Published in final edited form as:

Health Promot Pract. 2011 March ; 12(2): 229–234. doi:10.1177/1524839909332139.

Colorectal Cancer Screening in Primary Care: Theoretical Model to Improve Prevalance in the Practice Partner Research Network

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Abstract

Colorectal cancer (CRC) is the second leading cause of cancer death in the United States (US). Half of Americans above age 50 are not current with recommended screening; research is needed to assess the impact of interventions designed to increase receipt of CRC screening. The Colorectal Cancer Screening in Primary Care (C-TRIP) study is a theoretically-informed group randomized trial within 32 primary care practices. Baseline median proportion of active patients aged 50 years or older up-to-date with CRC screening among the 32 practices was 50.8% (N=55,746). Men were more likely to be screened than women (52.9% vs. 49.2% respectively). Patients 50–59 years of age were less likely to be up-to-date with screening (45.4%) than those in the 60–69 year and 70–79 years groups (58.5% in both groups). Opportunities exist to increase the proportion of CRC screening received in adults age 50 and older. C-TRIP evaluates the effectiveness of a model for improvement for increasing this proportion.

Introduction

Colorectal cancer (CRC) is the second leading cause of cancer death in the United States (US); approximately 145,000 new cases and 55,000 deaths from colorectal cancer occur annually.(Centers for Disease Control and Prevention, 2007) Screening can aid both in the diagnosis of CRC in its early, more treatable stages, and in the detection of precursor lesions which can be removed to prevent CRC. An economic evaluation has shown that colorectal cancer screening is cost-effective, with a cost of \$10,000 to \$25,000 per year of life saved. (Pignone, Saha, Hoerger, & Mandelblatt, 2002) Recently revised US Preventive Services Task Force (USPSTF) guidelines recommend screening average risk adults age 50 to 75 years old either by high sensitivity, at home fecal occult blood test (FOBT) or fecal immunochemical test (FIT) annually, sigmoidoscopy every 5 years with high sensitivity FOBT every 3 years, or colonoscopy every 10 years. (U. S. Preventive Services Task Force,

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This work was presented in part at the North American Primary Care Research Group October, 2007, Vancouver, BC, Canada and published in abstract form.

2008) Other national groups recommend additional tests be considered (Levin, et al., 2008), yet approximately half of eligible adults have not been screened.

National data on patient receipt of CRC screening are limited to findings from patient self-report surveys. The Behavioral Risk Factors Surveillance System (BRFSS) reported increased use of CRC screening tests in 2004, with FOBT within the year preceding the survey and/or endoscopy within ten years at 57.3% of adults aged ≥ 50 years compared with 54.4% in 2002. (Centers for Disease Control, 2006b) The National Health Interview Survey (NHIS) in 2000 and 2003 reported combined rates of endoscopy and FOBT at 43%. CRC screening is usually predicated on the recommendation of a primary care clinician. (Gilbert & Kanarek, 2005) Research is needed to develop and assess the impact of interventions designed to increase CRC screening in primary care settings. (C. N. Klabunde, et al., 2007) This research can be viewed as part of a broader agenda to develop and assess strategies for translating research into practice (TRIP), an area that has an underdeveloped research base. (Grimshaw, et al., 2004)

The Practice Partner Research Network (PPRNet) is a learning and research organization in more than 140 primary care practices across the US. All PPRNet practices use a common electronic medical record (EMR) (*Practice Partner™ McKesson, Inc, Seattle WA*) and pool data quarterly for benchmarking, quality improvement (QI), and research activities. PPRNet's- previous work on translating research into practice (TRIP) has been shown to improve the primary and secondary prevention of cardiovascular disease and stroke (S. Ornstein, et al., 2004), diabetes care, (S. M. Ornstein, et al., 2007) and broad set of measures related to primary care practice. (Nemeth, et al., 2007; Nietert, et al., 2007) The Colorectal Cancer Screening in Primary Care (C-TRIP) study evaluates the effectiveness of the PPRNet-TRIP QI model for improving provider recommendation and patient receipt of CRC screening. It is a two-year group-randomized trial in 32 PPRNet primary care practices. Sixteen practices randomized to the intervention group receive quarterly reports on CRC screening performance, and participate in four practice site visits and two network meetings designed to help them adopt strategies for improving CRC screening; the 16 practices randomized to the control group receive regular PPRNet reports that do not include CRC screening performance. The intervention began on July 1, 2007 and will be completed by July 1, 2009. This paper describes the theoretical model underlying the study design and provides baseline CRC screening performance among the participating practices prior to entry into the cluster randomized trial (C-TRIP).

Study Design and Methods

Theoretical Model

The PPRNet-TRIP QI model was developed using grounded theory methods within previous research (Chris Feifer & Ornstein, 2004) and includes intervention, improvement, and practice development components. (C Feifer, et al., 2006)

The intervention component includes practice performance (audit and feedback) reports provided on a quarterly basis; practice site visits for academic detailing (about the guidelines for specific measures under study) and QI participatory planning; and annual network meetings for sharing of best practices that are attended by practice liaisons and the PPRNet research team.

The improvement component emphasizes five core concepts that practices can consider within our research intervention: prioritizing performance, involvement of all staff, system redesign, patient activation, and enhanced use of the practice EMR tools. For the C-TRIP study, the improvement model specifies thirteen strategies that practices can use to improve

CRC screening (Nemeth, Nietert, & Ornstein, 2009), but it does not prescribe this set of actions without consideration of the context of the specific practice. These strategies can be used to promote the practice ordering of and patient receipt of CRC screening within the average risk adult at age 50 or older.

The practice development component is designed to help practice leaders (physicians and office managers) learn how to manage improvement in their practice. (Nemeth, Feifer, Stuart, & Ornstein, 2008) Through use of a conceptual framework that encourages practice leaders to set a vision for improvement with clear goals for the staff to buy into; involvement of all staff; enhancing communication systems within the practice; developing staff knowledge about the rationale for improvement; taking small steps to change processes; assimilating the EMR to maximize clinical effectiveness; and using performance feedback within a culture of improvement practices learn how to leverage the key contributions of staff members and providers within the practice setting which stimulates improvement. Using the three theoretical components of the PPRNet-TRIP model, practices in the CTRIP study intervention are encouraged to jump start and maintain improvement efforts within their individual and unique practice environments. This research was designed recognizing that primary care practices are complex adaptive systems that evolve within their local context.(Miller, Crabtree, McDaniel, & Stange, 1998)

Practice Recruitment

In June, 2006 all PPRNet primary care practices were invited to participate through an email message that included a consent document outlining the study in detail. Practices consenting to participate agreed to host an introductory site visit to discuss the project in more detail, appoint a nurse and physician liaison to lead the project in the practice, and coordinate a baseline EMR review of CRC screening. The consent document also specified that, if randomized to the intervention arm, practice liaisons would participate in two annual network meetings with the research team and with liaisons from other practices, and that the practice would host four half-day practice site visits over the two year intervention. As a benefit for participating in the study, practices were offered complimentary quarterly PPRNet practice performance reports on more than 50 measures of care; a benefit that could cost up to \$500 per clinician annually otherwise. Based on power calculations, the intent was to enroll 30 practices in C-TRIP.

Introductory Site Visits

From August 2006 through May 2007 an introductory site visit was conducted in each practice that completed the consent document. At this visit, the goals of the study and the protocol for verification of the practices' electronic medical record (EMR) data on CRC screening were reviewed. The site visit included presentation of a revised version of the Centers for Disease Control (CDC) *Call to Action* slide presentation (Centers for Disease Control, 2006a), which outlined the natural history and epidemiology of colorectal cancer, as well as provided the evidence and guidelines for screening. A family physician and nurse on the research team attended each of the site visits and alternated making these presentations. All clinical staff were strongly encouraged to attend the site visit. The two investigators spent additional time with the practice liaisons to refine methods for reviewing and updating their EMR, a process designed to standardize recording of CRC screening in a section of the EMR that is reliably captured in the PPRNet data extraction and analyses programs.

Electronic Medical Record Audit

Subsequent to the introductory site visit and by July 1, 2007, practice study liaisons coordinated the EMR review of the records of all active patients 50 years of age or older.

Patients were considered “active” if a progress note was recorded in the EMR within the previous year. Liaisons were asked to assure that any information concerning completed colonoscopy, flexible sigmoidoscopy, or at home FOBT within recommended intervals *recorded anywhere in the EMR* was documented in the health maintenance section. They were also asked to include, in this section, information about these procedures that had been ordered and not completed, patient refusal, and if CRC screening was not indicated due to significant co-morbidity, such as dementia or terminal illness. Subsequent to the review, liaisons were asked to complete a survey documenting their approach to the EMR review. Practices that did not complete the review or conduct it according to the protocol were excluded from the study.

Data Analyses

During the first week of July 2007, practices remaining in the study ran an EMR extract program to provide data for the baseline analyses. Demographic, health maintenance, and patient activity data were combined in SAS (Cary, NC) datasets for analyses. Analyses were performed on all active patients 50 years of age or older. An active patient was defined as one with a progress note in the EMR on or after July 1, 2006, unless they had died or transferred from the practice after that date. Patients were considered up-to-date with CRC screening if they had a record of either a colonoscopy done from July 1, 1997 through June 30, 2007, a FOBT from July 1, 2006 through June 30, 2007 or a sigmoidoscopy from July 1, 2002 through June 30, 2007. Overall percentages of patients that were up-to-date were calculated for each practice, with subgroup analyses by age and gender. The median percentage and Achievable Benchmark of Care (ABC™) (Catarina I. Kiefe, et al., 2001) were calculated across all practices. The ABC™ is a benchmark reflecting care provided to at least 10% of the total eligible patient population. Using this methodology for calculation, high performers (i.e. practices) with small numbers of cases do not unduly influence the level of the benchmark. (C. I. Kiefe, et al., 1998a; Weissman, et al., 1999; Wessell, et al., 2008) For each practice, the proportion of patient up-to-date by each screening modality was calculated.

Results

One hundred eleven primary care practices were in PPRNet as of June 2006 and received an email invitation to participate in C-TRIP. Fifty practices returned consent agreements; no information was solicited from the non-responders. One practice was excluded for non-adherence to prior research study protocols, and six practices withdrew prior to an introductory site visit. Introductory site visits were made to the other 43 practices. Subsequent to the introductory visit, seven practices withdrew from the study, largely for reasons related to the work involved in conducting the EMR chart review. The remaining 36 practices conducted an EMR review; however three practices did not adhere to the review protocol and were withdrawn. Baseline data were received from the remaining 33 practices. One practice had very little data on CRC screening recorded in their EMR, and they were excluded from further participation in the study. Baseline data is presented on the remaining 32 practices.

The 32 practices have 174 health care providers (143 physicians, 13 physician assistants, and 18 nurse practitioners) in 19 states (Arkansas, Arizona, Colorado, Connecticut, Florida, Iowa, Illinois, Michigan, Montana, North Carolina, Nebraska, New Jersey, New York, Ohio, Pennsylvania, Tennessee, Vermont, Washington and Wisconsin). Eleven of the practices have one or two providers (HCP), 11 have three or four HCP and 12 have 5 or more HCP. Two practices are family medicine residency programs, 25 are community based family practices, and 5 are community based internal medicine practices. The median number of active patients at least 50 years of age among the practices was 1129 (range 154–5913). The

median number of these patients per provider was 398 (range, excluding the residency programs was 110 to 891).

Among the 55,746 patients 50 years of age or older in the 32 practices, the median proportion up-to-date with CRC screening on July 1, 2007 was 50.8% (inter-quartile range [IQR]: 44.8% to 57.4%). The Achievable Benchmark of Care (ABC™) (Catarina I. Kiefe, et al., 2001; C. I. Kiefe, et al., 1998b) was 67.3%. Table 1 reports the proportion of all patients up-to-date with CRC screening per decade of age and by gender. Males were more likely than females to be up-to-date with screening. Patients 60–79 years of age were more often up-to-date with screening than those patients in their fifties. Among the 28,273 patients in the study cohort up-to-date with screening as of July 1, 2007, 89.2% had been screened by colonoscopy, 7.4% by FOBT alone, 2.9% by flexible sigmoidoscopy alone, and 0.5% by both FOBT and flexible sigmoidoscopy.

Discussion

PPRNet has successfully recruited a diverse sample of primary care practices for the C-TRIP study. Forty-five percent of all PPRNet practices signed consent to participate in the study and 64% of this initial sample completed the steps needed to be randomized in the study.

CRC screening at baseline in C-TRIP was similar to that in recent national surveys (Centers for Disease Control, 2006b) and indeed just above the national Healthy People 2010 goal (U.S. Department of Health and Human Services, 2000) of 50%. The sources of the data we present here were validated through the electronic medical records of practices rather than potentially inaccurate self-report by patients. As in other reports, (Meissner, Breen, Klabunde, & Vernon, 2006) men were more likely to be up-to-date with screening than women. Some have suggested that women may have more negative expectations regarding endoscopy, and are concerned with pain and embarrassment more so than men. (Farraye, et al., 2004; Friedemann-Sanchez, Griffin, & Partin, 2007)

Unique in this report is the very high proportion of patients that are up-to-date with screening by colonoscopy. Trends towards increased use of lower endoscopy for CRC screening has been noted within the two most recent BRFSS and NHIS reports. (Centers for Disease Control, 2006b) Patients who have insurance coverage and who have routine doctor visits are more likely to have up-to-date colonoscopy. (Ioannou, Chapko, & Dominitz, 2003; Klabunde, Meissner, Wooten, Breen, & Singleton, 2007) Over the past decade, Medicare has progressively increased access to CRC screening and has allowed a screening colonoscopy every ten years for average risk adults. (US Department of Health and Human Services, 2007) Increased screening and earlier detection and diagnosis in an elderly population have been associated with expansion of Medicare benefits for screening colonoscopy. (Gross, et al., 2006) (DeWilde & Russell, 2004; Carrie N. Klabunde, et al., 2007)

Since Medicare coverage does not begin for most patients until age 65, it is not surprising that we found that patients in the 50–59 year age group were less likely to be up-to-date with screening, than those 60–69 years or 70–79 years. Given that patients in the 50–59 year age group have the most potential years of life to be saved by screening, and comprise 42% of all patients 50 years of age or older in our study population, increasing screening among patients in this age group may be a focus among practices in the project, an emphasis encouraged by others. (Cokkinides, Chao, Smith, Vernon, & Thun, 2003)

Given baseline findings and the number of patients and practices in the study, C-TRIP will have power > 80% to detect an absolute difference of 10% in improvement in CRC screening between intervention and control groups. We expect that there will be secular

improvements in both groups, as both clinician and public awareness about CRC screening will likely increase during the study period. The Hawthorne effect will likely play a role particularly since each practice in the control group also completed a baseline EMR audit. (Grufferman, 1999) Improved documentation will also likely occur in both groups, if clinicians more reliably record CRC screening performed elsewhere in their EMR.

Given the importance of CRC screening, if the C-TRIP intervention study does result in a 10% absolute improvement in the intervention group compared to the control group, we believe that an improvement of this magnitude will be important. Although only 9% of physician practices currently use comprehensive EMR systems (Hing, Burt, & Woodwell, 2007), this proportion is expected to rise soon. The C-TRIP intervention, though unique to PPRNet at this time, has components that can readily be implemented elsewhere. Practice improvement within primary care settings can potentially be enhanced through theoretically based interventions that are adapted to fit the local context.

Acknowledgments

This study has been funded by the National Institute of Health, National Cancer Institute, Grant Number 5 R01 CA112389.

Conflict of Interest

Dr. Ornstein is a consultant to McKesson Practice Partner® for activities not directly related to the study described in this manuscript. Drs. Nemeth, Jenkins and Nietert declare no conflicts of interest related to this manuscript. All of the authors are supported in part by the grant awarded by the National Institute of Health, National Cancer Institute.

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Table 1

Baseline colorectal cancer screening by gender and decade as of July 2007

	# Screened (numerator)	Number of patients (denominator)	Percent Screened
Male	12727	24071	52.9
Female	15500	31527	49.2
50–59	10569	23288	45.4
60–69	9585	16395	58.5
70–79	5679	9709	58.5
80–89	2238	5332	42.0
90–99	202	1022	19.8
Total	28273	55746	50.8