

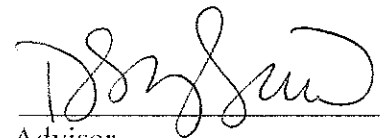
Development and Initial Testing of a Computer-Based Patient Decision Aid to Promote Colorectal Cancer Screening for Primary Care Practice

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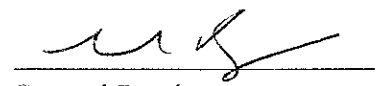
A Master's Paper submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Public Health in the Public Health Leadership Program.

Chapel Hill

2004



Advisor



Second Reader

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Abstract

Background: Colorectal cancer (CRC) is the second leading cause of cancer death in the United States and the third most commonly diagnosed cancer in men and women. Despite published guidelines advocating screening for average-risk adults 50 years and older, rates of screening remain low.

Purpose: To investigate whether a patient-directed, computer-based decision aid about colorectal cancer screening can increase patient interest in screening and raise screening rates.

Study Design: Before-after uncontrolled trial.

Setting: The University of North Carolina (UNC)-Chapel Hill general internal medicine clinic.

Population: A convenience sample of 80 patients 50-75 years old at average risk for CRC who were seen for a new or return appointment.

Methods: Patients viewed the decision aid in which all patients viewed a 3-5 minute introduction to CRC screening. They were then given a choice to view one to four 3-5 minute segments describing individual screening tests or comparative information about the tests. Subjects completed before- and after-questionnaires indicating their intent to ask their provider about screening, interest in being screened in the next six months, and their readiness to be screened for colorectal cancer. We reviewed

patient charts 3-6 months afterwards to assess screening test ordering and completion.

Results: At baseline, the mean intent to ask providers for screening was 2.8 as measured on a 4-point Likert scale (1=not at all likely to ask, 4=very likely to ask). After viewing the decision aid, mean intent increased to 3.2 ($p<0.0001$, paired t-test).

Interest in being screened, also measured on a 4-point Likert scale (1=not at all interested, 4=very interested), increased from 3.2 to 3.5 ($p=0.01$, paired t-test). 89% said the information increased their knowledge about colon cancer. After viewing the decision aid, 60% were ready to be screened, 18% wanted more information but were considering screening, and 22% were not ready for testing. Three to six months after viewing the decision aid, 46% of participants had a colorectal cancer screening test ordered and 39% of patients had completed tests. Among patients who were ready to be screened, 51% had tests ordered and 43% had completed screening tests.

Conclusions: In this pilot study, a computer-based colorectal cancer decision aid improved patients' interest in being screened and subjectively improved patient knowledge about CRC. Only approximately half of patients who were ready for screening had tests ordered and completed. Future research needs to be done to

test if the decision aid in combination with office systems support can effectively raise screening rates.

I. Burden of Suffering

Colorectal cancer (CRC) is the second leading cause of cancer death and third most diagnosed cancer in the United States. In 2004, an estimated 152,000 new cases and 57,000 deaths will occur due to CRC, accounting for approximately 10% of all new cancer cases and deaths nationwide.^{1,2} CRC has a high survival rate when detected at an early stage but when diagnosed in advanced stages, survival is poor. Individuals diagnosed with localized disease have a five-year survival rate of 90%, but those with distant disease have a five-year survival rate of only 9%.^{1,2} Both CRC incidence and death rates have declined in the past 30 years. Incidence rates for colorectal cancer began to decline in the mid-1980s and stabilized starting in 1995; death rates began to decline in the 1970s and continue to decline among men and women.³ Possible reasons for these declines in incidence and mortality include an increase in early detection as a result of screening as well as improvements in treatments such as adjunct chemotherapy.

Although incidence and mortality rates declined overall during the past twenty years, there are important differences by sex and race. Death rates from CRC remain approximately 40% higher in men compared to women.⁴ In addition, African-Americans continue to have the highest age-standardized

incidence and death rates compared to other races. From 1996-2000, the colorectal cancer death rate for black men was 34.6/100,000 and for white men, 25.3/100,000, with a similar absolute difference seen between black and white women.¹ Although overall death rates from CRC declined over the past decade at 2.2% per year for white men and 1.8% for white women, the declines were 50% less for blacks.^{4,5} In addition, more African-Americans are diagnosed at an advanced stage⁶ and have lower five-year survival rates at every stage of diagnosis¹ compared with whites. There are no conclusive explanations for these racial disparities but possible reasons include poor access to care resulting in delayed diagnoses, lower rates of screening,⁷ inadequate staging and treatment of disease, or a higher burden of comorbid diseases among African-Americans leading to poorer outcomes.

II. Colorectal Cancer Screening: Evidence and Guidelines

There is good evidence that screening for colorectal cancer using fecal occult blood testing (FOBT) leads to reductions in colorectal cancer incidence and mortality. Mandel et al. conducted a trial of 46,551 patients randomized to annual FOBT, biennial FOBT, or controls.⁸ After a follow-up period of 13 years, they found a 33% reduction in the cumulative mortality

rate in the annual FOBT group (5.88/1000) compared to controls (8.83/1000); this difference was statistically significant.

Additional data collected after 18 years of follow-up showed a persistent 33% mortality rate reduction in the annually screened group compared with controls. There was also a statistically significant 21% lower mortality rate in the biennial FOBT group compared to controls.⁹ Other large randomized controlled trials from Denmark¹⁰ and the United Kingdom¹¹ found significant 18% and 15% reductions in mortality, respectively, with biennial FOBT screening. Along with reductions in mortality rates, FOBT screening is also associated with reductions in the incidence of CRC. In the trial conducted by Mandel et al., cumulative incidence ratios for CRC were 0.80 and 0.83 for annual and biennial FOBT screening, respectively, after 18 years of followup.¹²

There is evidence from case-control studies that screening with sigmoidoscopy leads to decreased mortality from colorectal cancer. Selby et al. conducted a case-control study of 261 individuals who died from CRC compared with 868 age- and sex-matched controls.¹³ They examined the proportions of cases and controls who had screening via rigid sigmoidoscopy and found an odds ratio for CRC mortality of 0.41 (95% confidence interval (CI) 0.25-0.69), adjusted for personal history of CRC or

polyps, family history of CRC, numbers of digital rectal exams and FOBTs, and number of health visits over the previous 10 years. Another case-control study conducted using data from a cohort of 4411 veterans who had died of colon and rectal cancer between 1988-1992 showed a mortality benefit to large bowel endoscopy, including flexible sigmoidoscopy (FS), rigid proctosigmoidoscopy, and colonoscopy. The 4411 patients who had died of colorectal cancer were matched by age, sex, and race to four living and four dead control patients without colorectal cancer. This study found an odds ratio of 0.41 (95% CI, 0.33-0.50) for any diagnostic procedure of the large bowel.¹⁴ There are two ongoing large randomized trials of flexible sigmoidoscopy, the Prostate, Lung, Colorectal, and Ovarian trial^{15, 16} and the UK Flexible Sigmoidoscopy trial,¹⁷ that will provide additional data regarding the mortality benefit of flexible sigmoidoscopy.

There is one cohort study that showed a mortality benefit to the combination of FOBT and sigmoidoscopy compared to sigmoidoscopy alone but the results were of borderline statistical significance. Winawer et al. followed a cohort of 21,756 patients who were non-randomly assigned to an intervention group that received annual rigid sigmoidoscopy and FOBT or to a control group that received annual sigmoidoscopy alone.¹⁸ They found

that the CRC mortality rate in the intervention group was 0.36/1000 per year vs. 0.63/1000 per year in controls ($p=0.053$, one-tailed test). In addition, patient compliance to FOBT was poor. Given the borderline significance of these results, it is uncertain whether there is a true mortality benefit to annual FOBT and sigmoidoscopy vs. sigmoidoscopy alone.

There is no evidence from randomized controlled trials to support a mortality benefit for colonoscopy. There is evidence that colonoscopy and colon polypectomy can lead to a decrease in CRC incidence. The National Polyp Study was comprised of a cohort of 1,418 patients who had a complete colonoscopy with removal of one or more colon or rectal adenomas. The average follow-up time was 5.9 years.¹⁹ This cohort was compared to three reference groups, two cohorts who had not undergone colon polypectomy and one cohort representative of people at average risk in the general population. They found statistically significant decreases in cumulative incidence in the colon polypectomy group when compared to each of the reference groups. The observed CRC incidence in the intervention cohort was 0.6/1000 person-years compared to 5.8, 5.2, and 2.5/1000 person years, respectively, in the reference groups. A retrospective cohort study of 1693 colon polypectomy patients conducted in Italy also found decreased CRC incidence when

compared to the Italian general population.²⁰ Over a mean follow-up of 10.5 years there were 6 CRC cases compared to 17.7 cases expected in the reference population, with an incidence ratio of 0.34 (95% CI 0.23, 0.63) comparing observed vs. expected incidence.

In addition to decreasing CRC incidence, colonoscopy may be able to detect advanced colonic neoplasms that would not otherwise be detected via sigmoidoscopy. In a cohort of 3,121 veterans who underwent colonoscopy, 10.5% had adenomas >10mm in diameter, villous adenomas, high-grade dysplasia, or invasive cancer. Of 128 patients with advanced proximal neoplasia, 52% did not have distal adenomas. These results suggest that colonoscopy may be able to detect pre-malignant adenomas that would not be seen by sigmoidoscopy, but to date there are no randomized controlled trials to support this assertion or to show a mortality benefit to colonoscopy.

In 2002-2003, the American Gastroenterological Association along with a multi-disciplinary consortium panel, the U.S. Preventive Services Task Force (USPSTF), and the American Cancer Society published guidelines for the screening of average-risk adults 50 years and older.²¹⁻²³ Average-risk is defined as individuals without a family or personal history of CRC, no personal history of adenomatous polyps, and the

absence of an illness such as inflammatory bowel disease that predisposes individuals to CRC. Screening modalities endorsed by all three organizations include: 1) FOBT yearly; 2) flexible sigmoidoscopy (FS) every 5 years; 3) FOBT yearly combined with FS every 5 years; 4) double contrast barium enema every 5 years; and 5) colonoscopy every 10 years (Table 1). The organizations agree that any one of these methods is an appropriate means of screening but that there is no clear evidence that any one method is superior. They recommend that providers discuss these options with patients and decide on a strategy based on patient preferences for screening.

Colorectal cancer screening also appears to be cost effective. In 2002, Pignone et al. performed a systematic review of cost effectiveness analyses of CRC screening. They reviewed seven studies and found cost-effectiveness ratios of \$10-25,000 per life-year saved when compared with no screening.²⁴ No single screening modality was found to be superior in terms of cost-effectiveness. There was insufficient evidence to determine an appropriate age to stop screening for CRC.

III. Colorectal Cancer Screening Rates

Despite the evidence supporting screening and the existence of published guidelines advocating screening, data

from state and national surveys show that the self-reported rates of colorectal cancer screening in the U.S. population are low. The percentage of individuals 50 and over who reported ever having a screening test for colorectal cancer ranges from 25%²⁵ to 48%²⁶. Although current rates remain low, there has been a trend towards increased screening in the past decade. In the National Health Interview Survey (NHIS), an annual household survey of 49,000 households, there was a trend toward increased FOBT use; from 1987-1998, FOBT use in the past three years increased from 18% to 29% in men and from 21% to 26% in women.²⁵ Rates of sigmoidoscopy in the NHIS were low, although there was a trend towards increased use in both men and women. The Behavioral Risk Factor Surveillance System (BRFSS) survey also found recent increases in CRC screening. The BRFSS consists of self-report data collected from a state-based, random digit-dialed telephone survey administered yearly. From 1997-2001, the percentage of individuals reporting FOBT within the past 12 months rose from 19.4% in 1997 to 23.5% in 2001. Self-reported endoscopy rates within the past 5 years rose from 29.9% to 38.7% over the same time period.^{27, 28} Reasons for the differences in screening rates and test use estimates between the NHIS and BRFSS are unclear. One possible explanation is that the surveys, one national and one state-based, use different

survey methods resulting in the sampling of different populations.

There are limitations to these survey findings. One limitation is that these are self-reported data that do not differentiate between screening vs. diagnostic procedures, resulting in an overestimation of screening rates. Another limitation is that the surveys do not accurately measure compliance with current screening guidelines. The BRFSS cannot distinguish between sigmoidoscopy within the past 5 years and colonoscopy in the past 10 years, and the NHIS only reports data on sigmoidoscopy use within the past 3 years. There is also potential respondent bias given that response rates range from 51.1% in the 2001 BRFSS²⁸ to 74% in the 1998 NHIS²⁵.

Despite these limitations, these national surveys show that colorectal cancer screening rates less than half of adults over 50 reporting having been screened for CRC. These rates are far below those of mammography and pap smear testing^{25, 29, 30} and fall short of the goals set by Healthy People 2010 which are to increase the proportion of adults receiving FOBT in the past 2 years to 50% and the proportion of adults ever having received a sigmoidoscopy to 50%.³¹ Reasons for the low rates of screening include patient, provider, and systems-related factors.

IV. Barriers to Screening

1. Patient-related Factors

Patient non-adherence to colorectal cancer screening is caused by patients' perceptions that screening tests are inconvenient, patient misconceptions about screening tests, insurance and access issues, and poor patient-provider communication. A 1997 review of the literature on patient participation in colorectal screening³² found that reasons given by patients for nonparticipation included: 1) practical reasons, such as time conflicts, inconvenience, lack of interest, being too busy, and cost; 2) perceived lack of current health problems or symptoms of colorectal cancer; 3) anxiety or embarrassment about undergoing screening; and 4) not wanting to know about health problems or being anxious about test results. Practical reasons and perceived lack of health problems or symptoms were the most common reasons why patients did not complete screening tests such as FOBT and sigmoidoscopy.

Other patient-related barriers to screening are lack of insurance and poor access to health care. An analysis of 1999 BRFSS data found that underutilization of CRC screening tests was most common in those with lower education, a lack of health insurance, and low use of preventive services.³³ A retrospective analysis of a cohort of adults in an academic primary care

practice in San Francisco from 1995-1997 found that having private insurance was a significant predictor of FOBT screening compared with no insurance, and managed care insurance was a predictor of receiving sigmoidoscopy or any type of colon cancer screening.³⁴ Lack of insurance coverage has become less of a barrier in recent years due to Medicare's addition of colonoscopy to its list of covered services in 2001.³⁵ For individuals not yet eligible for Medicare, lack of insurance is still a barrier to screening.

Access to health care is another barrier that affects those in medically underserved areas and can prevent individuals from obtaining screening. A focus-group based analysis of 21 rural Medicaid patients' views on colorectal screening found that a main theme was patients' perception of poor access to quality healthcare.³⁶ These patients defined poor quality care as either not being offered screening or not having followup of test results. In this case, patients had access to a health care system but felt that the low quality of care interfered with their ability to comply with screening recommendations.

There is evidence that major barriers to CRC screening are poor patient understanding about CRC and the failure of health care providers to recommend screening. Beeker et al. conducted 14 focus groups among insured adults 50 and older in Georgia,

Kansas, and Pennsylvania.³⁷ They found that participants were poorly informed about colorectal cancer, including the causes and risk factors for CRC, and that few were aware of the benefits of screening. Many reported that they received little or no information about screening from their health care provider and identified this lack of counseling as a barrier to screening. Similarly, Weizman et al. conducted focus groups with 39 individuals in Massachusetts and found that there was a low level of knowledge about the prevalence and risk factors for CRC as well as a lack of information given by providers regarding screening.³⁸ A study of 397 African-Americans enrolled in a church-based health program found that the most common perceived barrier was that a health care provider had not recommended screening.³⁹ Provider recommendation was also important in a study of low-income African American women; physician recommendation was significantly associated with adherence to screening.⁴⁰ A survey of 70 patients enrolled in a CRC screening program in Alabama found that the most common reason for nonparticipation was being unaware that screening was due.⁴¹

Although many of these studies consisted of small volunteer samples from defined geographic regions, they provide insight into patient-related barriers to screening. These studies show that

many patients have misconceptions about colorectal cancer, including risk factors and knowledge about the disease, and that lack of provider counseling about screening is a significant barrier. These results point to the need for increased patient education about CRC and screening and the need for improved patient-provider communication about screening.

2. Provider-related factors

Other barriers to CRC screening are due to provider-related factors. Reasons that providers fail to counsel or order CRC screening tests include lack of time, lack of knowledge about current guidelines, concerns about screening effectiveness, provider forgetfulness, and misperceptions about patient preferences. As discussed previously, studies show that patients identify the lack of provider counseling as a barrier to screening. There is a need to address provider-level barriers to screening in order to identify areas for change and to increase screening rates.

One barrier to screening is providers' lack of time to counsel patients about screening. Patients and providers should discuss CRC screening together because of the range of test options available and the importance of incorporating patient preferences to ensure compliance. This process of shared decision making can be time-consuming and, with the time

constraints of primary care practice, conversations about screening are often brief or do not occur. One study by Yarnall et al. calculated a model of the time needed to provide all the preventive services recommended by the USPSTF. According to their calculations, a family physician would need 7.4 hours a day to counsel and provide clinical preventive services in a 2500 patient panel.⁴² Ellerbeck et al. observed 38 rural primary care physicians' counseling practices over an 8-week period. They found that only 14% of patients 50 and older were counseled about CRC screening.⁴³ Although the period of observation was only 8 weeks and did not account for prior history of screening, half the patients surveyed after the clinical encounter said they had not discussed FOBT within the past year or sigmoidoscopy within the past 5 years, suggesting that screening was overdue in these patients.

Another provider-level barrier to screening is lack of knowledge about existing guidelines and doubts about the effectiveness of screening tests. Guidelines for CRC screening were not uniform until all major organizations made recent revisions in 2002-2003 that advocated any of the five methods of screening discussed above. Despite existing guidelines, not all providers are knowledgeable about current recommendations and may have concerns about test effectiveness. Schroy et al.

surveyed Massachusetts internists and found that 80% were aware of at least one of the available published guidelines for screening but that physicians' perceived lack of efficacy data was associated with lower rates of offering sigmoidoscopy.⁴⁴

Klabunde et al. administered a national survey to primary care providers in 1999 to assess their knowledge about guidelines and their perceptions about test effectiveness.⁴⁵ There was variable knowledge about existing guidelines among the 1235 physician respondents. Forty-nine percent reported that current ACS guidelines were very influential on their screening practices, but 24% were unfamiliar with USPSTF guidelines and 37% were unaware of the GI Consortium guidelines. In terms of screening practices, there were discrepancies between guidelines and actual practice. Although more than 98% recommended some form of CRC screening, 43% started screening average-risk individuals at age 40, more than half of general practitioners recommended sigmoidoscopy every 1-3 years, and 64% of OB-GYNs said they used office-based FOBT and digital rectal exams exclusively for CRC screening. More than 80% of respondents rated colonoscopy as "very effective" and rated the other screening modalities lower in effectiveness. These results show that most providers recommend screening but there are variable levels of

provider knowledge about starting ages, recommended timing of screening tests, and efficacy data.

Another barrier to CRC screening is that providers may have incorrect perceptions about patients' acceptance of screening. Ling et al. conducted a cross-sectional survey of 217 patients and 39 physicians at an academic general medicine clinic in order to assess patient and physician preferences for CRC screening as well as physicians' perceptions of patient preferences.⁴⁶ They found significant differences in physician opinions about patient preferences compared to actual patient preferences; 64% of physicians felt that patients considered discomfort to be the most important feature when selecting a screening method, whereas only 15% of patients actually rated discomfort as most important. Likewise, 15% of physicians felt that patients thought that accuracy was the most important test feature when 54% of patients actually rated this most important. These discrepancies show that physicians in this study had incorrect opinions of patient preferences about screening, rating discomfort as most important to patients while most patients chose accuracy as most important.

Other surveys also show that providers perceive the most common concern for patients to be discomfort. A survey of 77 primary care providers in Massachusetts found that physicians

perceived the most common patient barriers to be discomfort and patients' assumptions that they will have symptoms if there is a problem.⁴⁷ Schroy et al.'s survey of Massachusetts internists found that these physicians rated patient fear and anxiety as the most common barrier to sigmoidoscopy.⁴⁴

Provider views on patient preferences can influence their screening recommendations to patients. If providers have incorrect perceptions about patients' preferences, they may offer or order screening tests that are not compatible with patients' actual preferences, possibly leading to lower rates of patient compliance.

3. Office systems-related factors

The time pressures on primary care providers likely contribute to the low rates of CRC screening. There is a need for office systems support given the competing demands of acute problems, management of chronic diseases, and the need for counseling regarding other preventive services. Support in the form of performance audits, chart reminder systems, patient reminders, and screening test tracking systems are potential means of improving the performance of screening.⁴⁸

Computerized or web-based systems that link patient data to patient- and provider-reminders are promising innovations that can help expedite and coordinate preventive care in a primary

care office setting.⁴⁹⁻⁵¹ Shea et al. conducted a meta-analysis of randomized trials of computer-based clinical reminder systems and found that computerized reminders improved the odds of colorectal screening compared to control groups who did not receive reminders.⁵⁰

Standing orders that can be initiated by a nurse based on patient preferences are another means of improving screening test ordering rates. Standing orders systems are recommended for preventive services such as pneumococcal vaccination⁵² and have been effective in raising pneumococcal vaccination rates in an outpatient setting.⁵³ In a standing orders protocol for CRC screening, nurses or other designated staff would be able to order screening tests for average-risk patients based on patient preferences for screening and a written protocol approved by the providers in the practice. Providers would be notified about the order and would have the ability to cancel or change the request if needed. The implementation of an office-systems infrastructure to support CRC screening has the potential to help address patient and provider barriers and improve screening rates.

V. Development and initial testing of a computer-based patient decision aid for colorectal cancer screening

1. Background: Colorectal cancer screening decision aids

Colorectal cancer screening is a complex issue given the many available options for screening and the different risks and benefits of each option. Optimally, colorectal cancer screening should involve both the patient and provider in a shared decision-making process where risks, benefits, and patient preferences are considered. Time limitations and lack of knowledge about current guidelines may prevent providers from adequately discussing screening with patients. This may lead to patients lacking the knowledge needed to make an informed decision about screening.

To address patients' need for education about screening, tools such as decision aids have been developed. Decision aids provide information that helps patients understand their options for screening as well as the risks and benefits of these options.⁵⁴ Formats include printed brochures, scripts read aloud to patients, videotapes, or interactive CD-ROMs. A systematic review found that patient decision aids improved knowledge, reduced decisional conflict, and helped patients become more active in the decision-making process.⁵⁴

A few decision aids for colorectal cancer have been developed and studied. Meade et al. conducted a randomized controlled trial of a print booklet and a videotape about colorectal cancer screening.⁵⁵ They randomized 1100 patients from a primary care clinic in Milwaukee to a booklet, videotape, or no intervention. Both the booklet and the videotape significantly improved scores on a test of colorectal screening knowledge by 23% and 26%, respectively, compared to a 3% improvement in knowledge among controls. Another CRC decision aid developed by Dolan et al. consisted of a short verbal description of colorectal cancer and screening tests.⁵⁶ In a randomized trial of 96 patients enrolled in general medicine practices, patients who received the decision aid had a significant decrease in decisional conflict due to increased knowledge, better clarity of values, and higher ratings of the quality of decisions they made vs. controls. There was no difference, however, in the rate of screening test completion between the two groups (52% of control group and 49% of intervention group).

These decision aids increased patient knowledge about CRC screening but did not increase actual screening rates. We conducted a randomized, controlled trial of a patient-directed, videotape-based decision aid for colorectal cancer along with a

targeted brochure and chart marker that improved patient interest in screening and increased rates of test ordering and completion.

2. Previous Research

We previously conducted a randomized controlled trial of an 11-minute videotape decision aid that contained information about susceptibility to colon cancer and descriptive information about screening tests.⁵⁷ In 1998 we enrolled 249 patients from three community primary care practices in North Carolina and randomized them to an intervention videotape about colon cancer screening or a control videotape about automobile safety. The intervention videotape reviewed how screening tests were performed, the meaning of positive and negative results, and included vignettes in which patients described their experiences with screening. It only contained information on flexible sigmoidoscopy and FOBT, the two recommended screening modalities at the time. After viewing the videotape, patients in the intervention group chose a color-coded brochure that indicated their stage of readiness to be screened. The color-coded brochures were based on Prochaska et al.'s transtheoretical model and stages of change.⁵⁸ Green indicated that the patient was currently ready to be screened, yellow that the patient was interested in screening but needed more information, and red that

they did not want screening. In addition to choosing a color-coded brochure, a chart marker of the same color chosen by the patient was attached to their charts. A research assistant reviewed medical records 3-6 months after patients viewed the decision aid to assess screening test ordering and completion.

There was a significant increase in test ordering and completion in the intervention group compared to controls and there was also an increase in patients' intent to ask providers for screening after viewing the intervention videotape. The participants' mean age was 63, 59% were female, 84% were white, and 73% were high school graduates. 3-6 months after the viewing the decision aid, test ordering was 21 percentage points higher in the intervention groups vs. controls (47% vs. 26%, 95% CI of the difference 9-33). Screening test completion was 14 percentage points higher (37% in the intervention group vs. 23% in controls, 95% CI of the difference 3-25). Among patients viewing the intervention video, the mean intent to ask providers for screening as measured on a 4-point Likert scale (1=very unlikely to ask, 4=very likely to ask) increased from 2.2 prior to viewing the decision aid to 3.1 afterwards ($p < 0.001$). The videotape decision aid in combination with a stage-targeted brochure and chart marker improved patient intent to be screened and increased screening rates in this primary care population.

Despite the videotape-based decision aid's success in raising screening rates, there were limitations to the format and content of the aid that necessitated changes. Because the decision aid was produced in videotape form only, it could not be easily updated to include information on new screening guidelines that now include colonoscopy and barium enema. In addition, the videotape could not be tailored to meet different levels of knowledge about CRC screening; all patients in the intervention group watched the same videotape. In light of these limitations, a revised, computer-based form of the decision aid was developed. Recent advances in web-based and CD-ROM technology since the development of the videotape decision aid made it possible to produce a revised version that can be updated to include new information and can be tailored to patients' individual knowledge needs.

3. Computer-based decision aid development

We based the educational content of the computer-based decision aid on the content used in the videotape version. Additional segments on colonoscopy, barium enema, and comparative information about the tests were added. The decision aid was programmed into a web-based format that directs patients toward an introductory overview of colorectal

cancer screening and then gives patients a choice to view one or more segments on individual screening tests or a segment comparing the tests. Questionnaires were programmed into the web-based version to be completed by patients before and after viewing the decision aid.

We conducted two rounds of usability testing with 12 representative patients per group. Based on feedback from these sessions, we increased font sizes and more clearly labeled controls to facilitate use of the decision aid. After these changes, patients with varying levels of computer experience were able to successfully navigate through the choices presented.

Purpose of the current study

The goals of this study are to test whether a computer-based, patient-directed decision aid can increase patient interest and knowledge about screening and improve the ordering and completion of colorectal cancer screening tests.

4. Methods

Study Design

We enrolled a convenience sample of 80 patients from the University of North Carolina (UNC)-Chapel Hill general internal medicine clinic from June 2003 through April 2004. **Population**

The participants were adults 50 to 75 years old who were currently enrolled in the general internal medicine clinic and presented to their provider for a scheduled appointment.

Eligibility

Eligibility criteria were: 1) the absence of a personal or family history of colon cancer in a first degree relative; 2) sufficient general health to undergo screening as determined by the research assistant (RA) or the primary care provider; and 3) the ability to communicate in English. We attempted to enroll patients who were not up to date with screening, defined as those who did not have FOBT performed within the past year, flexible sigmoidoscopy or barium enema within the past 5 years, or colonoscopy within the past 10 years. If it was found after patients were enrolled, however, that they were up to date with screening, they were allowed to continue in the study.

Enrollment

The RA identified eligible patients from a daily review of clinic rosters. The medical records of patients ages 50-75 were reviewed to determine if these patients were up to date with screening. Providers were given a general overview of the study, and the RA asked providers for permission to approach eligible patients prior to each clinic session. In addition to RA

recruitment, providers also referred eligible patients for participation in the study. Eligible patients who presented to the clinic were consecutively approached either before or after their scheduled appointment and asked to enroll. If the patient agreed to participate in the study, the RA explained the study's purpose, described the decision aid and the estimated time needed to complete the study, and obtained written informed consent.

Intervention

The decision aid consisted of an introduction and five additional segments that described individual screening tests. A physician provided narration for all segments. All patients viewed the introduction that described the importance of colorectal cancer screening, the benefits of early detection of neoplasms, and gave a brief overview of the five available screening options. After viewing the introduction, patients were directed to a menu of choices that allowed them to choose segments on FOBT, flexible sigmoidoscopy, colonoscopy, barium enema, or comparative information about the tests. Each segment was approximately 3-5 minutes long and described each screening test, preparation for the test, how the test is performed and its risks and benefits. All segments included multiple vignettes in which patients talked about their experiences with CRC screening.

Once written informed consent was obtained, participants viewed the decision aid on a computer in a private area in the clinic. The RA provided computer assistance as necessary. Patients also completed on-line questionnaires before and after viewing the decision aid (**Appendix A**). The questionnaire administered before viewing the decision aid asked about patients' interest in being screened for CRC in the next 6 months, intent to ask their physician about screening, interest in shared decision-making, history and type of previous CRC screening, and demographic information. After viewing the decision aid, participants completed a questionnaire that again asked about interest in screening and intent to ask their physician about screening. They were also asked if they had gained knowledge from using the decision aid, usefulness of the aid in deciding whether to be screened, and stage of readiness to be screened. Participants indicated their stage of readiness by choosing one of three color-coded stages: green indicated that they were ready to be screened, yellow that they needed more information, and red that they did not want screening. Patients then completed an additional questionnaire based on their stage of readiness that asked about their preferences for screening tests or the reasons why they did not want to be screened.

Outcome measures

Patient-centered outcome measures were: change in interest in CRC screening before and after viewing the decision aid, usefulness of the information presented, and change in knowledge about CRC screening. Intent to ask providers for screening was measured on a 4-point Likert scale (1=not at all likely to ask, 4=very likely to ask). Patients' interest in being screened for CRC in the next 6 months was also measured on a 4-point Likert scale (1=not at all interested, 4=definitely interested). The mean Likert scores before the decision aid were compared to the mean scores after viewing the decision aid. Change in knowledge about screening was based on patients' self-assessment of whether their knowledge had increased after viewing the aid.

The primary outcome measure was the proportion of CRC screening tests ordered and completed. Three to six months after patient completion of the decision aid, the RA conducted a chart review to determine if CRC screening tests were ordered and completed. Test ordering was defined as an FOBT order recorded in the clinic's computer database or a colonoscopy or sigmoidoscopy order entered into the patient's computerized medical record. Test completion was defined as the record of a completed FOBT test in the computer database or the report of a

completed colonoscopy or sigmoidoscopy in the medical record. The FOBT clinic database is a Microsoft Access-based system that tracks FOBT ordering and completion. Whenever an FOBT is ordered, nurses enter the patients' name, medical record number, and date of test ordering into the database. Although this system has not been formally evaluated, all patients who had an FOBT ordered by a provider should be entered in the clinic database at the time of test ordering. Patients who are not listed in the database did not have FOBT tests ordered. The patients are sent follow-up letters if they fail to return the FOBT cards to clinic, and all returned FOBT results are recorded in the database.

Statistical Analysis

We initially examined the characteristics of the sample by using univariate analysis to determine the distribution of each variable. The mean, range, and standard distribution were calculated for continuous variables and frequencies and percentages were tabulated for categorical variables. We used paired t-tests to compare the difference in continuous Likert scores before and after viewing the decision aid. Frequencies and percentages were tabulated for categorical variables in the questionnaires, test ordering, and test completion. Pearson's chi-square test was used to compare the percentage ordering and completing tests by stage

of readiness to be screened. A two-sided p-value <0.05 was considered statistically significant. Stata version 8.2 (College Station, TX) was used for all analyses. Prior approval for the study was obtained from the UNC Institutional Review board.

5. Results

Demographic characteristics of the 80 patients are shown in **Table 2**. The mean age was 60 years. Fifty-nine percent were male and 29% were African American. 81% had health insurance; of those with insurance, 18% had Medicare and 46% had private insurance. Approximately half of participants had previously been screened for colon cancer and 19% were up to date with screening. When asked about how they had been screened, 48% reported having FOBT, 21% sigmoidoscopy, 19% colonoscopy, and 10% barium enema. Almost two-thirds of patients said that a provider had discussed CRC screening with them in the past.

Intent to ask providers about screening and interest in screening both rose significantly after viewing the decision aid, and most patients said that their knowledge about screening increased and they found the information useful. Patients' intent to ask for screening increased from a mean score of 2.8 before viewing the decision aid to 3.2 afterwards ($p<0.0001$, paired t-

test, **Figure 1**). There was also an increase in patients' interest in being screened in the 6 months after viewing the decision aid. Prior to viewing the aid, the mean score for interest in being screened at was 3.2; this increased to 3.5 (difference, 0.3; $p=0.01$, paired t-test). Eighty-nine percent said that the information presented increased their knowledge about colon cancer, 78% said that the information presented helped them decide whether to be screened, and 90% felt that the amount of information in the decision aid was just right. Ninety percent preferred to make decisions together with their physician. The mean amount of time spent viewing the decision aid was 19 minutes.

Table 3 shows the percentage of participants who had screening tests ordered and completed as determined by chart review and a search of the clinic FOBT database 3-6 months after completing the decision aid. 16 of the 80 patients were not entered into the computer FOBT database and thus did not have an FOBT ordered. For test ordering, 46% (37/80) of patients had either an FOBT or endoscopy ordered 3-6 months after viewing the decision aid. Twenty-five percent (20/80) had an FOBT ordered and 25% had an order for endoscopy. Three patients had orders for both FOBT and endoscopy. For test completion, 39% (31/80) participants completed either FOBT or endoscopy. 16%

(14/80) of patients completed FOBT and 24% (19/80) had completed endoscopies.

Most patients reported that they were ready to be screened for CRC. When asked about stage of readiness to be screened, 60% chose green, indicating that were ready to be tested, 18% chose yellow (needed more information) and 22% chose red (not ready to be screened). We did an analysis to determine whether those who were ready to be screened were more likely to have tests ordered and completed than patients who were not ready or needed more information. There was a greater percentage of test ordering and completion among patients choosing green compared to those choosing yellow or red but these differences did not reach statistical significance (**Table 4**). Of the 47 patients who chose green, 51% had a test ordered after 3-6 months compared to 40% of those choosing yellow and 39% of those who chose red ($p=0.59$). In terms of test completion, 43% of patients who chose green completed a screening test compared to 33% of those choosing yellow and 33% of those choosing red ($p=0.71$). We conducted another analysis after excluding patients who were up to date with screening because these patients might be less likely to have tests ordered or completed after viewing the decision aid. There was no significant change in the percentage of patients having tests

ordered and completed by stage of readiness after excluding these patients.

Among the 47 patients who were ready to be screened, diagnostic accuracy was the most important criteria for a screening test, and the most preferred test was colonoscopy. Fifty-five percent of patients choosing green said that the ability of tests to find cancers or polyps was the most important criteria in selecting a screening test. The next most important criteria were the preparation required for the test (16%) and medications needed (11%). Forty-two percent preferred colonoscopy, with the next most preferred tests being FOBT alone (20%) and FOBT in combination with flexible sigmoidoscopy (20%).

6. Discussion

In this study we found that a computer-based CRC decision aid increased patient interest in screening and subjectively improved their knowledge about screening. Participants responded that they were more likely to ask their providers about screening after viewing the decision aid. These results are comparable to those from the videotape decision aid trial where patients' intent to ask providers for screening increased significantly after viewing the decision aid. In our current study, the computer-based decision aid also subjectively

improved patients' knowledge about screening and was useful to most in making decisions about whether to be screened. Other studies have also found that CRC decision aids increased patients' level of knowledge about screening; the videotape- and print-based versions developed by Meade et al. improved patient knowledge about screening as determined by a change in score from expert-validated pre- and post-tests.⁵⁵ Dolan et al. found that patients subjectively reported improved knowledge after using a CRC decision aid.⁵⁶ Improved knowledge is thought to lead to increased patient participation in medical decision making by empowering patients to make informed decisions with their provider. Incorporating patient values in the decision making process can potentially lead to the ordering of tests based on patient preferences. Although it is thought that patient involvement in medical decisions may lead to increased patient compliance with recommendations,^{59, 60} there is no research to date that links shared decision making to increased patient compliance with screening tests. Future studies should be done to assess whether there is an association between shared decision making, test ordering based on patient preferences, and patient compliance with screening.

Our decision aid differs from previously developed versions for CRC screening in that, after viewing an overview

about screening, patients were able to interact with the aid via its computer-based format and choose to view additional segments on individual screening tests. In this way, patients could tailor the decision aid to meet their knowledge needs. Message tailoring is thought to stimulate cognitive activity, improve the relevance of the information presented, and make the message more effective, thus leading to a greater likelihood of behavior change.^{61, 62} Tailored interventions have been used to increase other health promoting behaviors such as mammography screening.⁶³ The decision aid was not truly tailored in the sense that the information in the decision aid was not targeted towards individual patients' stage of readiness to be screened. Each patient, however, was able to select the amount and content of information they received about screening through the choices offered in the computer-based decision aid. In this way, the message about CRC and the importance of screening may have achieved greater relevance to patients and increased their interest and completion of screening.

When asked about stage of readiness to be screened, most patients responded that they were ready to be screened after viewing the decision aid; of these patients, only about half had a test ordered and 43% completed a screening test. These results indicate that not all patients who want screening are having tests

ordered, but that most patients who had tests ordered completed their tests. There are a number of possible reasons for the low rates of test ordering. One possibility is that our intervention was patient-directed and did not have a system for prompting providers about screening. Although patients may have indicated an interest in screening, providers may not have discussed or ordered CRC screening tests during the patient encounter. Another reason for the low rates of test ordering is that some patients may have viewed the decision aid after seeing their provider and thus did not have the opportunity to discuss screening at that visit. Patients who were already up to date with screening prior to viewing the decision aid may not have had tests ordered even if they responded that they were ready for screening. Excluding these patients from the analysis, however, did not increase the proportion of tests ordered and completed among patients who were ready to be screened.

The proportion of tests ordered and completed for patients who answered green (ready for screening) was higher than for patients who answered yellow or red (need more information or not ready for screening), but the differences were not statistically significant. There were small numbers of patients in our sample and there may not have been enough power to detect a significant difference between the groups. It is

interesting that approximately 40% of patients choosing yellow or red had tests ordered and one-third completed screening tests. It may be that these patients and providers had subsequent conversations about screening that led to test ordering or that some providers ordered tests without knowing patients' preferences for being screened. In the videotape decision aid study, only 7% of patients choosing red had tests ordered, and 4% completed tests. More research needs to be done to determine why patients who were uncertain or not ready for screening had tests ordered and completed.

In order to achieve higher screening rates among those ready to be tested, the decision aid may need to be implemented with a provider reminder system or standing orders for screening tests. A patient-oriented decision aid alone may be insufficient to increase test ordering and completion. Multifaceted interventions that target a combination of providers, patients, or office systems may be more likely to increase screening rates.⁶⁴ Dolan et al.'s patient-oriented decision aid was implemented without additional office systems or physician interventions. In their study there was no increase in CRC screening test completion among patients who viewed the decision aid vs. controls.⁵⁶ Our previously developed videotape decision aid included a provider notification component; the videotape was paired with a color-

coded chart marker that notified providers about patients' readiness to be screened. The combination of the decision aid and chart marker resulted in a statistically significant increase in the percentage of tests ordered and completed in the intervention group vs. controls.⁵⁷ Physician prompting has been shown to increase performance of preventive care, including cancer screening,^{65, 66} and may be a necessary component in a screening program to ensure that physicians order recommended tests. In a standing orders protocol, test ordering can be initiated by a nurse based on patient preferences and a previously developed screening policy agreed upon by providers in the practice. If the patient or provider later decide against screening, the order can be cancelled. Implementing the computer-based decision aid with a standing orders protocol or a provider prompting system may help to improve rates of screening test ordering.

Among the 47 patients who were ready to be screened, most rated the ability to find cancer as the most important factor in deciding on a screening test, and 42% chose colonoscopy as their preferred method for screening. Those patients who value accuracy may be more likely to choose colonoscopy for its ability to detect and remove neoplasms. Previous studies on patient preferences for colorectal cancer screening have also found that patients rank accuracy as the most important feature

of a screening test. Ling et al. found that 54% of patients considered accuracy to be the most important factor in selecting a screening method.⁴⁶ Among those who most valued accuracy, colonoscopy was the preferred method of screening. Interestingly, this study also found that providers viewed discomfort as the most important factor for patients when deciding about screening. Accuracy appears to be a very important factor for many patients in screening and should be considered by providers when discussing test options with patients.

There are a number of limitations to this trial. First, it was an uncontrolled trial without a comparison group, so it is unclear whether the proportion of patients having tests ordered and completed represents an increase compared to patients who did not view the decision aid. The baseline rates of CRC screening test ordering and completion in our clinic are not known and it is uncertain whether our results represent an increase over baseline clinic CRC screening rates for average-risk adults 50 and older. Although clinic screening rates are unknown, our results appear to be fairly comparable with those from the videotape decision aid trial; among patients viewing the videotape decision aid, 47% of individuals had screening ordered, and 37% completed tests. It may be useful to conduct a randomized trial comparing the

decision aid to a control group to see if viewing the decision aid can increase the rates of screening test ordering and completion.

Another limitation is possible selection bias; the responses of those who chose to participate may be different from those who did not participate. The fact that some of the patients were referred by providers may have resulted in an increase in the proportion of patients who were ready to be screened and may have elevated rates of test ordering and completion. Our results also may have been biased by the fact that many participants had previously been screened; 48% had been previously screened for CRC and 19% were up to date with screening. Patients who have previously been screened may have been more ready for screening than those who had never been tested. In addition, those who were already up to date with screening may have been less likely to have tests ordered, although excluding these patients from the analysis did not change the proportion of patients having tests ordered or completed.

Because our study was conducted at a single site among a clinic population, our study findings may not be generalizable to other populations. Other patient populations, including individuals not currently enrolled in medical care, might respond differently to the decision aid. In addition, patients in our sample

had high levels of education and most had health insurance. Although Medicare covers CRC screening and added colonoscopy to its list of covered services in 2001,³⁵ cost is still an issue for patients without insurance or those whose plans may not cover CRC screening. Testing of the decision aid in population-based samples will provide information on whether the decision aid is useful to patients of varying levels of education and insurance status.

A final limitation is that the decision aid may be difficult to use for those unfamiliar with computers. Patients who have limited computer skills may find it hard to navigate through the menu of choices in the decision aid. Such patients may not be able to view the decision aid without assistance. Most patients in this study completed the decision aid successfully and required limited, if any, computer assistance, so computer literacy may be an issue for only a subset of patients.

7. Conclusions and Implications

Despite these limitations, our computer-based decision aid increased patient interest in screening, improved self-rated knowledge about screening, and was useful to patients in deciding whether to be screened. It is interactive, easy to use, and takes approximately 20 minutes of patient time. Most patients

could independently navigate through the menu of choices to select video segments that met their knowledge needs.

There are many ways in which the decision aid can be incorporated into primary care practice. Patients can view the decision aid in preparation for a visit with their provider. Because the decision aid explains the importance of CRC screening and describes each screening test with its risks and benefits, the decision aid can potentially save providers time in counseling patients about screening. Its web-based format can be made accessible to patients and can be viewed by patients via their home computers prior to their appointments. Nurses can identify patients at triage who are due for CRC screening, and these patients can view the decision aid in the office while waiting to see their provider. The computer-based format allows for modifications if there are changes in screening recommendations or new research findings about screening tests. It can also be translated into different languages to reach non-English speaking patients; a Spanish language version is currently under development. This translated version will allow for dissemination of the aid to Spanish-speaking patients and will help inform their decisions about CRC screening.

In this study, a computer-based, patient-directed decision aid increased patient interest in colorectal cancer screening and

subjectively improved knowledge about screening options. Most patients were ready to be screened after viewing the decision aid but only half of the patients who wanted to be screened had tests ordered. Future research needs to be done to determine whether implementation of the decision aid with other interventions such as provider reminders or a standing order system can effectively raise screening rates in a primary care setting.

Table 1: Colorectal Cancer Screening Guidelines for Average Risk Individuals 50 years and older*^{1, 21-23, 67}

<p>Any one of the following:</p> <ol style="list-style-type: none"> 1. Yearly fecal occult blood testing (FOBT) 2. Flexible sigmoidoscopy (FS) every 5 years 3. Combined yearly FOBT and FS every 5 years** 4. Colonoscopy every 10 years 5. Double-contrast barium enema every 5 years
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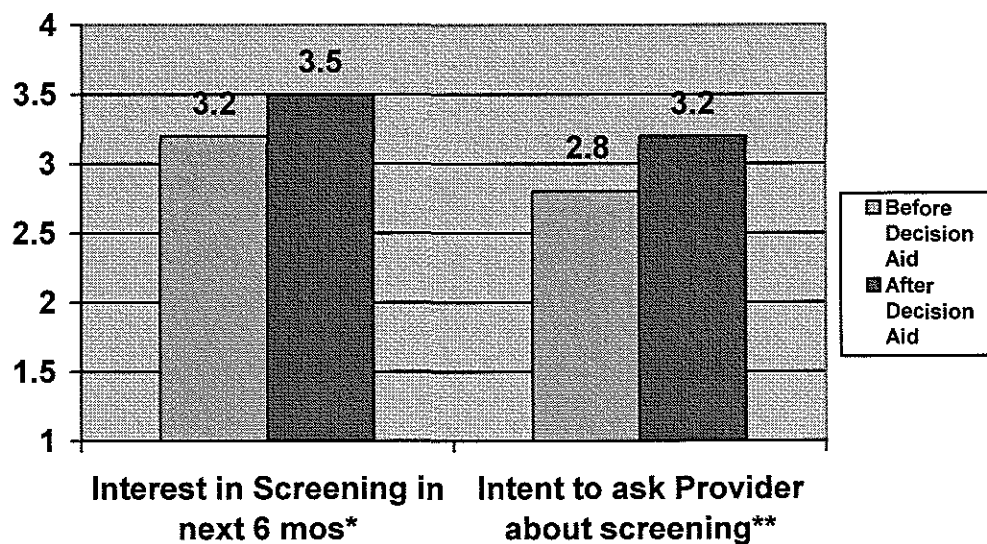
*Recommendations of the American Gastroenterological Association Consortium Panel, US Preventive Services Task Force, American Cancer Society (ACS)

**ACS recommends the combination of FS and FOBT over either test alone

Table 2. Characteristics of the sample (n=80).

Characteristic	Mean (range) or percent
Mean age	60 (49-75)
% Male	59
% White	69
% African American	29
% Insured	81
% More than high school education	65
% Self-rated excellent-good health	67
% Screened for colorectal cancer in the past	48
% Up to date with screening	19

Figure 1. Change in intent to be screened after viewing the decision aid



* $p=0.01$, paired t-test. Based on 4-point Likert scale, 1=not at all interested, 4=very interested

** $p<0.0001$, paired t-test. Based on 4-point Likert scale, 1=not at all likely to ask, 4=very likely to ask

Table 3. 3-6 month follow-up: Screening test ordering and completion (n=80)

	Total	FOBT	Colonoscopy/ sigmoidoscopy
% Ordered	46	25	25
% Completed	39	16	24

Table 4. Test ordering and completion by stage of readiness to be screened

Stage of Readiness	n	% ordering test*	% completing test**
Green: ready to be tested	47	51	43
Yellow: need more Information	18	40	33
Red: not ready for screening	15	39	33

*p=0.59, Pearson's chi-square test

**p=0.71, Pearson's chi-square test

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