT; (2) high-risk condition (personal history of colorectal cancer or polyps, family history of colorectal cancer or polyps involving one or more first degree relatives, or chronic inflammatory bowel disease); (3) lack of fluency in written and spoken English; or (4) comorbidities that preclude CRC screening by any recommended method.

Three different recruitment strategies were used during the course of the study. The vast majority of patients (N=637) were recruited using an investigator-initiated "opt-out" approach in which patients due for screening were identified from monthly audits of Boston Medical Center's electronic medical record 2–4 weeks prior to a scheduled office visit and contacted directly by telephone by one of the research assistants if deemed appropriate by the patient's primary care provider. Those expressing interest were provided with a brief overview of the study, evaluated for eligibility and invited to participate using a passive informed consent process. Two other strategies, including a provider-initiated, "opt-in" electronic flagging approach (N=12) and a provider-mediated, "out-in" letter approach (N=17), were used initially but discontinued after 6 months due to low enrollment. As opposed to the "opt-out" investigator approach whereby potential subjects could decline to be recruited after being contacted by the research team without prior permission, the "opt-in" approach required that potential subjects grant permission to be contacted from the onset

and a non-response prohibited further communication. The relative cost-effectiveness of each of our approaches has recently been published.[35]

Provider Characteristics and Training

Fifty full-time primary care providers, including 47 board-certified general internists and 3 nurse practitioners, practicing at both Boston Medical Center and the South Boston Community Health Center participated in the study. A pre-trial survey of 30 participating providers indicated that virtually all (97%) preferred a shared decision-making approach when selecting an appropriate screening strategy for their patients. Pre-trial seminars were conducted at both sites to educate providers about the current status of CRC screening highlighting the recommendation for shared decision-making, provide an overview of the study design and elicit support. Because of provider turnover, brief annual meetings were also conducted to insure that new providers were aware of the study, understood its design and expressed a willingness to participate. The meetings also provided a venue for informing participating providers about the status of recruitment and addressing any logistic problems that they were experiencing related to the study. No formal training in shared decision-making was undertaken.

Outcome Measures

The key outcome measures of interest for assessing the impact of our decision aid on SDM were patient knowledge, patient preferences, satisfaction with the decision-making process, screening intentions, and test concordance (i.e., agreement between patient preference and test ordered).

Knowledge was assessed at baseline (pretest) and at the time of the exit survey (posttest) based on responses to a 12-item questionnaire (True/False/Don't know) that inquired about CRC risk factors, the rationale and goals of screening, and age at which screening should begin (see **Appendix I** for individual questions). The content was derived from key messages endorsed by the National Colorectal Cancer Roundtable [36] and Massachusetts Department of Public Health [37] for public education. Cumulative knowledge scores (range, 0–12) were derived by summing correct responses to the 12 individual knowledge questions.

Patient preferences and factors influencing choice of options were obtained from response data captured electronically in the decision aid's decision-making module.

Patient satisfaction with the decision-making process was assessed on the posttest using the validated 12-item Satisfaction with the Decision-Making Process scale (**Appendix II**),[38] which has excellent reliability (Cronbach's $\alpha = 0.85$) and discriminant validity. Five ordered response categories were used for each item. Each response was assigned a point score ranging from 1 for "strongly disagree" (or "poor") to 5 for "strongly agree" (or "excellent"). A cumulative score was calculated based on the summed response scores for each item (maximum score = 60). Mean item substitution was used to impute missing data for patients answering between 8 and 11 items; patients answering fewer than 8 items were excluded from analysis.

Screening intentions were also assessed as part of the posttest. Subjects were asked how sure they were that they would schedule an appointment to get screened for colorectal cancer and how sure they were that they would complete the screening test they scheduled. An ordered 5-point response frame was used ranging from “not at all sure” to “completely sure”.

Concordance between patient preferences and test ordered was assessed for the two intervention groups only since preferences were not elicited from the control group. Test ordered was ascertained from “Orders” section of the electronic medical record. Concordance was defined as the percentage of patients who had their preferred screening test ordered.

Statistical Analyses

Based on crude estimates of baseline adherence, we calculated that a target sample of 825 patients provided 80% power of detecting a 54% vs. 40% pair-wise difference in the percent of patients completing a CRC screening, using a Bonferroni adjustment to overall alpha level of 0.05 to account for the three group study design.

As a check on randomization, the three study groups were compared on demographic characteristics, prior screening, and desired role in decision-making through the chi-square test of independence. The three study groups were also compared on cumulative pre-test and post-test knowledge scores, satisfaction with the decision-making process (SDMP) scores and intention scores through separate one-factor analysis of covariance (ANCOVA); Bonferroni’s adjusted multiple comparison procedure was used to investigate pairwise differences following a significant three group comparison. ANCOVA was also used for subgroup analyses comparing SDMP scores across the three study groups after stratification by desired role in decision-making (mostly patient, shared, and mostly provider). For the SDMP analyses, mean item substitution was used to impute missing data for patients who answered at least 8 items. To evaluate the possible bias of this approach, we employed multiple imputation analysis to generate 5 data sets using the EM algorithm and found that the results agreed closely with those derived using mean item substitution. Differences between study groups on adjusted means from the ANCOVA are described through effect sizes (d) calculated as the difference in adjusted means divided by the pooled standard deviation estimate from the ANCOVA. Descriptive statistics were used to describe patient preferences for the five screening test options and factors influencing choice; associations between demographic characteristics and patient preferences (colonoscopy versus FOBT) were examined through a series of multiple logistic regressions. Test concordance, i.e., the association between patient preference and test ordered, was examined through the chi-square test of independence. Associations between test concordance and desired role in decision-making were tested through the chi-square test of independence, whereas associations between test concordance and both SDMP and intention scores were compared through the independent sample t-tests. We controlled for study site (Boston Medical Center and South Boston Community Health Center) in the analyses of all outcome measures, using ANCOVA regression models for measurement outcomes and Cochran-Mantel-Haenszel analyses or logistic regression analyses for categorical outcomes. Data are expressed as

mean [standard deviation], unless otherwise stated. *P* values less than 0.05 were deemed significant.

Results

Patient Characteristics

Of the 9648 patients identified as potentially eligible for screening (aged 50–75) for whom permission to contact was granted, 6542 (68%) were deemed ineligible (mostly due to prior screening) and 2440 (25%) were excluded. Reasons for exclusion were inability to contact (*n* = 2027), disinterest (*n* = 210), scheduling conflict (n=151), failure to keep appointment (*n* = 37), or failure to complete posttest (n= 15) (Figure 2). The remaining 666 patients (62% of eligible subjects contacted) were enrolled and randomized to decision aid plus *Your Disease Risk* (*YDR*) arm (*n* = 223), decision aid alone arm (*n* = 212) or control arm (*n* = 231).

As shown in Table 1, the three study arms were well-balanced with respect to patient age, sex, race, ethnicity, education, prior FOBT, insurance status, and decision-making preference. Overall, the study group was predominantly less than 65 years of age, female, non-Hispanic, and Black with at least a high school degree. Although most had some form of health care insurance, nearly two-thirds were covered by Medicare, Medicaid or Massachusetts' "free care" program. Most had no prior experience with FOBT. Importantly, the majority preferred a patient-dominant (28%) or shared decision-making approach (53%) for selecting a preferred CRC screening option.

Knowledge

Mean [SD] cumulative pretest knowledge scores were comparable (*P*=0.91) for the 3 groups (decision aid plus *YDR*, 7.6 [2.8]; decision aid alone, 7.7 [2.9]; control, 7.5 [2.7]). Cumulative posttest scores, however, were significantly higher (*P*<0.001) for the two intervention groups (decision aid plus *YDR*, 10.7 [1.8]; decision aid alone, 10.9 [1.6]) compared with the control group (8.6 [2.7]), with differences corresponding to large effect sizes of d=1.15 and d=1.27 for the decision aid plus *YDR* group and decision aid alone group vs. control, respectively. The mean increase in scores from pretest to posttest was also significant (*P*<0.001) for both intervention groups (decision aid plus *YDR*, 3.0 [2.5]; decision aid alone, 3.2 [2.6]) but not the control group (0.8 [2.2]). There were no significant differences in cumulative posttest scores or change in scores between the two intervention groups.

Patient Preferences and Factors Influencing Choice

Screening test preferences for patients randomized to the two intervention arms are depicted in Table 2. Colonoscopy was preferred by a majority of patients (59%) followed by FOBT (26%), flexible sigmoidoscopy (5%), DCBE (4%) and FOBT plus flexible sigmoidoscopy (3%); only 3% either declined testing or could not identify a preferred option. No significant differences were observed between the two intervention groups. Patients who chose colonoscopy were most likely to identify test accuracy (81%) as the most important feature influencing their choice; in contrast, patients who chose FOBT were most likely to identify concerns about discomfort (31%), inconvenience (23%) and bowel preparation (18%) as the

most influential features. Logistic regression analysis found no significant independent associations between demographic factors (age, sex, race, ethnicity, education, insurance status or study site) and preference for colonoscopy versus FOBT [data not shown].

Satisfaction with the Decision-Making Process (SDMP)

Overall, 636 subjects (96% overall) responded to ≥8 items of the SDMP scale and were included in the analysis; there were no significant differences in the percentage of patients answering all 12 items vs. 8 to 11 items vs. <8 items (excluded) across the three study groups (P=0.31). As shown in Table 3, mean SDMP scores were significantly higher for the two intervention arms compared to controls, with differences corresponding to moderate effect sizes of 0.53 and 0.61 for the decision aid plus *YDR* and decision aid alone groups vs. control, respectively. Scores for the two intervention groups were comparable. Subgroup analysis found that satisfaction was also higher among intervention patients who preferred a shared or patient-dominant role in decision-making; a similar trend was observed for patients who preferred a provider-dominant approach but the differences between the intervention and control groups did not achieve statistical significance.

Intentions

Mean intention scores [SD] were significantly higher (P<0.001) for the two intervention groups (decision aid plus *YDR*, 4.3 [1.0]; decision aid alone, 4.4 [1.0]) compared to the control group (3.9 [1.4]) when asked “How sure are you that you will schedule a colorectal cancer screening test?” Mean intention scores were also significantly higher (P<0.001) for the two intervention groups (both 4.3 [1.0]) compared to controls (3.9 [1.3]) when asked “How sure are you that you will complete a colorectal cancer screening test?” Differences in intention to schedule or complete a screening test for the two intervention groups vs. control correspond to moderate effect sizes ranging between 0.36 and 0.44. Scores were comparable for the two intervention groups.

Concordance between Patient Preference and Test Ordered

Concordance between preference and test ordered is shown in Table 4. Among the 415 patients expressing a preference, 244 (59%) had their preferred test ordered, 79 (19%) had an alternate test ordered (colonoscopy, 85%; FOBT, 14%; flexible sigmoidoscopy, 1%), and 92 (22%) had no test ordered. For individual tests, concordance between patient preference and test ordered varied from 79% for colonoscopy to ≤ 30% for all other options. For the discordant group, virtually everyone (96%) who preferred a test other than colonoscopy had a colonoscopy ordered. Patients who preferred colonoscopy were more likely to have any test ordered than those who preferred a test other than colonoscopy (83% vs. 70%; P<0.002).

As shown in Table 5, there was no association between concordance and desired role in decision-making, demonstrating that patients who preferred a patient-dominant or shared decision-making style were no more likely to have a concordant test ordered than those who preferred a provider-dominant style. There was also no significant association between SDMP scores and concordance. Importantly, however, intention scores were significantly higher when there was concordance between patient preference and test ordered compared

to when they differed. The positive associations between test concordance and screening intentions replicated significantly within the independent test-preference groups (colonoscopy and "other").

Overall, patients in the intervention arms were more likely to have a test ordered than patients in the control arm (75% vs. 68%, $P<0.05$), regardless of whether there was concordance or discordance with test preference (data not shown). Colonoscopy (82%) was the most commonly ordered test for control patients with any test ordered followed by FOBT (12%) and flexible sigmoidoscopy (1%), thus affirming a strong provider preference for colonoscopy.

Discussion

Most authoritative groups, including the US Preventive Services Task Force, American Cancer Society, US Multi-Society Task Force on Colorectal Cancer, and American College of Radiology,[2, 3] endorse a SDM approach when selecting an appropriate CRC screening strategy but implementation into clinical practice encounters many barriers.[21] The purpose of this study was to assess the extent to which use of a novel CRC screening decision aid circumvents some of these barriers and facilitates effective SDM in the primary care setting. Like similar such studies, [6–9, 12, 13, 15–18, 26] our study finds that the tool enables users to identify a preferred screening option based on the relative value they place on individual test features. Our study also finds that while users are more knowledgeable, more satisfied with the decision-making process and more intent to undergo screening than non-users overall, screening intentions and test ordering are negatively influenced in situations where patient and provider preferences differ, regardless of a patient's desired role in decision-making. Together, these observations suggest that the utility of our decision aid for promoting effective SDM is dependent upon the extent to which providers are willing to comply with an informed patient's screening preferences. Importantly, however, screening intentions were still higher for discordant users than for nonusers, suggesting that use of the decision aid is nonetheless superior to nonuse.

A critical question that arises when interpreting these findings relates to whether our outcomes of interest are valid measures of effective SDM. As previously noted, SDM has been defined as a process in which both the patient and provider engage in information exchange, deliberation (value clarification), negotiation and mutual decision-making.[19, 20] Accordingly, we opted to include patient knowledge, satisfaction with the decision-making process, concordance between patient preference and test ordered, and screening intentions as appropriate measures of SDM within the context of this conceptual framework.

The notion of information exchange implies that there was a reciprocal exchange of information between the patient and health care provider. Because the primary intent of our decision aid was to educate users about the rationale for screening and the pros and cons of the different screening options so as to make an informed choice about screening and test preference, our knowledge outcome is a more reliable measure of IDM than SDM. The finding that knowledge scores did not increase after the provider encounter for the control group, however, suggests that most providers failed to convey relevant information about

the rationale for screening, risk factors, goals and benefits when discussing CRC screening with their patients.

The SDMP outcome provides a useful measure of patient involvement in the decision-making process from the patient perspective. As with decision aids for other conditions,[25] our findings suggest that our tool also empowered users to participate in the decision-making process at a desired level, particularly those who preferred a shared or patient-dominant role in decision-making. We speculate that our tool's format and inclusion of specific messages encouraging patients to take a proactive role in the decision-making process provided meaningful guidance in deliberation and/or communication.

Our concordance and intention outcomes are arguably the most relevant measures of "effective" SDM. Concordance provides a measure of the extent to which providers are willing to respect patient autonomy in the decision-making process and comply with patient preferences when selecting an appropriate screening test. Intention provides a measure of the degree to which the patient is committed to the chosen course of action and, in the case of SDM, provides perspective on the extent to which the final decision reflects successful negotiation and mutual agreement. Intention is also a powerful predictor of CRC screening adherence.[39, 40] In this study, we found that concordance was high for colonoscopy but relatively low for the other options, suggesting that providers were much more likely to comply with patient preferences that agreed with their own screening preferences. We also found that the likelihood of having the preferred test ordered was unaffected by the extent to which patients wished to engage in the decision-making process, suggesting that most providers either fail to assess their patients' desired level of participation or assume decisional authority, regardless of the preferred role. Perhaps most importantly, we found that when there was concordance between patient and provider preferences, patients had stronger screening intentions and a greater likelihood of having any screening test ordered compared to when patient and provider preferences differed. In the aggregate, these observations suggest that our decision aid facilitates effective SDM in settings where providers truly endorse a SDM approach and are willing to comply with patient preferences when selecting an appropriate screening test. In settings where providers feel compelled to endorse a single screening option, regardless of patients' desired level of participation in the decision-making process, use of the tool may compromise effectiveness, possibly due to enhanced decisional conflict and/or dissatisfaction with the process or decision itself.

One of the principal goals of both IDM and SDM for CRC screening is the elicitation of a value-concordant patient preference for one of the recommended screening tests. Our findings corroborate a body of evidence demonstrating that patients have distinct CRC screening test preferences that are influenced by the value they place on one or more test features.[5–18] As in our prior study,[16] we found that colonoscopy was preferred by a majority (59%) of intervention patients, most of whom identified test accuracy as the predominant reason for their selection; in contrast, most of the remaining patients (26%) preferred FOBT primarily because of concerns about discomfort, inconvenience and bowel preparation. Both Hawley et al.[18] and Marshall et al.[17] also observed a dominant preference for colonoscopy compared to FOBT, flexible sigmoidoscopy and barium enema. Although the surge in media campaigns promoting colonoscopy in recent years might explain this predilection for

colonoscopy, a similar trend has not been reported in other recently published studies.[12–15] Differences in the study population, options discussed, framing and methodologies used to elicit preferences may be important factors in accounting for these disparate results. Collectively, however, these findings support the rationale for eliciting patient preferences within the context of IDM and/or SDM.

Our study also provides new evidence suggesting that providers also have a dominant preference for colonoscopy. Using test ordered as a proxy for provider preference, we found that providers referred the majority (~82%) of control patients for colonoscopy and that providers were unlikely to order tests other than colonoscopy, regardless of patient preferences, for the two intervention groups. This predilection for colonoscopy mirrors national trends in utilization [4] and may be explained by highly publicized studies affirming superior accuracy for detecting advanced neoplasia compared to other screening modalities,[41–44] expanded coverage by Medicare and many health insurers, and an increase in patient demand due to heightened public awareness efforts.[45] The extent to which liability concerns, socio-demographic factors, health care coverage, patient co-morbidities and/or lack of adequate systems for follow-up (as in the case of FOBT) influence provider recommendations when dealing with individual patients is less well-defined. A reliable risk prediction model that could accurately stratify patients into different risk categories for the presence of advanced colorectal adenomas and cancer at screening colonoscopy would be invaluable in this regard since it would bestow providers with objective decisional support when considering patient preferences and thereby enhance the effectiveness of SDM. In the interim, however, the growing tendency to promote colonoscopy independent of patient preferences undermines the spirit of SDM and its potential effectiveness as a strategy for increasing CRC screening rates.

Our decision aid has several features that distinguish it from other currently available CRC screening decision aids. First, the tool employs culturally-sensitive video narratives, simple graphics and animation to enhance its appropriateness, acceptability and comprehensibility for use by a diverse target audience with variable literacy skills. Second, it provides an overview of CRC and CRC screening that incorporates key messages endorsed by the National Colorectal Cancer Roundtable to heighten awareness and entice interest in screening.[36] Third, one version also incorporates the *YDR* risk assessment tool to enable users to incorporate personalized risk estimates into their decision-making. Of note, however, we observed no significant associations between personalized risk feedback and patient preferences or other outcomes of interest. We speculate that the lack of difference between the two intervention arms may be due to the offsetting effects of informing some patients in the *YDR* arm that they were at above average risk and others below average risk. Alternatively, the lack of difference may also be due to the fact that the information was disregarded by many of those receiving personalized feedback, possibly because it was perceived to be incorrect.[46] Fourth, unlike more complex decision-making approaches, such as conjoint analysis[18] and analytic hierarchy analysis[12, 26], the tool employs descriptive attribute-based comparisons of the different screening tests, as well as option-based summaries, to enable users to identify a value-concordant preference. Fifth, it provides optional links to more detailed information about the preparation, test itself and patient

testimonials to insure that users have as much information as desired to make an informed choice. Lastly, it provides users with a no screening option and explores reasons for their decision. The major drawbacks of the tool in its current form are its length, if users opt to view all segments, and its linear arrangement. Enhancements that permit tailored navigation to fit the informational needs of users are required for optimal Internet dissemination.

Our study has several notable strengths. First, the study provides new insight into the utility of decision aids for facilitating SDM related to CRC screening by assessing the extent to which such tools enhance satisfaction with the decision-making process and the extent to which concordance between patient preferences and provider preferences influence screening intentions and test ordering. Second, the use of a randomized controlled study design, a large sample size, and a racially diverse study population enhances both the internal and external validity of its findings. Third, implementation of the decision aid as a point-of-contact intervention attests to the feasibility of use in the primary care setting. Finally, the inclusion of mostly unscreened patients minimizes the potential confounding.

Our study also has several notable limitations. First, the lack of provider blinding might have negatively influenced the magnitude of the interventions' effect on several outcomes of interest, most notably satisfaction with the decision-making process. Second, no attempt was made to assess the quality of the patient-provider discussion. Even though satisfaction with the decision-making process was universally high (albeit higher in the intervention groups), recent data suggest that most patient-provider discussions related to CRC screening fail to incorporate key elements of IDM.[47–49] Third, no attempt was made to assess factors influencing provider preferences, as previously noted, nor provider satisfaction related to either the use of the decision aid or the decision-making process. Fourth, we failed to explore whether users experienced greater decisional conflict or uncertainty when their preferences differ from those of their provider. Fifth, we opted to exclude cost information in our tool when discussing attributes because of conflicting data regarding its impact on decision-making in this setting[7, 50, 51] and because of the complexity of presenting such information in a meaningful way given the variability in coverage under different health plans. Lastly, despite its obvious importance, we opted to exclude data on patient adherence in this interim analysis because of incomplete follow-up. Although extrapolation of our findings suggests that failure to comply with patient preferences may have negative consequences on screening behavior, it could be that providers who can effectively communicate their reasoning for recommending colonoscopy and facilitate its completion may be successful in getting their patients screened, regardless of their preferences. Existing data, however, would suggest that providers who focus on colonoscopy tend to adopt a more paternalistic approach with little exchange of information or attention to barriers.[52]

In conclusion, our study finds that our decision aid facilitates SDM related to CRC screening by enabling patients to identify a preferred screening option based on the values they place on individual test features and screening intentions. Although use of the tool also enhances satisfaction with the decision-making process, this empowerment may compromise the effectiveness of SDM in situations where patient and provider preferences differ. Future studies are needed to better understand factors that influence provider preferences and identify effective strategies for reconciling these differences. Pending a final analysis of our

adherence data, our findings suggest that providers who utilize decision aids to facilitate SDM for CRC screening should be willing to comply with patient preferences when selecting an appropriate screening test in instances where the patient expresses a desire to participate in the decision-making process, the choice is informed and there are no mitigating factors to warrant an alternate recommendation. Failure to do so undermines not only the spirit of patient-centered decision-making but also the potential effectiveness of SDM as a strategy for increasing uptake of CRC screening.

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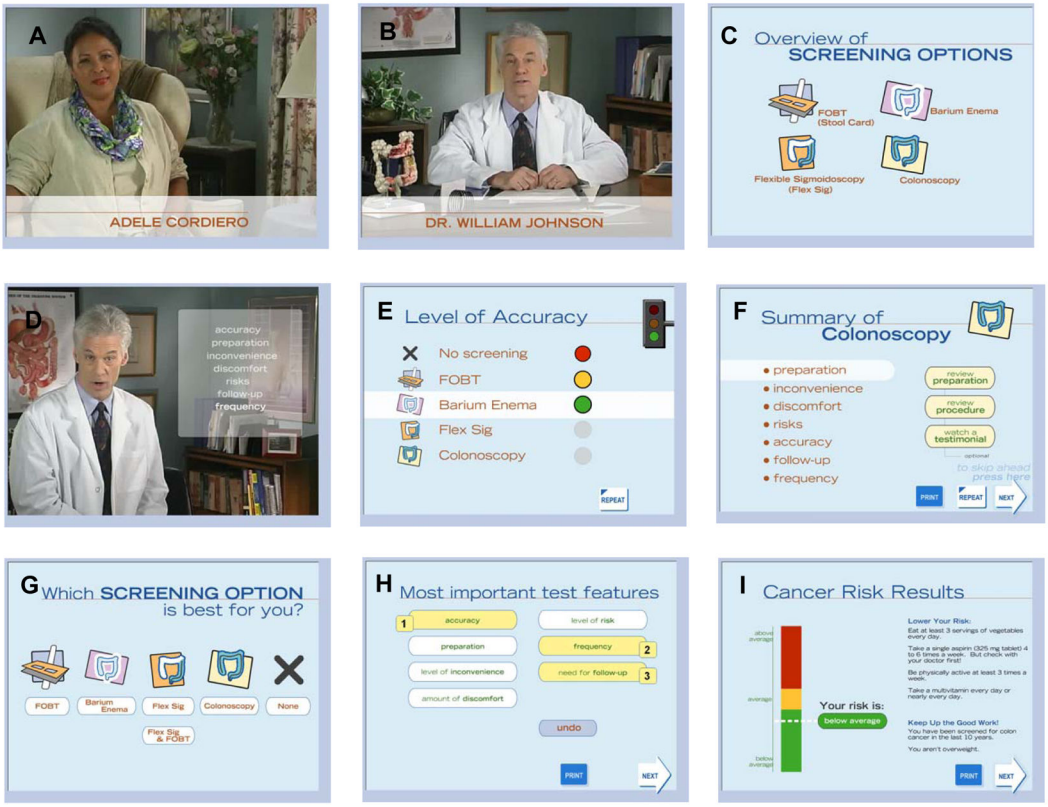

Figure 1.

Decision Aid. Representative screens from the different segments of the tool including the introductory module (A); overview of colorectal cancer and colorectal screening (B); brief descriptions of each screening option (C); list of test features discussed (D); comparisons of screening options with respect to individual test features . (E); summaries of attributes for each option with links to more detailed information about the preparation, procedure itself and patient testimonials (F); and the decision-making module, where users are asked to identify a preferred option (G) and rank order test features influencing choice (H). One version of the tool also includes the “Your Disease Risk” risk assessment tool, which calculates personalized 10-year estimates for developing CRC (I).

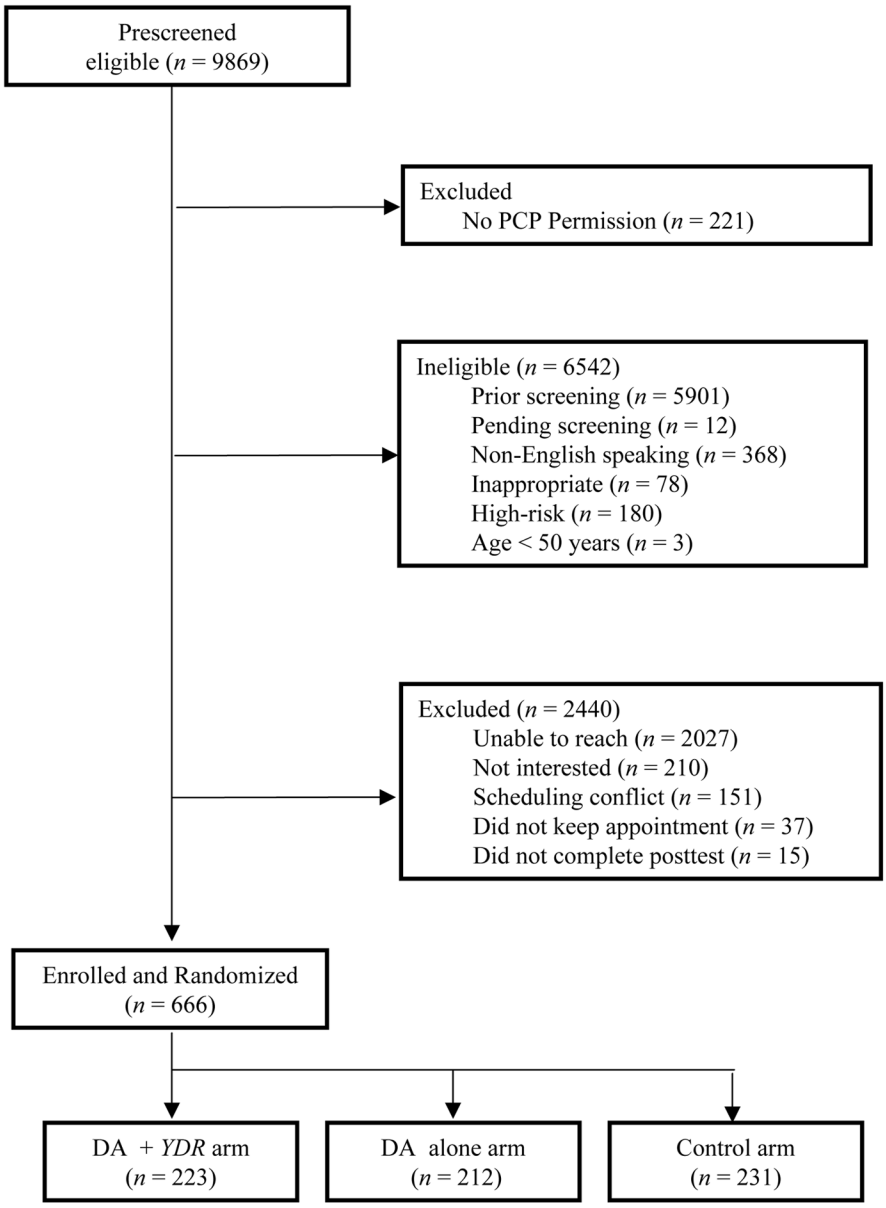

Figure 2.
Study flow diagram. DA, decision aid; *YDR*, *YourDiseaseRisk* risk assessment tool

Table 1

Characteristics of Study Participants (*N*=666)

Characteristic	DA + YCR (*n*= 223)	DA alone (*n*=212)	Control (*n*=231)	*P* value
Age, *n* (%)				0.41
< 65 years	181 (81)	182 (86)	191 (83)	
≥ 65 years	42 (19)	30 (14)	40 (17)	
Sex, *n* (%)				0.79
Female	137 (61)	125 (59)	135 (58)	
Male	86 (39)	87 (41)	96 (42)	
Ethnicity, *n* (%)				0.75
Non-Hispanic	209(94)	202 (95)	217 (94)	
Hispanic	14 (6)	10 (5)	14 (6)	
Race, *n* (%)				0.21
Black	139 (62)	124 (58)	155 (67)	
White	78 (35)	76 (36)	71 (30)	
Asian	2 (1)	6 (3)	1 (1)	
Other	4 (2)	6 (3)	4 (2)	
Education, n (%)				0.56
≥ High school	170(76)	159 (76)	165 (73)	
< High school	52 (24)	49 (24)	62 (27)	
Insurance, *n* (%)				0.61
Private/HMO	78 (39)	73 (39)	77 (36)	
Medicare	65 (33)	47 (25)	66 (31)	
Medicaid	44(22)	54 (29)	53 (25)	
Free care	9 (4)	11 (6)	19 (5)	
None	3 (2)	2 (1)	6 (3)	
Prior FOBT				0.90
Yes	29 (13)	30 (14)	34 (15)	
No	189 (87)	180 (86)	196 (85)	
Desired role in decision-making, *n* (%)				0.68
Mostly patient	60 (27)	53 (25)	70 (30)	
Shared	120 (54)	120 (57)	115 (50)	
Mostly doctor	43 (19)	39 (18)	46 (20)	

DA, Decision Aid; *YDR, YourDiseaseRisk*; HMO, Health Maintenance Organization; FOBT, fecal occult blood testing.

Table 2

Patient preferences and most important test feature influencing test preference (intervention groups only, *N*=435[a]).

	Patient Preference, n (%)					
	Colon	**FOBT**	**Flex Sig**	**FOBT + Flex Sig**	**DCBE**	**None**
Study Group [a]						
DA+*YDR*	132 (60)	53 (24)	13(6)	6(2)	8 (4)	8 (4)
DA alone	120 (57)	58 (28)	11(5)	5(3)	9 (4)	7 (3)
Combined [b]	252 (59)	111 (26)	24(5)	11(3)	17 (4)	15 (3)
Most important test feature [c]						
Accuracy	205 (81)	16 (14)	11(46)	6(54)	4 (24)	--
Preparation	13 (5)	20 (18)	3(12)	1(9)	2 (12)	--
Amount of discomfort	3 (1)	34 (31)	2(9)	2(18)	2 (12)	--
Inconvenience	4 (2)	25 (23)	4(17)	0	4 (24)	--
Risk of complications	5 (2)	9 (8)	3(12)	2(19)	4 (24)	--
Frequency	14 (6)	0	0	0	1 (6)	--
Need for further testing if results abnormal	8 (3)	1 (3)	1(4)	0	0	--

DA, decision aid, *YDR*, *YourDiseaseRisk*, Colon, colonoscopy; FOBT, fecal occult blood testing; Flex Sig, flexible sigmoidoscopy; DCBE, double-contrast barium enema.

[a] Percentages relate to rows

[b] Data missing, *n*=5

[c] Percentages relate to columns

Table 3

Satisfaction with the Decision-Making Process (SDMP) Scores[a]

	DA + *YDR*	DA Alone	Control	*P*-value
Overall	50.5 (6.2)	50.7 (6.2)	46.7 (7.9)	<0.001[b]
	n = 214	*n* = 205	(*n* =217)	
Decision-making preference				
Mostly patient	49.4 (6.2)	50.2 (6.5)	46.0 (8.3)	0.01 [b]
	n = 58	*n* = 50	*n* = 66	
Shared	50.8 (6.4)	50.6 (6.3)	46.6 (7.9)	<0.001 [b]
	n = 115	*n* = 116	*n* = 108	
Mostly provider	51.4 (5.4)	51.5 (5.3)	49.0 (6.7)	0.06
	n = 41	*n* = 39	*n* = 43	

DA, Decision Aid; *YDR, YourDiseaseRisk*

[a]Data expressed as mean (SD); maximum score = 60.

[b]One-factor ANCOVA showed a significant difference in satisfaction between the three study groups, with pairwise comparisons showing no significant differences between the two intervention groups and significantly lower satisfaction for those in the control group overall and after stratification by decision-making preference.

Table 4

Concordance between patient preference and test ordered (intervention groups only [a]).

	Patient Preference, n (%)					
Test Ordered	**Colon (*n* = 252)**	**FOBT (*n* = 111)**	**Flex Sig (*n* = 24)**	**DCBE (*n* = 17)**	**FOBT + Flex Sig (*n* = 11)**	**Overall (n=415)**
Same	199 (79)	34 (30)	5 (21)	4 (24)	2 (18) [b]	244 (59)
Different	10 (4)	44 (40)	12 (50)	7 (41)	6 (55)	79 (19)
None	43 (17)	33 (30)	7 (29)	6 (35)	3 (27)	92 (22)

Colon, colonoscopy; FOBT, fecal occult blood testing; Flex Sig, flexible sigmoidoscopy; DCBE, double-contrast barium enema.

[a] Intervention patients with no preference (*n*=15) or missing data (*n*=5) not included

[b] "Same" infers that at least one of the two preferred tests was ordered.

Table 5

Association between test concordance and desired role in decision-making preference, satisfaction with the decision-making process and screening intentions (intervention groups only).

	Test Concordance [a]		
Outcome	**Same**	**Different**	***P* value**
Desired role in decision-making, n (%)			0. 9 [d]
Mostly patient	60 (75)	20 (25)	
Shared	138 (75)	45 (25)	
Mostly doctor	45 (75)	15 (25)	
SDMP score [b]	51.3 (6.4)	49.4 (5.8)	0.20 [e]
Intention [c]			
Schedule test	4.6 (0.7) n = 241	4.2 (1.1) n = 75	<.001 [e]
Complete test	4.6 (0.7) n = 243	4.2 (1.1) n = 74	<.001 [e]

SDMP, satisfaction with the decision-making process

[a] Agreement between patient preference and test ordered

[b] Mean cumulative scores (SD); maximum = 60

[c] Mean scores ± SD where 5= “very sure” and 1 = “very unsure”

[d] Cochran-Mantel-Haenszel chi-square analyses controlling for site

[e] ANCOVA controlling for site