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<td>Body Mass Index</td>
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<tr>
<td>CAI</td>
<td>Computer Assisted Instruction</td>
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<td>CI</td>
<td>Confidence Interval</td>
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<td>CRC</td>
<td>Colorectal Cancer</td>
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<td>CT</td>
<td>Computed Tomography</td>
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<td>DA</td>
<td>Decision Aid</td>
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<td>FIT</td>
<td>Fecal Immunohistochemical Test</td>
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<td>FOBT</td>
<td>Fecal Occult Blood Test</td>
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<td>OR</td>
<td>Odds Ratio</td>
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<tr>
<td>REALM</td>
<td>Rapid Estimate of Adult Literacy in Medicine</td>
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ABSTRACT

Background: Patients with low health literacy have difficulty understanding health information and receive fewer preventive services. We sought to determine whether a literacy-sensitive, web-based decision aid (DA) could increase colorectal cancer (CRC) screening rates in both low and high literacy patients.

Methods: Patients at a community-based health center who were overdue for CRC screening were randomized to view either the web-based CRC screening DA or a control program about medication safety. All patients completed a baseline and post-program survey. Blinded chart review determined screening test ordering and completion rates.

Results: Of the 248 patients who completed the study, 54% had limited health literacy. Compared to the control patients, DA patients were more likely to report a testing preference (84% vs. 53%, p<0.0001) and an increase in readiness to receive screening (29% vs. 10%, p<0.001). More DA patients had CRC screening tests ordered (31% vs. 23%) and completed (19% vs. 14%), but the differences were not statistically significant (multivariate p=0.08 and 0.07 respectively). Similar results were found when stratifying by literacy level.

Conclusions: The DA increased patients’ test preferences and intent to receive screening. Future studies should investigate how to link the DA with other supportive strategies to increase screening rates.
CHAPTER I: INTRODUCTION

COLORECTAL CANCER IN THE UNITED STATES

Incidence and Risk Factors

Colorectal cancer (CRC) is the third most common non-cutaneous cancer in the United States. The American Cancer Society estimates there will be 147,000 new cases of CRC in the United States in 2009.\(^{1}\) The lifetime risk of developing CRC is 5.5% for men and 5.1% for women.\(^{2}\) Incidence increases with age, with 91% of cases occurring after age 50.\(^{2}\)

Other risk factors can be divided into modifiable and non-modifiable factors. Non-modifiable factors include a family history of CRC, a personal history of inflammatory bowel disease, a personal history of adenomatous polyps, and race. Modifiable risk factors include diet, smoking, obesity, and physical inactivity.\(^{1;2}\)

One of the strongest non-modifiable risk factors is family history. Risk of CRC increases with the number of family members with a history of CRC and their genetic proximity to the individual.\(^{3;4}\) Individuals with a single affected second or third-degree relative have a 50% increased risk of developing CRC. In comparison, individuals with two affected first-degree relatives have a 3 - 4 fold increased risk of developing CRC.\(^{4}\) The risk of CRC increases further if a family member is diagnosed before age 45.\(^{3}\)

Certain disease states also predispose an individual to CRC. Individuals with inflammatory bowel disease, which includes Crohn's disease and ulcerative
colitis, have an increased risk of CRC.(5) For individuals with ulcerative colitis, the risk of CRC increases with duration of colitis.(6) In addition, individuals with a personal history of colonic adenomatous polyps have at least a 2-fold higher risk of CRC.(7)

CRC incidence varies by race. Blacks have the highest incidence followed by non-Hispanic whites, American Indians/Alaskan Natives, Asian/Pacific Islanders, and Hispanic whites (Figure 1.1).(8) CRC mortality is also higher in minority groups with Blacks having a mortality rate 43.5% higher than whites.

Several dietary factors have been linked to CRC. A large cohort study of over 148,000 adults in the United States found a positive association of colon cancer incidence to consumption of red meat and processed meats.(9) Individuals in the highest tertile of processed meat consumption over time had a 50% greater incidence of distal colon cancer, as did individuals who consumed...
the highest ratio of red meat to poultry and fish. Others have found an association of glycemic load with colon cancer. High glycemic load foods may trigger an increased release of insulin and insulin-like growth factor (IGF-1), hormones implicated in cell proliferation. A cohort study of over 38,000 women found higher rates of CRC in women who consumed the highest dietary glycemic load foods and highest amounts of carbohydrates. In contrast, diets high in fiber have been found to be protective against CRC.

Alcohol and tobacco are other risk factors for CRC. Individuals who consume more than 2 drinks of alcohol a day have a higher CRC incidence. Smokers also have higher CRC rates. A meta-analysis of 106 observational studies found a relative risk of 1.18 for CRC among ever smokers compared to never smokers. Similarly, current smokers have over twice the risk of colonic adenomas compared to never smokers.

Both CRC incidence and mortality increase with body mass index (BMI), a measure of obesity. A meta-analysis of prospective cohort studies found a risk ratio for CRC of 1.24 for every 5kg/m2 increase in BMI. In a separate nationally representative cohort study, CRC mortality correlated with BMI. Men with BMIs > 35.0 have an 84% greater rate of CRC death, and women have a 36-46% higher CRC death rate. Potential mechanisms for the higher rates of CRC incidence and death include increased levels of insulin, IGF-1, and leptin, all known growth factors.

Regular physical activity can protect against CRC. A systematic review found that individuals with the highest activity levels across studies had a 50%
lower incidence of CRC. (21) Exercise may exert its protective effect by decreasing bowel transit time, thereby limiting the colon’s exposure to potential carcinogens. Exercise also decreases insulin resistance and lowers prostaglandin E2 levels, both of which stimulate cell proliferation. (22)

**Colorectal Cancer Mortality**

In 2009, there will be an estimated 49,920 deaths from CRC in the United States making it the second leading cause of cancer death. (23) 5-year survival rates for CRC vary according to the stage at diagnosis. (Figure 1.2) Localized disease is defined as tumors confined to the colonic wall. Regional disease refers to local spread of the tumor, and distant disease describes tumor that has spread to other sites. Between 1999 and 2005, 39% of new CRC cases were...
localized, 37% were regional, and 19% were distant at the time of diagnosis.\(^{(8)}\)

The excellent prognosis of localized CRC in contrast with the poor prognosis of distant disease highlights the importance of early detection through screening.

**Natural History of Colorectal Cancer**

CRC develops over an estimated 10-15 years as the result of a combination of genetic defects.\(^{(24)}\) Cellular mutations in the APC gene eventually lead to the formation of adenomatous polyps. Approximately one in 20 polyps will grow into large adenomas which have the potential to develop into CRC. Data abstracted from the National Polyp Study found that large polyps (>1cm) require a mean of 5.5 years to develop into CRC.\(^{(25)}\) Overall, the timeframe from small polyp formation to CRC is approximately 10 years. This lengthy time makes it possible to prevent CRC by identifying and removing polyps before CRC develops.

**Screening for Colorectal Cancer**

The goal of CRC screening is to discover asymptomatic polyps or early stage CRCs that can be removed easily with a colonoscope. Removing polyps makes CRC a preventable disease, and early stage CRCs can be cured by excision. Polyps and early stage CRCs may be detected through either stool tests or by visualization with either endoscopy or radiography.

Advanced adenomatous polyps and early stage CRCs may bleed or shed DNA from local minor trauma from passing fecal material. The fecal occult blood
test (FOBT) and fecal immunohistochemical test (FIT) involve a patient collecting a small stool sample from three separate bowel movements over at least three days. Patients apply the samples to small paper cards which are then returned to the physician's office for testing. A developing solution is applied to the cards which elicits a color change in the presence of blood. Any sample testing positive for blood is considered a positive screen. The sensitivity of a single FOBT varies significantly by the test kit used and the study design. However, because it takes years for a polyp to transform into an invasive cancer, yearly FOBT testing can detect up to 92% of cancers and lower CRC mortality by 33% over 13 years. Newer tests are being developed to search for DNA markers of CRC in stool, but these are not currently widely available.

A second approach to screening for CRC is direct visualization. Flexible sigmoidoscopy and colonoscopy both use a thin flexible tube with fiber optics to examine the colon. Flexible sigmoidoscopy examines only the distal third of the colon whereas a colonoscopy examines the entire colon. Because a colonoscopy is more invasive, it requires conscious sedation. For both tests, patients must first cleanse their bowels with enemas and/or laxatives to allow for clear visualization. If a growth is seen on sigmoidoscopy or colonoscopy, the physician may remove it at the time of the procedure making endoscopy both diagnostic and therapeutic. In case-control studies, sigmoidoscopy has been associated with a 60% to 80% lower CRC mortality for tumors within the reach of a sigmoidoscope. There are no trials examining the effect of colonoscopy alone on CRC mortality for average risk individuals, but colonoscopy is inferred
to be protective based on its inclusion in studies of other screening modalities (such as FOBT) and based on results of trials of sigmoidoscopy.\textsuperscript{(26)}

Polyps and early-stage CRC can also be visualized by radiographic techniques. A double-contrast barium enema has a sensitivity of 52\% for detecting adenomas 6mm or larger.\textsuperscript{(28)} Sensitivity is higher for the detection of CRC with studies reporting sensitivities from 85\% to 97\%.\textsuperscript{(26)} A newer technology is CT colography or “virtual colonoscopy”. Similar to a colonoscopy, patients must first cleanse their bowels with a laxative solution. Oral contrast is often used, and air is insufflated into the colon via a small rectal catheter. Through 3D reconstruction, a map of the wall of the colon can be created allowing for visualization of polyps and cancers. A meta-analysis of prospective studies of CT colography using colonoscopy or surgery as the gold standard reports a sensitivity of 70\% for polyps 6 to 9mm, and 85\% for polyps > 9mm.\textsuperscript{(29)}

Current screening guidelines from several national organizations recommend starting CRC screening at age 50 and continuing at least through age 75 for average risk individuals.\textsuperscript{(26;30;31)} Given the effectiveness of the various CRC screening modalities, patients and clinicians have a choice of screening options. Each screening option has a recommending timing frequency (Table 1.1).
Table 1.1. CRC Screening Tests and Recommended Screening Intervals.

<table>
<thead>
<tr>
<th>Screening Test</th>
<th>Recommended Interval</th>
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<tbody>
<tr>
<td>FOBT or FIT</td>
<td>Yearly</td>
</tr>
<tr>
<td>Stool DNA test</td>
<td>Interval uncertain</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy</td>
<td>Every 5 years (alone or with annual FOBT/FIT)</td>
</tr>
<tr>
<td>Double-contrast barium enema</td>
<td>Every 5 years</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>Every 10 years</td>
</tr>
<tr>
<td>CT Colonography</td>
<td>Every 5 years</td>
</tr>
</tbody>
</table>

Source: American Cancer Society guidelines, 2009 (32)

BARRIERS TO COLORECTAL CANCER SCREENING

Despite its proven efficacy, CRC screening remains underutilized in the United States. Data from the 2006 Behavioral Risk Factor Surveillance System showed that only 55% of Americans aged 50 – 64 had been appropriately screened for CRC.(33) The Health Belief Model can help explain low screening rates. According to the Health Belief Model, for a person to undergo screening, he or she must know that they are susceptible to a given disease, believe that the disease is sufficiently severe to warrant action, believe that effective treatment exists, believe that the barriers to taking action are sufficiently small, and believe they are capable of taking action (self-efficacy). Later, the construct
of a Cue to Action was added to this model, indicating that the individual also
needs a specific prompt to act.(34)

A major barrier to CRC screening is lack of knowledge which results in
patients underestimating their personal susceptibility to CRC and failing to
recognize the full benefits for screening. Patients who have not received CRC
screening frequently report lack of knowledge of the importance of screening.(35)
Unscreened individuals are also more likely to report no knowledge of the
available screening tests.(35;36) A systematic review of observational studies
examining barriers to CRC screening identified lack of knowledge of the need for
screening, lack of knowledge of the available screening tests, and lack of
knowledge of the guidelines as major barriers.(37) These findings are supported
by results from the 2000 National Health Interview Survey where approximately
two-thirds of unscreened individuals reported that their primary reason for not
receiving CRC screening was that they were unaware they needed it.(38)

Negative attitudes toward CRC screening tests and lack of self-efficacy
are other prominent barriers. Prior studies have cited patients' beliefs that CRC
screening tests are embarrassing, painful, and costly as impediments to
screening. Patients also believe that many of the CRC screening tests are
difficult to complete, either due to specific requirements of the test or scheduling
issues.(35;37;39) Summarizing these results in terms of the Health Belief Model,
unscreened individuals typically have less awareness of their susceptibility to
CRC, less knowledge of the efficacy of screening, greater perceived barriers to
screening, and less self-efficacy. For patients with low health literacy, these barriers to screening may be especially challenging.

Health Literacy

Definition and Prevalence. The Institute of Medicine defines health literacy as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”(40) Possessing adequate health literacy requires more than the ability to read text. To make appropriate health decisions, individuals also must be able to interpret documents such as dosing tables, perform basic calculations to understand risk and benefit, and be able to adequately communicate with their physicians.

Over one-third of Americans have limited health literacy skills.(41-43) Those with less education tend to have lower health literacy, but even 25% of high school graduates have low or marginal health literacy, and half of those with less than a high school education may have adequate health literacy.(41) Therefore, health literacy is a more sensitive and specific risk factor than education for health care communication barriers.

Measuring Health Literacy. Health literacy is most commonly measured using either the Rapid Estimate of Adult Literacy in Medicine (REALM) or the Test of Functional Health Literacy in Adults (TOFHLA).(44;45) Both tests are administered in person. The REALM requires the subject to read aloud 66
medical related words (Table 1.2). Subjects are given one point for each word pronounced correctly, and a total score is tallied which then corresponds to a

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<tr>
<th>List 1</th>
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<td>Fat</td>
<td>Fatigue</td>
<td>Allergic</td>
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<td>Pelvic</td>
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<td>Jaundice</td>
<td>Testicle</td>
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<td>Dose</td>
<td>Infection</td>
<td>Colitis</td>
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<td>Eye</td>
<td>Exercise</td>
<td>Emergency</td>
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<td>Stress</td>
<td>Behavior</td>
<td>Medication</td>
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<tr>
<td>Smear</td>
<td>Prescription</td>
<td>Occupation</td>
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<tr>
<td>Nerves</td>
<td>Notify</td>
<td>Sexually</td>
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<tr>
<td>Germs</td>
<td>Gallbladder</td>
<td>Alcoholism</td>
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<td>Meals</td>
<td>Calories</td>
<td>Irritation</td>
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<td>Disease</td>
<td>Depression</td>
<td>Constipation</td>
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<td>Miscarriage</td>
<td>Gonorrhea</td>
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<td>Caffeine</td>
<td>Pregnancy</td>
<td>Inflammatory</td>
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<td>Arthritis</td>
<td>Diabetes</td>
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<td>Menopause</td>
<td>Antibiotics</td>
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<td>Appendix</td>
<td>Diagnosis</td>
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<td>Abnormal</td>
<td>Potassium</td>
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<td>Syphilis</td>
<td>Anemia</td>
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<td>Asthma</td>
<td>Hemorrhoids</td>
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<td>Rectal</td>
<td>Nausea</td>
<td>Osteoporosis</td>
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<td>Incest</td>
<td>Directed</td>
<td>Impetigo</td>
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reading grade level. The TOFHLA uses a modified cloze method where subjects are given a passage with every 5th to 7th word blanked out and asked to choose the correct word from a short list of options. The TOFHLA also includes measures of numeracy, or the ability to work with numbers to solve simple problems. Both the REALM and TOFHLA have been previously validated and used in numerous research studies. The REALM has the advantage of being shorter to administer, requiring only 3 or 4 minutes to complete.

Individuals are typically classified as having low, marginal, or adequate health literacy which predicts the amount of difficulty they may encounter with printed materials. Low health literacy (reading below the 7th grade level) is associated with difficulties reading printed materials and interpreting prescription labels. Individuals with marginal health literacy (7th - 8th grade) will understand some written materials but struggle with others. Individuals with adequate health literacy (9th grade level or higher) are able to understand most patient education materials and effectively participate in health care discussions.

Relationship of Health Literacy to Colorectal Cancer Screening Barriers. Prior research has documented that those with low health literacy are less likely to access medical services and more likely to experience poorer health outcomes. In a study of a Medicare managed care enrollees, Scott et al. found that those with low health literacy were less likely to receive preventive medicine interventions such as mammography, Papanicolaou smears, influenza vaccination, and pneumococcal vaccination. In a younger population of
Latinas, Garbers and Chiasson found that the odds of low health literacy women ever having a Pap smear were only 1/16th those of adequate literacy women.(47) On a systems level, patients with low health literacy experience poorer health status including worse physical function, worse mental health, and higher rates of hospitalization and mortality.(48-52) Hence, health literacy is associated with disparities in health care.

Low health literacy may result in poorer health outcomes through three mechanisms. First, patients with low health literacy have less medical knowledge. Studies of patients with hypertension, diabetes, and asthma have demonstrated that patients with low health literacy are less likely to have the basic knowledge needed to properly manage their illness.(53;54) Low literacy patients are also less likely to be knowledgeable of recommended tests to screen for cervical cancer and colon cancer.(55-57) This lack of knowledge serves to decrease patients’ awareness of the benefits of receiving cancer screening.

Second, patients with low health literacy may have more negative attitudes towards recommended tests and treatments. Dolan reported that male veterans with low health literacy were more likely to feel that colorectal cancer screening tests would be messy or embarrassing.(56) Another study found that women with low health literacy were more likely to have concerns that mammography would be painful, harmful, or troublesome.(58) Therefore, those with low health literacy may perceive the barriers to screening to be higher.

Lastly, low literacy patients have greater difficulty participating in their medical visits. One recent study analyzed a series of recorded office visits and
found that low literacy patients more frequently asked their clinicians to repeat statements suggesting poorer understanding. At the same time, low literacy patients asked significantly fewer questions. These results suggest that low literacy individuals have greater difficulty obtaining and understanding information from their health care providers which decreases self-efficacy and compounds the other knowledge and attitude barriers previously mentioned.

Unfortunately, most patient education materials are written at grade levels too advanced for the 43% of American adults reading at the basic or below basic level. A review of a random sample of 171 patient education publications from the American Academy of Family Physicians found that the average grade level of written material was 9.4. Only 5% of materials were written at the 6th grade level or below, and 21% were written at the 11th or 12th grade levels. A similar review of 51 booklets published by the American Cancer Society found that the average reading grade level was 11.9 with only 1 of the 52 written below the 6th grade level. A limitation of this study is that it was published in 1992, and newer materials tend to be written at lower grade levels. Still, a review published in 2003 of 10 cancer-related brochures from medical organizations found a mean written grade level of 12.1.

**COMPUTER-ASSISTED INSTRUCTION**

Computer-assisted instruction (CAI), the use of computers to deliver an educational message, may overcome literacy barriers by minimizing reliance on
the written word. In contrast to brochures and other printed material, CAI can incorporate audio, graphics, video, and animations. In particular, video testimonials can encourage patients to adopt healthy behaviors, particularly if the person delivering the testimonial is viewed as a potential peer. CAI also has the advantage of letting learners set their own pace, pausing to absorb some concepts and choosing to repeat specific sections of the program. Programs can include interactivity to allow users to choose specific topics for viewing and to tailor the message delivered.

Feasibility of CAI in Patient Education

Several randomized trials have demonstrated that CAI can increase patients’ knowledge about health topics.\(^{65-71}\) Other studies have found that CAI results in greater knowledge retention compared to traditional printed materials.\(^{17;20}\) Furthermore, many patients prefer CAI over educational pamphlets.\(^{13;21}\)

Nationally, 74% of American adults go online, including 72% of Americans aged 50 – 64, decreasing potential barriers for patients to use CAI.\(^{72}\) However, even patients with no computer experience can effectively navigate an educational program. In a trial of approximately 150 patients, Miller and colleagues found that most computer naïve patients were able to successfully use a CAI program without assistance.\(^{71}\) The prevalence of self-service touch screen systems in major retail outlets, gas stations, and transportation hubs
suggests that most Americans are using computerized interfaces routinely. Incorporating a touch screen interface in CAI could increase ease of use.

**Theoretical Model for CAI in CRC Screening**

Figure 1.3 displays a theoretical model for CRC screening based on the Health Belief Model. CAI has the potential to increase CRC screening rates by acting at the three main steps along the screening pathway. First, CAI can positively affect patients’ attitudes and beliefs about CRC screening. Informing patients of the risk of CRC heightens their perceived susceptibility and the perceived severity of the disease. Informing patients of CRC screening increases the perceived benefits and improves self-efficacy by giving them needed knowledge. Video testimonials from patients who have undergone screening can highlight the benefits of screening, decrease perceived barriers, and again improve self-efficacy.

The combination of patients’ attitudes and beliefs about CRC screening translates into an intention to receive screening. As the Health Belief Model points out, patients then need a Cue to Action. A CAI program delivered immediately before a medical visit can serve as this Cue to Action, or physical reminder that screening is needed. Patients who view a program are encouraged to speak with their physician about their desire to receive CRC screening.

A mixture of System Factors and Patient Factors then influence the actual ordering and completion of a CRC screening test. CAI can positively influence
Figure 1.3. Theoretical Model for Computer-Assisted Instruction in CRC Screening.

Patient Attitudes/Beliefs
1. Perceived Susceptibility
2. Perceived Severity of CRC
3. Perceived Benefits of Screening
4. Perceived Barriers (Costs)
5. Self-Efficacy

Health System Interactions

System Factors
1. Ease of Scheduling
2. Delivery of Screening Instructions
3. Screening Cost

Patient Factors
1. Convenience of Appt
2. Comprehension of Instructions
3. Ability to Complete Prep
4. Transportation to Appt

Computer Assisted Instruction

Cue to Action

Intention to Receive Screening

Receipt of Screening
some of these factors, but not all. For example, CAI may increase the ease of scheduling a screening test and improve the delivery of screening instructions, but CAI cannot significantly influence the cost of screening. Focusing on patient factors, CAI can improve patients’ comprehension of screening instructions and in turn their ability to complete screening, but it cannot significantly influence transportation factors. Nonetheless, CAI has the potential to significantly improve CRC screening rates by acting on patients’ attitudes and beliefs, providing a cue to action, and positively affecting self-efficacy and many health system interactions as previously described.

CONCLUSIONS AND SPECIFIC AIMS

In summary, CRC is the third most common non-cutaneous cancer in the United States, and the second leading cause of cancer death.(1) Routine screening of the general population beginning at age 50 can reduce CRC incidence and mortality. A variety of screening tests have been proven effective, giving patients a choice of screening options.(26) Despite the proven effectiveness of CRC screening over 40% of Americans have not been appropriately screened.(33) Prior research has elucidated many barriers to CRC screening, many of which may be greater in low literacy patients. Computer-assisted instruction (CAI) is a newer technology with the potential to overcome literacy barriers and better inform patients of the benefits of CRC screening and
decrease negative attitudes toward screening. In this manner, CAI may increase CRC screening rates.

The specific aims of this study are:

1. To determine if patients who view a web-based, multimedia educational computer program about CRC screening can form a screening test preference.

   Hypothesis 1: A greater proportion of patients who view the CRC computer program will be able to state a screening test preference, when compared with patients who view a control program about prescription medication safety.

2. To determine if a web-based, multimedia educational computer program can increase patients’ intent to receive CRC screening

   Hypothesis 2: A greater proportion of patients who view the CRC computer program will increase their readiness to receive screening, when compared with patients who view a control program about prescription medication safety.

3. To determine if a web-based, multimedia educational computer program can increase the number of CRC screening tests ordered by clinicians.

   Hypothesis 3: Clinicians will order a greater proportion of CRC screening tests for patients who view the CRC computer program, when compared with patients who view a control program about prescription medication safety.
4. To determine if a web-based, multimedia educational computer program can increase CRC screening rates.

Hypothesis 4: A greater proportion of patients who view the CRC computer program will complete a CRC screening test within 24 weeks, when compared with patients who view a control program about prescription medication safety.

5. To determine if a web-based, multimedia educational computer program is effective in both low and high literacy patients.

Hypothesis 5: Differences in patients’ ability to form a CRC screening test preference, intention to receive screening, screening test ordering, and screening test completion will be similar for both low and high literacy patients.

These specific aims will be addressed through a randomized-controlled trial conducted in a community-based primary care practice. Patients aged 50 – 74 who are due for CRC screening will be enrolled. All patients will have their health literacy level measured at study entry.
ABSTRACT

Background: Despite its proven effectiveness, colorectal cancer (CRC) screening remains underutilized in the United States. Low health literacy, which interferes with patients' ability to understand health information, may contribute to low screening rates.

Objective: To determine whether a literacy-sensitive, web-based CRC screening decision aid can increase CRC screening in low and adequate literacy patients.

Design: Randomized-controlled trial conducted at a university-affiliated, community-based internal medicine practice.

Participants: Patients aged 50-74 years at average risk for CRC who were overdue for CRC screening, and who were scheduled to see a primary care provider for a routine visit.

Interventions: A web-based, multimedia, CRC screening decision aid versus a control program about medication safety.

Primary outcome: Completion of CRC screening within 24 weeks of enrollment.

Secondary outcomes: Patients' ability to state a screening test preference, change in readiness to receive screening, and CRC screening tests ordered.

Key Results: Of the 248 patients who met inclusion criteria, 54% had limited health literacy and 76% had annual household incomes < $20,000. Patients
were more likely to report a CRC screening preference after interacting with the decision aid compared to the control program (84% vs. 53%, p<0.0001). Intervention patients also were more likely to report an increase in readiness to receive screening (29% vs. 10%, p<0.001). More intervention patients had CRC screening tests ordered (31% vs 23%) and completed (19% vs 14%), but the differences were not statistically significance (adjusted OR 1.7 [95% CI 0.95-2.9] for ordering; adjusted OR 1.8 [95% CI 0.95-3.5] for completion). Similar results were found when stratifying by literacy level.

**Conclusions:** The web-based decision aid increased patients’ ability to form a test preference and their intent to receive screening, but not screening test ordering or completion. Future studies should investigate how to link the decision aid with other supportive strategies to achieve increased screening rates.

**ClinicalTrials.gov ID:** NCT00558233

**Key Words (up to 5):** Computer assisted instruction; Decision aids; Colorectal cancer; Health literacy; Screening
INTRODUCTION

Colorectal cancer (CRC) is the third most common non-cutaneous cancer in the United States, and the second leading cause of cancer death.\(^{(1;2)}\) To both prevent CRC and reduce CRC mortality, several national organizations recommend routine CRC beginning at age 50.\(^{(3-5)}\) A variety of CRC screening tests are cost-effective, giving patients and clinicians a choice of screening options.\(^{(6)}\)

Despite the widespread recommendations for routine screening, CRC screening remains underutilized in the United States. Approximately 45% of Americans remain unscreened.\(^{(7)}\) Barriers to CRC screening include patients’ unawareness of the threat of CRC or the benefits of screening, negative attitudes toward specific CRC screening tests, and lack of self-efficacy.\(^{(8-10)}\) For the one-third of Americans with limited health literacy skills, these barriers may be even greater.\(^{(11-13)}\)

Decision aids can overcome these barriers by informing patients of screening options, confronting inaccurate beliefs, and encouraging self-efficacy. A prior randomized-controlled trial found that a videotape-based CRC screening decision aid increased rates of CRC test ordering and completion.\(^{(14)}\) A more recent study of a web-based decision aid found a higher rate of immediate preferences for CRC screening and CRC screening test completion.\(^{(15)}\) However, neither of these studies measured health literacy, and the web-based decision aid was primarily text-based. It is unknown whether a decision aid can positively influence CRC screening in both low and adequate literacy patients.
Although low literacy patients have greater informational needs, most patient education materials and decision aids are written at advanced grade levels inaccessible to limited literacy patients. A study of over 170 published patient education materials found that only 5% were written at or below the 6th grade level. In addition, a recent systematic review of web-based cancer decision aids found that none were written at less than the 8th grade level, and only one-third incorporated audio or video components.

A well-designed, multi-media decision aid may overcome health literacy barriers by incorporating audio, video, graphics, and animations. Computer-assisted programs also can incorporate interactivity to engage the user and target the content delivered. Given the prevalence of personal computers in the medical office and community, a web-based program could facilitate access and dissemination. For these reasons, we hypothesized that a literacy-sensitive web-based decision aid would increase CRC screening in both low and adequate literacy patients. To test this hypothesis, we conducted a randomized-controlled trial in a large medical practice.

METHODS

We conducted the study at a community-based university-affiliated internal medicine faculty-resident practice. The practice serves a primarily socioeconomically disadvantaged patient population. The Wake Forest University Institutional Review Board approved the study protocol. All participants provided written informed consent.
We enrolled patients aged 50-74 years old who were scheduled for a routine medical visit and were overdue for colorectal cancer (CRC) screening. We considered patients overdue for screening if they failed to complete a home fecal occult blood test (FOBT) within the last year, a flexible sigmoidoscopy within the last 5 years, or a colonoscopy within the last 10 years. We excluded patients who reported recent rectal bleeding, who had obvious physical or mental impairments that would prevent them from participating, or who did not speak English. Potentially eligible patients were identified by querying the practice’s appointment schedule. A research assistant then called each patient to confirm eligibility and invite them to participate.

Each participant arrived to the clinic 45 minutes before their scheduled appointment time. A research assistant verbally administered a baseline questionnaire that included the Rapid Estimate of Adult Literacy in Medicine (REALM) to determine health literacy level(21). We defined limited health literacy as reading below the 9th grade level as determined by the REALM. Patients were then randomized, stratified by literacy level, to view either a web-based CRC screening decision aid or a control program about prescription drug refills and safety. Both programs were displayed on a computer with a touch screen monitor and external speakers. The research assistant left the room allowing each participant to view the assigned program in privacy.

The CRC screening decision aid, called CHOICE (version 6.0), was based on a previously validated video-tape decision aid.(14;22) The program includes audio, video, graphics, animations, and interactivity.(Figure 1) CHOICE begins
with a short introductory overview of CRC screening including the prevalence of CRC, the rationale for screening, and a description of common screening tests (fecal occult blood testing, flexible sigmoidoscopy, and colonoscopy). The program then allows participants to choose to learn more about a specific test, view comparisons of the tests, or make a screening decision. Prior to exiting, the program asks each participant to indicate their level of readiness to receive CRC screening (ready to receive screening, need more information, or do not want to receive screening). The program then prints a one-page color hand-out tailored to the respective decision. The control program about prescription drug refills and safety also included graphics, animations, pictures, audio, and interactivity. Both programs were written in Flash (Adobe Systems Inc., San Jose, California) and displayed in web browsers.

Following the program, participants completed a verbally administered post-program survey and then proceeded directly to their scheduled medical appointments. Medical providers were not notified of their patients’ enrollment in the study.

Outcomes Assessment

Our primary outcome of interest was receipt of CRC screening within 24 weeks of study enrollment. Secondary outcomes included patients’ ability to state a CRC test preference, patients’ change in readiness to receive CRC screening, and CRC test ordering.

We designed our study to have 80% power to detect a 20% absolute
increase in screening completion rates within individual literacy strata (low literacy and adequate literacy). Assuming a baseline screening completion rate of 15%, our target sample size was 146 patients in each literacy level. We ended enrollment with 135 low literacy patients and 113 adequate literacy patients due to slower than anticipated recruitment. This gave us a final calculated power of 76% in low literacy patients, 69% in adequate literacy patients, and 95% overall.

Receipt of CRC screening and test ordering was determined by chart review conducted by data collectors who were masked to study assignment. Two researchers independently reviewed a random sample of 10% of all charts, and there was 100% agreement. Patients’ ability to state a test preference was assessed with a single item on the post-program survey that asked patients which CRC screening test they would want if all tests were free. Responses were coded dichotomously (“I don’t know enough about the tests to decide” vs. choosing a specific testing option or choosing never to be tested).

We measured readiness to receive screening with two questions which appeared on both the baseline and post-program surveys: “Are you interested in being screened for colon cancer in the next 3 months?” and “Do you plan to ask your doctor about being screened for colon cancer at this visit?” Each question was answered on a 5-point Likert scale. We used responses from these items to map each patient to a readiness state according to the TransTheoretical Model’s Stages of Change.(23) “Precontemplative” patients were those not interested in being screened within the next 3 months. “Contemplative” patients were those unsure if they wanted to be screened but were planning to discuss
screening at this visit, or those who were interested in being screened in the next 3 months but not at this visit. "Preparing for action" patients were interested in being screened within the next 3 months and planned to discuss screening immediately. We determined change in readiness to receive screening by comparing patients’ readiness stage after the program to their baseline stage.

Data Analysis

We assessed group differences in the baseline characteristics of our study sample using chi-square tests for proportions and t-tests for means. We first examined the association of each baseline characteristic with our outcomes of interest bivariately. We then constructed logistic regression models for each outcome. We included in our models any baseline characteristic that were distributed unevenly by arm (p<0.20) or were associated with the outcome of interest in bivariate analyses (p<0.20). Potential covariates included patient sociodemographic factors (age, sex, race, income, employment status, marital status, health insurance status), patients’ self-rated health status, patients’ baseline readiness stage for screening, and the training level of the clinician. In each model, we also included literacy level and tested for possible interactions between intervention and literacy. Similarly, we tested for a possible interaction between intervention and baseline readiness stage given that the program may have different effects in patients with varying baseliness readiness to receive screening. We retained interaction terms in the final models if the p-values were less than 0.05.
Two of our outcomes of interest were partially dependent on healthcare providers (test ordering and test completion). For these outcomes, we used generalized estimating equations to control for potential clinician clustering. We used SAS software (SAS Institute, Cary, NC) for all analyses. The Wald Statistic was used to compute p-values for all multivariable models. All tests for statistical significance were two-sided with an alpha of 0.05.

RESULTS

We enrolled 264 patients between November 2007 and September 2008. After stratifying by literacy level, an equal number were randomized to the CRC decision aid (CHOICE) and the control program. Following randomization, 16 patients were excluded for failing to meet prespecified eligibility criteria, leaving 124 patients in the CHOICE arm and 124 patients in the control arm (Figure 1). The most common reason for exclusion was being current for CRC screening (15 of 16 patients). The one other excluded patient reported recent rectal bleeding. Sensitivity analyses found that including these 16 patients did not significantly change our results.

Table 1 displays patients’ baseline characteristics. A majority of the 248 eligible patients were female, African-American, unemployed, had annual household incomes of < $20,000, and received their care from a resident physician or mid-level provider. Over one-third were uninsured. The average age was 57.5 years. Approximately half rated their health status as poor or fair (52%), and had low or marginal health literacy skills (54%).
Of the 124 patients randomized to the CHOICE program, 123 patients (99%) viewed the 6.3 minute introductory overview, and 51 patients (41%) chose to watch at least one other segment of the program. One patient did not see the program due to a computer malfunction. Overall, patients spent an average time of 11.3 minutes interacting with the CHOICE program (range 7.0 – 27.9 minutes).

Overall Results

Table 2 summarizes the main outcomes of interest. Patients were more likely to report a preference for a specific CRC screening option after interacting with CHOICE compared to the control program (84% vs. 53%, OR 4.6, 95% CI 2.5 – 8.3, p<0.0001). After controlling for race, marital status, insurance status, literacy level, baseline readiness stage, and provider training, the odds of having a test preference were approximately 5 times greater for CHOICE patients compared to control program patients (OR 5.7, 95% CI 2.9 – 11.1).

CHOICE patients also were more likely to increase their readiness to receive CRC screening as measured by the Transtheoretical Model’s Stages of Change. On the post-program surveys, 29% (36/123) of CHOICE patients moved to a more favorable stage compared to 10% (12/123) of control patients (OR 3.8, 95% CI 1.9 – 7.8, p<0.001). Few patients moved to a less favorable stage (6 CHOICE patients and 0 control patients). The increased readiness for screening associated with CHOICE remained significant after controlling for demographics (race, marital status, insurance status, income level), literacy level, and self-rated health status (OR 3.3, 95% CI 1.3 – 8.3). Of note, 48% of all
patients entered the study in the Preparation for Action stage and therefore could not improve their readiness further. When limiting the analysis to patients who were in the Precontemplation or Contemplation stages at baseline, 53% of CHOICE patients increased their readiness to receive screening compared to 20% of control patients.

More decision aid patients had CRC screening tests ordered immediately after they viewed the program, but the difference was not statistically significant (31% vs. 23%, 95% CI for difference -2.2% to 20%, unadjusted OR 1.6, p=0.12). Adjusting for demographics (race, marital status, insurance status), literacy level, baseline readiness stage, and provider training, yielded similar results (OR 1.7, 95% CI 0.95 – 2.9, p=0.08). Similarly, there was a nonsignificant 5.7% higher rate of screening test completion among patients who viewed CHOICE (95% CI for difference -3.7% to 15.0%, OR 1.5, p=0.23). Adjustment for the same factors above found a slightly higher odds of test completion (OR 1.8, 95% CI 0.95 – 3.5, p=0.07).

Effect of Literacy Level

CHOICE had similar effects in both low and adequate literacy patients. After interacting with CHOICE, both low literacy and adequate literacy patients were more likely to state a test preference and increase their readiness to receive screening (Table 3). Regardless of literacy level, CHOICE patients had more screening tests ordered and completed, but the differences were not statistically significant compared to the control group. In our multivariable
models, limited literacy patients were more likely than adequate literacy patients to have a screening test ordered, regardless of intervention arm (OR 1.9, 95% CI 1.1 – 3.5). However, we found no statistically significant difference in test completion rates for patients with limited literacy compared to adequate literacy (OR 1.5, 95% CI 0.8 – 3.0). In all analyses, we found no significant interaction between CHOICE and literacy level, or between CHOICE and patients’ baseline readiness for screening.

Influence of Readiness to Receive Screening

At the conclusion of CHOICE, 56 patients (46%) selected that they were “ready to be tested,” 28 (23%) selected “need more information,” and 39 (32%) selected “don’t want to be tested now.” Patients’ selections showed moderate to high agreement with their derived Transtheoretical Model Stage as measured by the post-program survey (weighted kappa = 0.50, 95% CI 0.37 – 0.62).

Patients’ stage predicted test ordering and completion. Patients in the preparation for action stage were four times as likely to have a screening test ordered and over three times as likely to complete the test when compared to patients in the precontemplative stage (36% vs. 9% for test ordering; 22% vs 7% for test completion). After interacting with the computer programs, the percentage of patients in the Preparation for Action stage increased by 21% (95% CI 13% - 29%) for CHOICE compared to 6% (95% CI 2% - 10%) for the control program.

In a post-hoc analysis examining the effect of CHOICE in patients with
varying baseline readiness levels, the probability of having a screening test ordered or completed increased as patient readiness increased (Figure 3). In addition, CHOICE had a significant effect on test ordering for patients in the contemplation stage at study entry. 30% of contemplative CHOICE patients had a screening test ordered compared to 7% of control patients (p=0.03). For patients in the precontemplation and preparation for action stages, differences in test ordering rates were smaller and non-significant. Similarly, differences in test completion rates were not statistically significant regardless of baseline readiness.

DISCUSSION

We found that the decision aid (CHOICE) increased patients' ability to state a test preference and their readiness to receive screening, regardless of literacy level. In addition, more CHOICE patients had CRC screening tests ordered and completed, but these differences were not statistically significant.

Several mechanisms can explain how CHOICE increased patients' readiness to be screened. On the simplest level, CHOICE serves as a “just in time” patient reminder. Such reminders are a cue to action, and prior studies have documented that patient reminders increase cancer screening rates.(24-28) In addition to prompting patients to receive screening, CHOICE informs patients of screening options. Lack of knowledge of CRC screening is a major barrier, particularly for low literacy patients who are much less likely to understand CRC screening choices.(12;13;29) Other studies of CRC decision aids found they
increased patient knowledge and led to more informed decisions.\(^{(30;31)}\)

CHOICE also includes patient testimonials to address negative screening attitudes. Patients’ fears that CRC screening tests are painful, embarrassing, or difficult to complete discourage screening.\(^{(9;10;32)}\) By including interviews with patients who successfully completed screening, CHOICE may lessen test anxiety. In addition, CHOICE includes a direct physician recommendation to receive screening, one of the most potent predictors of CRC screening.\(^{(33-35)}\)

Despite patients’ increased readiness to be screened, we observed a dramatic drop-off between the number of patients who intended to ask their physician for screening and the actual number of screening tests ordered. Only one-third (36\%) of patients in the preparation for action stage had a screening test ordered. This finding suggests the presence of additional system barriers to CRC screening.

One prominent barrier is lack of time. Physicians often report insufficient time to address preventive services.\(^{(36-38)}\) Our enrollment strategy included any patient scheduled for a routine visit, regardless of whether the visit was for an annual exam or for chronic disease management. To the extent that patients presented with other acute problems requiring attention, less time would be available to discuss screening needs. CHOICE may be more effective if delivered immediately before an annual physical examination appointment.

Communication difficulties may also contribute to the gap between patient intent and screening. Low literacy patients are particularly vulnerable to communication difficulties.\(^{(39)}\) Low literacy patients are less likely to understand
their physicians’ instructions, and they are also less likely to ask questions in a medical visit. Although CHOICE encourages patients to discuss their screening decisions with their doctors, further patient coaching may be needed.

In addition to increasing patients’ test preferences and their screening readiness, CHOICE can help clinics maximize their scarce visit times. CHOICE requires little staff time and only 11 minutes of patient time to complete. By allowing patients to interact with CHOICE while they wait for their physician, the waiting time is converted to a patient education session. CHOICE also might allow busy health professionals to focus their time on answering specific questions about CRC screening rather than attempting to provide a broad overview of screening and all the available options. The prevalence of computers in the home and medical office facilitates implementing a computer-based decision aid such as CHOICE. This low cost of implementation argues for incorporating CHOICE into routine practice. Assuming the observed 5.7% increase in screening rates we observed is real, we would expect one additional patient to be screened for every 18 who viewed CHOICE. In measures of time, CHOICE would result in one additional patient screened for every 3.4 hours of patient viewing.

Our study has several limitations. Despite our randomized design, insurance status was not evenly distributed. For this reason, we included insurance status in all multivariable models although it did not change our results. In addition, our chart reviews to measure screening rates may have missed screening performed outside the institution. However, anecdotal experience at
the study clinic site indicates that the practice’s low income patients rarely receive screening services elsewhere. We also did not measure some factors that may affect screening utilization, such as transportation difficulties and comorbidities. Lastly, our sample size may have been too small to detect an actual increase in screening rates associated with CHOICE, and as with any single site study, our findings may not apply to other patient populations.

In conclusion, we found that a literacy sensitive web-based CRC screening decision aid effectively increases patients’ readiness to receive screening and may lead to higher screening rates in patients with varying literacy levels. For these reasons, CHOICE can be a valuable resource for time-strapped clinics. Future research should focus on ways decision aids such as CHOICE can be combined with other system level interventions to increase CRC screening rates.
References


Table 1. Demographic characteristics of study sample at baseline

<table>
<thead>
<tr>
<th></th>
<th>CHOICE (n=124)</th>
<th>Control Program (n=124)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>57.8 (6.8)</td>
<td>57.2 (6.5)</td>
<td>0.47</td>
</tr>
<tr>
<td>Female</td>
<td>82 (66%)</td>
<td>88 (71%)</td>
<td>0.41</td>
</tr>
<tr>
<td>African American</td>
<td>96 (77%)</td>
<td>86 (69%)</td>
<td>0.15</td>
</tr>
<tr>
<td>Annual Household Income</td>
<td></td>
<td></td>
<td>0.90</td>
</tr>
<tr>
<td>Less than $10,000</td>
<td>44 (38%)</td>
<td>46 (40%)</td>
<td></td>
</tr>
<tr>
<td>$10,000 - $19,999</td>
<td>44 (38%)</td>
<td>43 (37%)</td>
<td></td>
</tr>
<tr>
<td>$20,000 or greater</td>
<td>29 (25%)</td>
<td>26 (23%)</td>
<td></td>
</tr>
<tr>
<td>Married/Living Together</td>
<td>28 (23%)</td>
<td>38 (31%)</td>
<td>0.15</td>
</tr>
<tr>
<td>Employed</td>
<td>35 (28%)</td>
<td>29 (23%)</td>
<td>0.38</td>
</tr>
<tr>
<td>Uninsured*</td>
<td>40 (32%)</td>
<td>57 (46%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Health Literacy</td>
<td></td>
<td></td>
<td>0.90</td>
</tr>
<tr>
<td>Limited (&lt; 9th grade)</td>
<td>68 (55%)</td>
<td>67 (54%)</td>
<td></td>
</tr>
<tr>
<td>Adequate (&gt;=9th grade)</td>
<td>56 (45%)</td>
<td>57 (46%)</td>
<td></td>
</tr>
<tr>
<td>Self-reported Health Status</td>
<td></td>
<td></td>
<td>0.70</td>
</tr>
<tr>
<td>Poor</td>
<td>16 (13%)</td>
<td>20 (16%)</td>
<td></td>
</tr>
<tr>
<td>Fair</td>
<td>44 (35%)</td>
<td>48 (39%)</td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>45 (36%)</td>
<td>37 (30%)</td>
<td></td>
</tr>
<tr>
<td>Very Good/Excellent</td>
<td>19 (15%)</td>
<td>18 (15%)</td>
<td></td>
</tr>
<tr>
<td>Readiness for CRC screening</td>
<td></td>
<td></td>
<td>0.56</td>
</tr>
<tr>
<td>Precontemplation</td>
<td>44 (35%)</td>
<td>37 (30%)</td>
<td></td>
</tr>
<tr>
<td>Contemplation</td>
<td>24 (19%)</td>
<td>23 (19%)</td>
<td></td>
</tr>
<tr>
<td>Preparation for Action</td>
<td>56 (45%)</td>
<td>64 (52%)</td>
<td></td>
</tr>
<tr>
<td>Training Level of Clinician</td>
<td></td>
<td></td>
<td>0.41</td>
</tr>
<tr>
<td>Mid-level provider (PA, NP)</td>
<td>62 (50%)</td>
<td>54 (44%)</td>
<td></td>
</tr>
<tr>
<td>Resident physician</td>
<td>50 (40%)</td>
<td>52 (42%)</td>
<td></td>
</tr>
<tr>
<td>Attending physician</td>
<td>12 (10%)</td>
<td>18 (15%)</td>
<td></td>
</tr>
</tbody>
</table>

*Includes 9 patients with no commercial or governmental health insurance who were enrolled in a charity care program.
### Table 2. Patient outcomes, CHOICE versus control program.

<table>
<thead>
<tr>
<th>Patient Outcome</th>
<th>CHOICE (n=124)</th>
<th>Control (n=124)</th>
<th>Unadjusted OR (95% CI)</th>
<th>p-value</th>
<th>Adjusted OR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported a test preference</td>
<td>103 (84%)</td>
<td>65 (53%)</td>
<td>4.6 (2.5 – 8.3)</td>
<td>&lt;0.001</td>
<td>5.7 (2.9 – 11.1)*</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Increased readiness for screening</td>
<td>36 (29%)</td>
<td>12 (10%)</td>
<td>3.8 (1.9 – 7.8)</td>
<td>&lt;0.001</td>
<td>4.3 (1.9 – 9.5)†</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Had screening test ordered</td>
<td>39 (31%)</td>
<td>28 (23%)</td>
<td>1.6 (0.9 – 2.8)</td>
<td>0.12</td>
<td>1.7 (0.95 – 2.9)*</td>
<td>0.08</td>
</tr>
<tr>
<td>Completed screening test</td>
<td>24 (19%)</td>
<td>17 (14%)</td>
<td>1.5 (0.8 – 3.0)</td>
<td>0.23</td>
<td>1.8 (0.95 – 3.5)*</td>
<td>0.07</td>
</tr>
</tbody>
</table>

*Adjusted for race (black vs. other), marital status (married/living together vs. other), health insurance (yes/no), literacy level, baseline readiness stage, and provider training level (resident physician vs. attending/mid-level provider).

†Adjusted for race (black vs. other), marital status (married/living together vs. other), health insurance (yes/no), literacy level, annual household income (<$20,000 vs. $20,000 or greater), and health status (poor/fair/good vs. very good/excellent).
Table 3. Patient outcomes stratified by literacy level.

<table>
<thead>
<tr>
<th>Patient Outcome</th>
<th>Limited Literacy</th>
<th>Adjusted OR (95% CI) p-value</th>
<th>Adequate Literacy</th>
<th>Adjusted OR (95% CI) p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHOICE (n=68)</td>
<td>Control (n=67)</td>
<td></td>
<td>CHOICE (n=56)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adjusted</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OR (95% CI)</td>
<td>p-value</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reported a test preference</td>
<td>51 (76%)</td>
<td>32 (48%)</td>
<td>4.3 (1.8 – 9.9)*</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Increased readiness for screening</td>
<td>22 (33%)</td>
<td>8 (12%)</td>
<td>4.0 (1.4-11.1)†</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Had screening test ordered</td>
<td>25 (37%)</td>
<td>19 (28%)</td>
<td>1.7 (0.8 – 3.5)*</td>
<td>0.16</td>
</tr>
<tr>
<td>Completed screening test</td>
<td>14 (21%)</td>
<td>11 (16%)</td>
<td>1.7 (0.7 – 4.5)*</td>
<td>0.26</td>
</tr>
</tbody>
</table>

*Adjusted for race (black vs. other), marital status (married/living together vs. other), health insurance (yes/no), baseline readiness stage, and provider training level (resident physician vs. attending/mid-level provider).

†Adjusted for race (black vs. other), marital status (married/living together vs. other), health insurance (yes/no), annual household income (<$20,000 vs. $20,000 or greater), and health status (poor/fair/good vs. very good/excellent)
Figure 1. Representative screen shot from CHOICE program

All written text is read aloud by a narrator. Patients interact with the program via a touch screen monitor.
15 patients were excluded for being current with CRC screening, and 1 patient reported recent rectal bleeding.

Figure 2. Patient enrollment and randomization.
Figure 3. CRC Screening Test Ordering and Completion Rates, by Baseline Readiness*

*adjusted for race (black vs. other), marital status (married/living together vs. other), health insurance (yes/no), literacy level, and provider training level (resident physician vs. attending/mid-level provider).

†p=0.03 for comparison of CHOICE vs. Control. All other p-values non-significant.
Patients with low health literacy have greater difficulty understanding information needed to make appropriate healthcare decisions. Consequently, low health literacy patients receive fewer preventive health services and suffer worse health outcomes. Although low literacy patients are more likely to report communication difficulties with their physicians, they are also less likely to ask questions in a medical encounter.

To address this knowledge acquisition barrier, we developed and tested a web-based CRC screening decision aid (CHOICE version 6.0). The decision aid incorporated simple language, audio, graphics, animations, and video to make it accessible to low literacy patients. The decision aid was well received by patients with over 99% of patients reporting they found the program easy to use and they would recommend it to others. These positive program evaluations were consistent with our finding that 84% of patients who viewed the decision aid were able to state a CRC screening test preference compared to 53% of control patients ($p<0.0001$). Decision aid patients were also more likely to increase their readiness to receive screening (29% vs. 10%, $p<0.001$). Despite these improvements in knowledge and intention, CRC test ordering and completion rates were similar in both groups (31% vs. 23% for test ordering; 19% vs. 14% for test completion).
REQUIREMENTS FOR SUCCESSFUL CRC SCREENING PROGRAMS

Successful completion of CRC screening requires several factors: a motivated patient, access to the screening test, and a patient’s belief that he or she can complete the test. CHOICE was designed to affect patient motivation by focusing on the perceived susceptibility to CRC, the severity of CRC, and the benefits of screening, all constructs from the Health Belief Model. Our results show that CHOICE succeeded in increasing patients’ intentions to receive screening. After interacting with CHOICE, 21% of patients shifted to the Preparation for Action Stage compared to 6% of control group patients. Overall, two-thirds of CHOICE patients indicated they planned to talk to their doctors about CRC screening immediately after using the program.

The second needed factor, access to screening tests, requires several components. First, in current practice, a physician must order the test. CHOICE attempted to influence this step indirectly by encouraging patients to discuss screening with their doctors. However, patients with limited literacy may be more hesitant to request tests from their physicians, as is suggested by their propensity to ask fewer questions in medical visits.(59) Time restrictions also limit physicians’ abilities to adequately discuss CRC screening options with their patients. Furthermore, some screening tests, such as colonoscopy, require a physician to place a referral, adding more time demands. To the extent that patients have acute or chronic medical illnesses requiring immediate care, physicians may not have the time to adequately discuss preventive health needs and may defer such discussions to an upcoming annual physical exam. Our
study included any patient scheduled for a medical visit, not only those scheduled for annual health maintenance exams. Therefore, it is likely that the medical visits’ agenda was already full leaving no room for screening discussions. More pressing health concerns and patients’ hesitancy to request screening may explain why only 39% of patients who stated they were “ready to receive screening” had a screening test ordered at their initial visit.

Access to a screening test also requires the test to be affordable. The cost of CRC screening tests varies widely, from less than $20 for fecal occult blood testing to over $1000 for a colonoscopy. For uninsured patients, a colonoscopy is likely not financially accessible. Of note, colonoscopies accounted for 29% of all screening tests ordered for uninsured patients in our study sample.

In addition to financial factors, physical location affects patients’ ease of access. FOBT poses the least physical barriers as patients can complete the testing at home and return the completed test kit by mail. On the other extreme, a colonoscopy requires a patient to follow a bowel preparation regimen, travel to a hospital or specialist’s office where the colonoscopy will be performed, and arrange for a driver to transport them home afterwards. Despite the greater financial and physical barriers of colonoscopy, a greater percentage of patients completed colonoscopies than FOBT’s (Table 3.1). This finding suggests that difficult access was not a major cause of patients’ failure to complete screening tests. Rather, the lowest completion rates were observed for FOBT alone. The study practice routinely calls patients before their flexible sigmoidoscopy or
colonoscopy appointments. These reminder calls may encourage completion by serving as an additional cue to action, resulting in the higher completion rates observed for endoscopy.

Table 3.1. CRC screening test completion rates, by insurance status.

<table>
<thead>
<tr>
<th>CRC Test Ordered</th>
<th>Uninsured* (n=34)</th>
<th>Insured† (n=63)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number Ordered</td>
<td>Number Completed</td>
</tr>
<tr>
<td>Fecal Occult Blood Test (FOBT)</td>
<td>19</td>
<td>5 (26%)</td>
</tr>
<tr>
<td>FOBT + Flexible Sigmoidoscopy</td>
<td>3</td>
<td>2 (67%)</td>
</tr>
<tr>
<td>Flexible Sigmoidoscopy</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>12</td>
<td>6 (50%)</td>
</tr>
</tbody>
</table>

* p=0.24
† p=0.72

Lastly, patients must believe they are capable of completing the screening test ordered. This belief is termed “self-efficacy.” CHOICE attempted to increase self-efficacy by giving patients knowledge needed to complete the tests and by displaying video testimonials from patients sharing their views that the screening process was easy. Although we did not measure self-efficacy, we did ask patients to specify which screening test they would prefer. Ordering the screening test which the patient preferred should maximize self-efficacy as patients are likely to believe they are capable of completing the test they want.
Table 3.2 displays how often the ordered screening tests matched patients' stated preferences. Overall, the ordered test matched patients' preferences less than 50% of the time. A possible explanation for this discrepancy is that we asked patients which test they would prefer assuming all tests were free, but the actual tests ordered reflect real-world financial constraints. However, the highest degree of agreement was observed for colonoscopy, arguing against cost constraints forcing patients to forego their preferred test.

Table 3.2. Patients’ Preferences and Agreement with Screening Tests Ordered.

<table>
<thead>
<tr>
<th>Patients’ Preferred Test</th>
<th>n</th>
<th>Agreement with Test Ordered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fecal Occult Blood Testing (FOBT)</td>
<td>21</td>
<td>11 (52%)</td>
</tr>
<tr>
<td>Flexible Sigmoidoscopy</td>
<td>7</td>
<td>1 (14%)</td>
</tr>
<tr>
<td>FOBT + Flexible Sigmoidoscopy</td>
<td>10</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>25</td>
<td>18 (72%)</td>
</tr>
<tr>
<td>Don’t want testing</td>
<td>1</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

An alternate explanation for this disagreement is poor communication in the medical visit. Patients may not have informed their physicians of their desired test or may have not objected if their physician suggested a different test for them. Surprisingly, test agreement was not significantly associated with test completion in our study. Patients completed 47% of screening tests that
matched their test preferences and 41% of screening tests that did not match (p=0.66).

EFFECT OF STAGE OF CHANGE ON SCREENING BEHAVIOR

According to the TransTheoretical Model, patients proceed through sequential Stages of Change before they change a health behavior.(75) The earliest stage is “precontemplation”, the time when a patient is unaware of the need to make any change in behavior. In the context of CRC screening, the precontemplative stage describes the person who is not even aware of CRC or the need for screening. Next, patients enter the “contemplative” stage in which they are aware of CRC and are considering the risks and benefits of screening. Once a decision to receive screening is made, patients enter the “preparation for action” stage. In this stage, patients discuss screening with their doctors and make arrangements to be screened. The final stage is “action” in which the patient successfully completes the screening test.

The majority of patients will progress only one stage at a time. It is unlikely that patients who have never heard of CRC (precontemplative) will immediately shift to asking their doctors for a specific screening test (preparation for action). Therefore, CHOICE should increase immediate screening the most for patients who are already considering screening but have not yet made a decision (the contemplators). Analyzing test ordering by patients’ stage of change at presentation supports this hypothesis. Patients who were in the
contemplative stage and viewed CHOICE had an odds ratio of 5.9 (95% CI 1.2 – 28.6) for having a CRC screening test immediately ordered, compared to odds ratios of only 1.5 (0.4 – 5.6) for precontemplative patients and 1.3 (0.6 – 2.7) for preparation for action patients. Therefore, CHOICE may be more effective if offered to patients over multiple visits. Initially, CHOICE may move a patient from the precontemplative to contemplative stage. At a subsequent medical visit, the now contemplative patient could interact with CHOICE again, increasing the likelihood of the patient deciding to be screened.

ARGUMENTS FOR IMPLEMENTING CHOICE

Even though CHOICE increased absolute CRC screening rates by a modest 5% (a difference too small to be statistically significant), there are several reasons to implement decision aids such as CHOICE in routine medical practice. First, over 99% of patients indicated they liked CHOICE and would recommend it to their peers. Given that the decision aid does not harm patients, offering it in a practice would increase patient benefit by giving them access to a resource they value.

Second, CHOICE unloads a complex patient education task from busy nurses and physicians. For patients to make informed CRC screening decisions, they must understand their personal risk for CRC, the benefits of diagnosing CRC early, and the risks and benefits of individual screening test options. Current practice relies on nurses and physicians to educate patients about these
topics. However, primary care physicians report inadequate time to counsel patients on preventive health issues. CHOICE can decrease these time demands by providing basic CRC screening education. Physicians can then focus their time clarifying patients’ specific CRC screening questions, contributing their unique knowledge where it is most needed.

CHOICE also standardizes the screening message, ensuring that all patients receive the same standard of care. Educational messages delivered by physicians and nurses are affected by the amount of time they have available and their personal views of screening. A physician who is 30 minutes behind in the office is unlikely to spend as much time discussing CRC screening options compared to the physician who is running on time or even ahead of schedule. In addition, a clinician’s unintentional bias may affect how screening tests are described and recommended. In contrast, CHOICE is standardized to provide the same fundamental information in each session regardless of time constraints or personal opinion.

Lastly, CHOICE is a low cost intervention. The program is freely available on the internet (http://intmedweb.wfubmc.edu/choice/choice.swf), and it will work with a standard mouse if a touch screen monitor is not available. For offices currently connected to the web, offering CHOICE requires no additional equipment. Although the absolute increase in screening rates was modest (1 additional person screened for every 20 who interacted with the program), the low cost of offering CHOICE makes it cost-effective.
There are several reasons why CHOICE may be more effective in actual practice than we observed in our study. Our study was limited to individuals overdue for CRC screening, suggesting they are harder to reach either due to negative attitudes about screening or difficulty accessing care. Expanding CHOICE to all patients greater than 50 years old may result in higher screening rates. Offering CHOICE at times patients are most likely to discuss screening with their physicians, for example at the time of an annual physical exam, should also increase its effectiveness, as would letting patients' interact with CHOICE over multiple medical visits or in their homes.

STRATEGIES FOR IMPLEMENTING CHOICE

The decision to use CHOICE can be assigned to patients, healthcare providers, or healthcare systems. Because CHOICE is web-based, it can be accessed in a patient's home or in the medical office. One strategy for implementing CHOICE would be to send patients a letter or e-mail asking them to view CHOICE before their next scheduled medical visit. According to national surveys, 74% of American adults use the internet, and 63% have broadband access in their homes. Although more young adults use the internet than older adults, even the majority of Americans aged 50 – 64 have home broadband access. Public libraries offer free access to the web for any individual without a home broadband connection.
Just as computers are prevalent in homes, they are also prevalent in medical practices. On the simplest level, a computer could be set aside in the patient waiting room for patient use while they wait to be called to an exam room. Such a strategy would require very little staff time, but would rely on patients to take the initiative to locate and launch the program. Precontemplative patients who do not understand the need for CRC screening may never decide to view the program without prompting.

Rather than leaving the decision to use CHOICE up to the patient, the responsibility for using CHOICE can be placed on physicians. If a physician planned to discuss CRC screening with her patient, she could ask the patient to interact with CHOICE while she stepped outside to see another patient, then returning to the exam room to continue the CRC screening discussion. Alternatively, the physician could ask the patient to view CHOICE immediately before or after the medical encounter.

Often, the most effective strategies for increasing guideline adherence involve changes to the healthcare system. Incorporating CHOICE into a system of care could be done by writing an office protocol requiring patients 50 - 75 to be offered the program before their health maintenance visits unless their chart indicates they have been screened. In this system, nurses would start the program in an individual exam room allowing patients to interact with the program while they wait for their doctor to enter. This strategy would convert a patients’ idle time into a patient education session. The short length of CHOICE (requiring an average of 11 minutes to complete) allows it to fit in brief waiting periods.
FINAL CONCLUSIONS

Low health literacy interferes with patients’ ability to understand information needed to make appropriate healthcare decisions and manage chronic diseases. The barrier of low health literacy results in less understanding, greater difficulty accessing care, and worse health outcomes. Computer assisted decision aids, such as CHOICE, can overcome some of these barriers by effectively giving patients needed information, increasing self-efficacy, and encouraging communication with medical providers. Computer assisted programs also have the advantage of being standardized, immune to time pressures, and low cost.

However, computer assisted decision aids are insufficient to affect positive medical outcomes when used in isolation from a medical encounter. Rather, the decision aids should be viewed as tools for use in conjunction with counseling from health professionals and a physician’s evaluation and tailored advice. To have the greatest impact on screening outcomes, the healthcare system should also support patients who want to be screened. Reminder calls, patient navigators, and efforts to streamline test scheduling can help patients complete screening tests once ordered. In summary, computer-assisted decision aids such as CHOICE represent a cost-effective strategy for educating patients in the context of a larger, supportive healthcare system.
REFERENCES


(13) Schatzkin A, Park Y, Leitzmann MF, Hollenbeck AR, Cross AJ.


