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Risk Stratification and Shared Decision-Making for Colorectal Cancer Screening: A Randomized Controlled Trial

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Abstract

Background—Eliciting patient preferences within the context of shared decision-making has been advocated for colorectal cancer (CRC) screening, yet providers often fail to comply with patient preferences that differ from their own.

Purpose—To determine whether risk stratification for advanced colorectal neoplasia (ACN) influences provider willingness to comply with patient preferences when selecting a desired CRC screening option.

Design—Randomized controlled trial

Setting/Participants—Asymptomatic, average risk patients due for CRC screening in an urban safety net healthcare setting.

Intervention—Patients were randomized 1:1 to a decision aid alone (n=168) or decision aid plus risk assessment (n= 173) arm between September 2012 and September 2014.

Outcomes—The primary outcome was concordance between patient preference and test ordered; secondary outcomes included patient satisfaction with the decision-making process, screening intentions, test completion rates and provider satisfaction.

Results—Although providers perceived risk stratification to be useful in selecting an appropriate screening test for their average-risk patients, no significant differences in concordance were observed between the decision aid alone and decision aid plus ACNI groups (88.1 vs. 85.0%, p=0.40) or high- and low-risk groups (84.5 vs. 87.1%, p=0.51). Concordance was highest for colonoscopy and relatively low for tests other than colonoscopy, regardless of study arm or risk group. Failure to comply with patient preferences was negatively associated with satisfaction with the decision-making process, screening intentions and test completion rates.

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Presentations: None

Limitations—Single institution setting; lack of provider education about the utility of risk stratification into their decision-making.

Conclusions—Providers perceived risk stratification to be useful in their decision-making but often failed to comply with patient preferences for tests other than colonoscopy, even among those deemed to be at low risk of ACN.

Introduction

Colorectal cancer (CRC) remains the second leading cause of cancer-related death.¹ Although screening is a highly cost-effective strategy for reducing the public health burden of this disease,² nearly one-third of eligible individuals remain unscreened and racial/ethnic disparities persist.³ Eliciting patient preferences for one of recommended screening options within the context of shared decision-making (SDM) has been advocated as an appropriate and potentially effective strategy for increasing participation.⁴⁻⁶ To facilitate this process, patient-oriented decision aids have been developed to enable patients to identify a value-concordant screening preference. Besides helping patients make informed choices,^{7,8} decision aids can also facilitate SDM and increase screening uptake.^{9,10} Nevertheless, existing data suggest that providers are often unwilling to comply with patient preferences when they differ from their own.^{9,11} Failure to comply with patient preferences not only undermines the spirit of shared decision-making but might also negatively impact on screening intentions and adherence.^{9,11-13}

Much of the discordance between patient and provider preferences relates to the value each places on various test attributes. Colonoscopy has emerged as the preferred screening method by most providers because of superior perceived effectiveness,¹⁴ whereas many patients prefer less invasive and less costly screening options.⁹ Risk stratification for the presence of advanced colorectal neoplasia (ACN), the target lesion for colorectal cancer screening,¹⁵ enables providers who endorse a SDM approach to use objective criteria to inform their decision-making when considering patient preferences. The current trend towards personalized medicine and the use of individualized risk prediction to guide screening decisions for other cancers (e.g., breast¹⁶ and prostate¹⁷) provide a precedent for this approach. Risk stratification optimizes the harm-benefit ratio of colonoscopy for high-risk patients, regardless of preference, and the use of alternative screening methods for low-risk patients who prefer tests other than colonoscopy, especially when such patients might otherwise refuse screening. Accurate probabilistic information about individual disease risk also facilitates more effective risk communication, a critical element of SDM.¹⁸ Moreover, in a recent survey of primary care providers, respondents identified risk as a critical determinant in their decision-making and a willingness to use risk stratification for ACN for patients who declined colonoscopy, but acknowledged a lack of knowledge about risk factors other than age and family history.¹⁹ Hence, the overall objective of this study was to determine whether risk stratification for ACN influences provider decision-making when considering patient preferences within the context of SDM. More specifically, we wanted to test the hypothesis that providers who incorporate risk estimates of ACN in their decision-making are more likely to comply with patient preferences for options other than colonoscopy among those deemed to be at low risk than providers lacking this information.

Methods

Study Design

A prospective, unblinded, parallel-group randomized controlled trial was conducted between September 2012 and September 2014 at Boston Medical Center (BMC) to evaluate the impact of risk stratification for ACN on shared decision-making for CRC screening. Potentially eligible patients due for screening were identified from weekly 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 granted permission to contact by the patient's primary care provider. Patients expressing interest were provided with a brief overview of the study, evaluated for eligibility and invited to participate using a passive informed consent process. Enrollment ceased after the target sample size was achieved.

Eligible patients expressing interest in participating were instructed to arrive one hour before a prearranged chronic care visit with their primary care provider. After obtaining informed consent, patients were administered a 10-minute, electronic pretest in a private office to capture baseline data on demographics, perceived risk, stage of readiness for CRC screening, self-efficacy related to speaking with their provider about CRC screening, reasons for lack of prior screening, numeracy and decision-making autonomy. Prior to randomization, all patients reviewed the interactive web-based decision aid (<http://www.colorectalcancerscreening4u.com>) in the presence of one of the research assistants for the purpose of identifying a preferred screening option. Patients were then randomized 1:1 via a preset block randomization table within the study website that was inaccessible to study coordinators to a control arm (decision aid only) or experimental arm (decision aid plus risk assessment), within strata by provider. Patients randomized to the experimental arm then completed an electronic version of the 6-item risk assessment tool. Immediately after completing the interactive computer session, patients met with their providers to discuss screening and identify a course of action as defined by test ordered. Providers received a printed copy of the patient's preferred screening option, test attributes or factors influencing their choice and, for those in the experimental arm, risk category ("low" versus "intermediate/high"). Before leaving the clinic, patients completed a 10-minute electronic posttest to assess whether CRC screening was discussed, items related to satisfaction with the decision-making process scale, risk perception and screening intentions. Providers also completed a brief paper-based 3-item survey asking them to identify their test preference, factors influencing their choice and test agreed upon.

The study protocol was approved by the Boston University Medical Center's Institutional Review Board.

Setting

BMC is a private, not-for-profit, community-based, academic medical center. It is the largest safety net hospital in New England with a legislative mandate to provide care to low-income persons and other vulnerable populations regardless of their ability to pay. Approximately

70% of the center's patients are from racial (44% black) and ethnic minority groups and more than 95% have some form of health care insurance.

Participants

The study sample was comprised of asymptomatic, average-risk primary care patients cared for at BMC. Patients were deemed eligible if they were 50 to 75 years of age, under the care of a primary care provider, and due for CRC screening. Exclusion criteria included: (1) the presence of lower gastrointestinal symptoms or iron deficiency anemia; (2) conditions associated with an increased risk of CRC (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) for which colonoscopy was the preferred screening/surveillance method; (3) lack of fluency in written and spoken English; or (4) comorbidities that precluded CRC screening by any recommended method. There was no racial or gender bias in the selection of participants.

Provider Characteristics

Forty-three primary care providers, including 25 board-certified general internists, 9 board-certified family physicians and 9 nurse practitioners participated in the study. Pre-trial training seminars were conducted to educate providers about the current status of CRC screening highlighting the recommendation for SDM, provide an overview of the study design and elicit support. By design, providers received no formal training in SDM or risk assessment for CRC screening and were blinded to the content of the risk assessment tool.

Decision Aid

An updated web-based version (<http://www.colorectalcancerscreening4u.com>) of our validated DVD-formatted decision aid⁹ was employed in this study. Like its predecessor, the web-based version was comprised of a series of didactic modules that provided an overview of the rationale for CRC screening, risk factors and goals, the importance of polyps, brief and detailed descriptions of currently recommended screening options, a comparison of test attributes, and patient testimonials. The web-based version was modified to include an updated menu of screening options grouped into two categories: tests that detect both colorectal cancer and adenomatous polyps (colonoscopy, CT colonography, flexible sigmoidoscopy and double contrast barium enema) and tests that detect primarily cancer (high-sensitivity guaiac-based fecal occult blood testing, fecal immunochemical testing for occult blood and stool DNA testing).⁵ After completing the decision-making module, users were asked to print a copy of their test preferences and factors influencing their choice to hand-deliver to their provider. The decision aid took between 11 and 34 minutes to complete, depending on which modules users chose to review. All users viewed each of the required modules (rationale, risk factors/goals, polyps, and brief descriptions of all six screening options) and at least one screening option in detail (time, 11 minutes).

Risk Index

The risk index employed in this study was developed from a cross sectional study of 3,457 average-risk patients undergoing screening colonoscopy at BMC. The index consists of six

independent predictors of risk (age, sex, race/ethnicity, smoking history, daily alcohol intake, and use of non-steroidal anti-inflammatory drugs), each of which is assigned a weighted point score based on 0.25 increments of the adjusted model coefficients (Supplement 1). Patients with cumulative scores of less than 5 were classified as low risk, with a mean ACN rate of 3.1% (95% CI, 2.4% to 4.1%) and those with scores of 5 to 12 were classified as intermediate/high risk (hereafter referred to as high risk), with a mean rate of rate of ACN of 8.3% (95% CI, 7.1% to 9.6%). After completing the electronic risk assessment tool, patients received a printed form describing their risk category (low versus intermediate/high) and pictographs with absolute risk estimates (Supplement 2a and 2b).

The index represents a prototype version of the Advanced Colorectal Neoplasia Index.²⁰ The final version substitutes the height variable for NSAID use and an interaction term for sex and race/ethnicity. Discrimination, as defined by the area under the receiver-operator characteristic curve (C statistic), was similar for the two versions (prototype, C =0.68; final, C=0.69). Agreement between observed and expected rates of ACN across deciles (calibration) was acceptable for the prototype model (Hosmer-Lemeshow goodness-of-fit test, $P=0.06$) and good for the final model ($P= 0.72-0.93$).

Outcomes

The primary outcome was concordance between patient test preference and test ordered, which tracked using BMC's electronic medical record ordering system, respecting. Secondary outcomes included patient satisfaction with the decision-making process (SDMP), screening intentions, 6-month test completion rates, and provider satisfaction. SDMP was assessed on the posttest using the validated 12-item Satisfaction with the Decision-Making Process scale.²¹ Screening intentions were also assessed as part of the posttest. Patients were asked how sure they were that they would complete the screening test that got scheduled. Test completion rates were tracked using BMC's electronic medical record, which captures results for all endoscopic procedures, imaging studies, and fecal occult blood testing. Provider satisfaction was assessed based on responses to a 3-item pretest administered prior to commencement of the study and a 4-item posttest.(see Table 4 for individual items). SDMP, screening intention and provider satisfaction each used an ordered 5-point response frame.

Sample size estimate

Sample size and power considerations focused on the primary outcome of concordance between patient preference and test ordered. Accordingly, we postulated that concordance was likely to increase among patients deemed to be at low risk of ACN who preferred tests other than colonoscopy. From our previous work, we assumed that: (1) approximately one-third of patients would prefer a test other than colonoscopy; (2) 45% of patients would be classified as low risk; and (3) concordance in the control group would be approximately 51%.^{10,20} Based on these assumptions, we estimated that a sample size of 180 patients per group would give >80% power of detecting a 15% increase in concordance from 51% in the control group to 66% in the risk assessment group at the $P<0.05$ level.

Statistical Analysis

As a check on randomization, we compared the demographic characteristics between the two study arms using student t-tests for continuous variables and the chi-square test of independence for categorical variables. Our primary analysis focused on the bivariate association between concordance and study arms (decision aid versus decision aid plus ACNI) and between concordance and risk category (high versus low) among those in the decision aid plus ACNI arm. Our secondary analyses examined associations between concordance and demographic factors and desired role in decision-making, SDMP, screening intentions, and test completion rates. Logistic regression models were created with interaction terms to assess potential effects on concordance by randomization arm. Generalized estimating equation models were used to further adjust for potential clustering by provider. We also compared pre- and post-study responses to survey questions related to provider perspectives on the usefulness of risk assessment, potential reduction in visit times with risk assessment, and receptivity to patient preferences using Wilcoxon rank sum tests. In each case, significance was defined at the $P<0.05$ level. All statistical analyses were performed using SAS, version 9.3 (Cary, NC).

Results

Baseline Characteristics

Of the 2,683 prescreened eligible patients, 352 were enrolled in the study and randomly assigned to the decision aid alone arm ($n=172$) or decision aid plus risk assessment arm (180); 11 patients were later excluded due to ineligibility after the study visit ($n=9$) or missing outcome data ($n=2$), resulting in a total of 168 and 173 patients, respectively, in the final analytic groups (Figure 1). As shown in Table 1, the two groups were well balanced with respect to all baseline characteristics and representative of the eligible BMC patient population aged 50-75 with respect to sex, ethnicity, race, marital status, education, insurance coverage, and decision-making preference. Among those in the decision aid plus ACNI arm, 103 (59.5%) were classified as high risk and 70 (40.5%) as low risk. Overall, participating providers saw a mean of 7 study patients (range, 1-29).

Patient preferences/Concordance

The majority of patients in both the decision aid alone and decision aid plus ACNI groups preferred colonoscopy (78.0% vs. 67.6%) followed by fecal occult blood testing (16.7% vs. 23.1%), flexible sigmoidoscopy (2.4% vs. 2.9%), barium enema (2.4% vs. 2.3%), stool DNA testing (0% vs. 1.2%) and CT colonography (0.6% vs. 0%); a small number patients choose no screening (0% vs. 2.9%). Patients who preferred colonoscopy were most likely to identify accuracy (81.9%) as the most important factor influencing their choice; in contrast, those who chose fecal occult blood testing were most likely to choose convenience (61.8%).

As shown in Table 2, regardless of preferences, there were no significant differences in concordance (i.e., agreement between patient preference and test ordered) between the decision aid alone and decision aid plus ACNI groups (88.1 vs. 85.0%, $P=0.40$) or high- and low-risk groups (83.5 vs. 87.1%, $P=0.51$). Overall, concordance was highest for colonoscopy (96.4%) and relatively low for tests other than colonoscopy (59.1%). Although

patients in the low-risk group who preferred FOBT were more likely to have FOBT ordered than those in the high-risk group (71.4% vs. 57.9%), the difference did not achieve statistical significance ($P=0.37$). Concordance showed no association with desired role in the decision-making process or demographic factors, including age, sex, race, ethnicity and education (Supplement 3) No significant clustering by provider was observed for either test ordered or concordance (data not shown).

Concordance and Patient-Related Outcomes

Regardless of study arm or risk category, both SDMP (51.6 [5.3] vs. 48.9 [6.1], $P<0.001$) and screening intention (4.6 [0.7] vs. 4.0 [1.1], $P<0.001$) scores were higher among patients who had their preferred test ordered than those who had a different test ordered (Table 3). Similarly, patients who had their preferred test ordered were also more likely to complete a screening test within 6 months of the study visit (37% vs. 15%, $P=0.004$).

Factors Influencing Provider Preferences

As shown in Table 4, providers in the decision aid alone and decision aid plus ACNI arm identified patient preferences (48.2% vs. 48.0%, $p=1.00$) and test accuracy (40.5% vs. 41.6%; $P=0.91$) as the most important factors influencing their recommendation. When examining the decision aid plus ACNI arm, providers were no more likely to identify patient preferences in low-risk patients as being more influential than in high-risk patients (57.1% vs. 41.8%, $P=0.06$) nor more likely to identify test accuracy for high-risk patients as being influential (37.1% vs. 44.7%; $P=0.35$).

Provider Perspectives on Risk Stratification

As shown in Table 5, providers perceived risk stratification to be useful in selecting an appropriate CRC screening modality for their average-risk patients and in making them more receptive to patient preferences for tests other than colonoscopy on both the pretest and posttest. They were more neutral when asked whether risk stratification reduced the amount of time required to select an appropriate screening modality or the risk of malpractice if they recommended a patient's preferred screening modality (posttest only).

Discussion

Unlike for conditions where the benefits of screening are less certain, authoritative groups, such as the US Preventive Services Task Force, agree that the primary goal of SDM for CRC screening is to enable informed patients to identify a preferred screening option rather than to decide whether or not to undergo screening.^{4,6,7,22} Available data would suggest that providers are often reluctant to comply with patient preferences when they differ from their own.^{9,11} We postulated that risk stratification for the presence of ACN at screening colonoscopy would enable providers to use objective criteria in their decision-making when considering patient preferences within the context of SDM. The findings of this study suggest that while many providers perceive risk stratification to be somewhat useful and influential in their screening recommendation, they remain reluctant to comply with patient preferences for tests other than colonoscopy, regardless of risk.

Risk stratification for CRC screening has traditionally focused on identifying patients at increased risk due to a family history or a predisposing condition (e.g., longstanding inflammatory bowel disease). In recent years, risk stratification of average-risk individuals has gained attention due to a better understanding of epidemiological determinants of risk and concerns about capacity constraints and costs resulting from the surge in demand for colonoscopy. Consequently, several risk prediction models for ACN have been proposed primarily for the purpose of tailoring the use of screening colonoscopy.²³ The use of risk stratification for facilitating SDM for CRC is intuitively appealing yet previously unstudied. The results reported herein suggest that providers often remain unwilling to comply with patient preferences for tests other than colonoscopy, even among those deemed to be at low risk of ACN. Besides patient and provider barriers to SDM, potential cognitive behavior explanations include fast and frugal heuristics wherein physicians with limited time may use a “take the best, ignore the rest” algorithm, especially in SDM involving minor one-reason decisions that have high certainty, e.g., the superiority of the accuracy of colonoscopy. Other possible explanations include a knowledge gap about the potential benefits of screening by methods other than colonoscopy, concerns about the additional time and effort required to track results and arrange appropriate follow-up testing for patients with positive results by methods other than colonoscopy, concerns that the difference in absolute risk between the high- and low-risk groups may not be sufficient to warrant a tailored recommendation, or the lack of uniform guidelines endorsing risk-based tailoring of screening colonoscopy for average-risk patients.^{6,24}

An important consideration is whether concordance between patient preferences and test ordered translates into better patient outcomes. Previous studies had provided conflicting results with respect to the compliance with patient preferences and test completion^{9-13,25} Extrapolations from studies finding no association suggest that providers who can effectively communicate their reasoning for recommending an alternative test, namely colonoscopy, may be successful in motivating their patients to complete a test regardless of preference or desired role in the decision-making process. In this study, we found that concordance was positively associated with satisfaction with the decision-making process, screening intentions and test completion rates, thus lending further credence to the importance of complying with patient preferences in settings devoid of financial or access-related barriers to specific screening options.

Our study has several notable limitations. First, the study was conducted at a single urban, safety-net medical center where the vast majority of patients had some form of medical insurance, so our findings may not be generalizable to other health care settings where financial barriers might limit screening options. Our findings may also lack generalizability to patient populations who are less motivated towards screening and thus less likely to identify a preferred screening option. Second no attempt was made to educate providers about emerging data on risk stratification of average-risk patients or incorporation of probabilistic estimates of disease risk into their decision-making when considering patient preferences. Nevertheless, many of the participating providers acknowledged that they were receptive to the use of a risk stratification tool when recommending a CRC screening test for select patients.¹⁹ Lastly, patients in the experimental group received personalized risk feedback after rather than before reviewing the decision aid because of our prior work

demonstrating that such information did not influence test preference but did have a negative impact on screening intentions.⁹ Patients were provided with a printout of their risk category and hence were not blinded to the results. It was assumed that this approach might stimulate discussion about risk during the patient-provider encounter.

Despite these limitations, this study also has several notable strengths. First, the use of a randomized clinical trial study design and racially diverse study population enhances both the internal and external validity of its findings. Second, the randomization scheme after stratification by provider minimizes potential confounding. Lastly, SDMP scores and screening intentions were high for both study groups, thus corroborating existing data on the utility of decision aids to facilitate shared decision-making.²⁶

In conclusion, providers perceived risk stratification to be useful in their decision-making but rarely complied with patient preferences for tests other than colonoscopy, even among those deemed to be at low risk of ACN. Failure to comply with patient preferences was negatively associated with SDMP, screening intentions and adherence to screening. Because of the negative impact on important patient outcomes, future studies are needed to determine whether provider education or quality improvement initiatives can promote use of the index in clinical practice and receptivity to patient preferences for tests other than colonoscopy.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Siegel R, Desantis C, Jemal A. Colorectal cancer statistics, 2014. *CA Cancer J Clin.* 2014; 64(2): 104–17. [PubMed: 24639052]
2. Pignone M, Saha S, Hoerger T, Mandelblatt J. Cost-effectiveness analyses of colorectal cancer screening: a systematic review for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2002; 137(2):96–104. [PubMed: 12118964]
3. CDC. Vital Signs: Colorectal Cancer Screening Test Use-United States, 2012. *MMWR.* 2013:621–8.
4. U.S. Preventive Services Task Force. Screening for colorectal cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2008; 149(9):627–37. [PubMed: 18838716]
5. Levin B, Lieberman DA, McFarland B, et al. Screening and surveillance for the early detection of colorectal cancer and adenomatous Polyps, 2008: a joint guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *CA Cancer J Clin.* 2008; 58(3):130–60. [PubMed: 18322143]
6. Qaseem A, Denberg TD, Hopkins RH Jr. et al. Screening for colorectal cancer: a guidance statement from the American College of Physicians. *Ann Intern Med.* 2012; 156(5):378–86. [PubMed: 22393133]

7. Briss P, Rimer B, Reilley B, et al. Promoting informed decisions about cancer screening in communities and healthcare systems. *Am J Prev Med.* 2004; 26(1):67–80. [PubMed: 14700715]
8. Sheridan SL, Harris RP, Woolf SH. Shared decision making about screening and chemoprevention. a suggested approach from the U.S. Preventive Services Task Force. *Am J Prev Med.* 2004; 26(1):56–66. [PubMed: 14700714]
9. Rimer BK, Briss PA, Zeller PK, Chan EC, Woolf SH. Informed decision making: what is its role in cancer screening? *Cancer.* 2004; 101(5 Suppl):1214–28. [PubMed: 15316908]
10. Schroy PC 3rd, Emmons K, Peters E, et al. The impact of a novel computer-based decision aid on shared decision making for colorectal cancer screening: a randomized trial. *Med Decis Making.* 2011; 31(1):93–107. [PubMed: 20484090]
11. Schroy PC 3rd, Emmons KM, Peters E, et al. Aid-assisted decision making and colorectal cancer screening: a randomized controlled trial. *Am J Prev Med.* 2012; 43(6):573–83. [PubMed: 23159252]
12. Hawley ST, Volk RJ, Krishnamurthy P, Jibaja-Weiss M, Vernon SW, Kneuper S. Preferences for colorectal cancer screening among racially/ethnically diverse primary care patients. *Med Care.* 2008; 46(9 Suppl 1):S10–6. [PubMed: 18725820]
13. Inadomi JM, Vijan S, Janz NK, et al. Adherence to colorectal cancer screening: a randomized clinical trial of competing strategies. *Arch Intern Med.* 2012; 172(7):575–82. [PubMed: 22493463]
14. Wong MC, Ching JY, Chan VC, et al. Informed choice vs. no choice in colorectal cancer screening tests: a prospective cohort study in real-life screening practice. *Am J Gastroenterol.* 2014; 109(7):1072–9. [PubMed: 24935273]
15. Klabunde CN, Lanier D, Nadel MR, McLeod C, Yuan G, Vernon SW. Colorectal cancer screening by primary care physicians: recommendations and practices, 2006–2007. *Am J Prev Med.* 2009; 37(1):8–16. [PubMed: 19442479]
16. Winawer SJ, Zauber AG. The advanced adenoma as the primary target of screening. *Gastrointest Endosc Clin N Am.* 2002; 12(1):1–9. v. [PubMed: 11916153]
17. Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst.* 1989; 81(24):1879–86. [PubMed: 2593165]
18. Thompson IM, Ankerst DP, Chi C, et al. Assessing prostate cancer risk: results from the Prostate Cancer Prevention Trial. *J Natl Cancer Inst.* 2006; 98(8):529–34. [PubMed: 16622122]
19. Edwards AG, Naik G, Ahmed H, et al. Personalised risk communication for informed decision making about taking screening tests. *The Cochrane database of systematic reviews.* 2013 2CD001865.
20. Schroy PC 3rd, Caron SE, Sherman BJ, Heeren TC, Battaglia TA. Risk assessment and clinical decision making for colorectal cancer screening. *Health Expect.* Jul 30.2013 Epub ahead of print.
21. Schroy PC WJ, O'Brien MJ, Chen CA, Griffith JL. A risk prediction index for advanced colorectal neoplasia at screening colonoscopy. *Am J Gastroenterol.* 2015; 110(7):1062–71. [PubMed: 26010311]
22. Barry MJ, Cherkin DC, Chang Y, Fowler FJ, Skates S. A randomized trial of a multimedia shared decision-making program for men facing a treatment decision for benign prostatic hyperplasia. *Disease Management and Clinical Outcomes.* 1997:15–14.
23. Ma GK, Ladabaum U. Personalizing Colorectal Cancer Screening: A Systematic Review of Models to Predict Risk of Colorectal Neoplasia. *Clin Gastroenterol Hepatol.* 2014; 12(10):1624–34. [PubMed: 24534546]
24. Rex DK, Johnson DA, Anderson JC, Schoenfeld PS, Burke CA, Inadomi JM. American College of Gastroenterology guidelines for colorectal cancer screening 2009 [corrected]. *Am J Gastroenterol.* 2009; 104(3):739–50. [PubMed: 19240699]
25. Multicentre Australian Colorectal-neoplasia Screening G. A comparison of colorectal neoplasia screening tests: a multicentre community-based study of the impact of consumer choice. *Med J Aust.* 184(11):546–50.
26. Stacey D, Legare F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. *The Cochrane database of systematic reviews.* 2014 1CD001431.

Figure 1.

Table 1

Characteristics of Study Participants (N=341)

Characteristic	Total (n=341)	Decision Aid (n= 168)	Decision Aid + ACNI (n=173)	P value *
Age, mean $\pm$ SD	56.4 $\pm$ 6.3	56.0 $\pm$ 5.9	56.8 $\pm$ 6.8	0.51
Sex, n (%)				0.88
Female	180 (52.8)	88 (52.4)	92 (53.2)	
Male	161 (47.2)	80 (47.6)	81 (46.8)	
Ethnicity, n (%)				0.46
Hispanic	23 (6.7)	13 (7.7)	10 (5.8)	
Non-Hispanic	317 (9.0)	154 (91.7)	163 (94.2)	
Refused	1 (0.3)	1 (0.6)	0	
Race, n (%)				0.53
White	75 (22.0)	33 (19.6)	42 (24.3)	
Black	208 (61.0)	104 (61.9)	104 (60.0)	
Other	58 (17.0)	31 (18.4)	27 (15.6)	
Education, n (%)				0.15
High school or less	212 (62.2)	98 (58.3)	114 (65.9)	
Greater than high school	129 (37.8)	70 (41.7)	59 (34.1)	
Marital status, n (%)				0.71
Married/living with partner	96 (28.2)	49 (29.2)	47 (27.2)	
Single/separated/divorced/widowed	244 (71.6)	119 (70.8)	125 (72.2)	
Refused	1 (0.3)		1 (0.6)	
Insurance, n (%)				0.16
Private/HMO	93 (27.3)	55 (32.7)	38 (22.0)	
Medicare	100 (29.3)	46 (27.4)	54 (31.2)	
Medicaid	86 (25.2)	37 (22.0)	49 (28.3)	
Free care	41 (12.0)	21 (12.5)	20 (11.6)	
Other	17 (5.0)	6 (3.6)	11 (6.4)	
None	4 (1.2)	3 (1.8)	1 (0.6)	
Desired role in decision-making, n (%)				0.37
Mostly patient	111 (32.6)	58 (34.5)	53 (30.6)	
Shared	176 (51.6)	88 (52.4)	88 (50.9)	
Mostly provider	54 (15.8)	22 (13.1)	32 (18.5)	
ACNI risk, n (%)				
High risk			103 (59.5)	
Low risk			70 (40.5)	

ACNI, Advanced Colorectal Neoplasia Index; HMO, health maintenance organization

* Student t-tests for continuous variables and chi-square tests of independence for categorical variables

Concordance between Patient Preference and Test Ordered

Preference	Concordance, n/N (%) *					
	Decision Aid Only (n=168)	Decision Aid + ACNI (n=173)	Decision aid + ACNI High Risk (n=103)	Decision Aid + ACNI Low Risk (n=70)	$\hat{\tau}$	P value
Overall $\hat{\tau}$	148/168 (88.0)	147/173 (85.6)	86/103 (83.5)	61/70 (87.1)		0.51
Colonoscopy	125/131 (95.4)	114/117 (97.4)	69/71 (97.2)	45/46 (97.8)		1.00
Other test	23/37 (62.2)	29/51 (56.9)	14/28 (50.0)	15/23 (65.2)		0.39
FOBT	19/28 (67.9)	26/40 (65.0)	11/19 (57.9)	15/21 (71.4)		0.51
FSIG	3/4 (75)	2/3 (66.7)	2/4 (50.0)	0/1 (0)		1.00
CTC	0/1 (0)	0/0 (0)	0/3 (0)	0/1 (0)		1.00
DCBE	1/4 (25)	1/4 (25)	1/3 (33.3)	0/1 (0)		1.00
Stool DNA	0/0 (0)	0/2 (0)	0/2 (0)	0/0 (0)		N/A
No screening	0/0 (0)	4/5 (80)	3/4 (75.0)	1/1 (100.0)		1.00

ACNI, Advanced Colorectal Neoplasia Index; FOBT, fecal occult blood testing; FSG, flexible sigmoidoscopy; CTC CT colonography (virtual colonoscopy); DCBE, double-contrast barium enema; N/A, not appropriate

* Concordance is defined as the number of patients who had their preferred test ordered (n) divided by the total number of patients who preferred the test (N).

Chi-square test of independence or Fisher's Exact test

Overall includes “no screening”

Associations between Concordance and Satisfaction with the Decision-Making Process, Screening Intentions and 6-Month Test Completion Rates

Table 3

Characteristic	Concordance (n=295) [*]	Discordance (n=46) [*]	P value [§]
SDMP, mean (SD) [‡]	52.0 (5.3)	48.9 (6.1)	<0.001
Intentions, mean (SD) [‡]	4.6 (0.7)	4.0 (1.1)	<0.001
Test completed within 6 months, n (%)	109 (37.0)	7 (14)	0.004

ACNI, Advanced Colorectal Neoplasia Index; SDMP, satisfaction with decision-making process

^{*} Data for SDMP and intentions missing for 11 patients in the concordant group and 6 patients in the discordant group.

[‡] Scores were derived from the 12-item SDMP scale.¹⁵ Individual items are assigned a point value ranging from 1 for “strongly disagree” (or “poor”) to 5 for “strongly agree” (or “excellent”). A cumulative score is then calculated based on the summed response scores for each item (maximum score = 60).

[§] Screening intentions were assessed based on responses to the question: “How sure are you that you will complete the screening test ordered?”. Scores ranged from 5 = “completely” to 1 = “not at all sure.”

[§] Wilcoxon rank-sum for continuous variables and chi-square test of independence for categorical variables

Table 4

Most Important Factor Influencing Provider Recommendation

Reason, n (%)	Decision Aid Only (n=168)	Decision Aid + ACNI (n=173)	P value *	Decision Aid + ACNI High Risk (n=103) ^a	Decision Aid + ACNI Low Risk (n=70)	P value *
Overall			1.00			0.37
Patient preference	81 (48.2)	83 (48.0)	1.00	43 (41.8)	40 (57.1)	0.06
Accuracy	68 (40.5)	72 (41.6)	0.91	46 (44.7)	26 (37.1)	0.35
Preparation	1 (0.4)	0	N/A	0	0	N/A
Convenience	4 (2.4)	5 (2.9)	N/A	4 (3.9)	1 (1.4)	N/A
Risks	2 (1.2)	1 (0.6)	N/A	1 (1.0)	0	N/A
Follow-up	4 (2.4)	4 (2.3)	N/A	3 (2.9)	1 (1.4)	N/A
Frequency	4 (2.4)	5 (2.9)	N/A	3 (2.9)	2 (2.8)	N/A
Cost	1 (0.4)	0	N/A	0	0	N/A
Co-morbidities	3 (1.9)	3 (1.7)	N/A	3 (2.9)	0	N/A

ACNI, Advanced Colorectal Neoplasia Index; N/A, not appropriate

* Fisher's Exact test

Table 5

Provider Perspectives on Risk Stratification and SDM for CRC Screening

Personalized risk assessment...	Ratings *		p value †
	Pretest (n=42)	Posttest (n=32)	
will be/was useful in selecting an appropriate CRC screening modality for you average –risk patients	4.0 (0.7)	3.9 (0.9)	0.70
will reduce/reduced the time to decide on a CRC screening modality	3.2 (1.0)	3.6 (1.0)	0.10
will make /made me more receptive to patient preferences and possibly order a screening test other than colonoscopy	3.8 (0.7)	3.8 (1.0)	0.86
reduces the risk of malpractice if I recommend a patient's preferred screening modality	---	3.2 (1.0)	

SDM, shared decision-making; CRC, colorectal cancer

* Mean scores (SD) where 5= “strongly agree” and 1 = “strongly disagree”

† Wilcoxon rank-sum