Implementing COLORECTAL CANCER Screening

WORKSHOP SUMMARY

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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Margie Patlak, Christine Micheel, and Robert German, *Rapporteurs*

National Cancer Policy Forum

INSTITUTE OF MEDICINE
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Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

George Isham, HealthPartners, Inc.
Thomas J. Kean, C-Change
Laura Seeff, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention
Robert A. Smith, American Cancer Society
Judith L. Wagner, Independent Consultant, Bethesda, Maryland

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the final draft of the report before its release. The review of this report was overseen by **Dr. Melvin Worth**. Appointed by the Institute of Medicine, they

were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authors and the institution.

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INTRODUCTION

In 2003, the National Cancer Policy Board estimated that modest efforts to implement what is known from social sciences and biomedical research on cancer prevention and early detection could result in a 29 percent reduction in cancer deaths in about 20 years (NRC, 2003). With consideration to the gravity of that finding, the National Cancer Policy Forum[1] sought to outline ways to increase the use of screening services in the United States. To maximize the impact of such a discussion, the NCPF chose to focus on colorectal cancer screening. Despite the strong evidence that screening is effective in preventing deaths and that there are effective health systems and community interventions to increase screening, use of colorectal cancer screening remains low. Therefore, the purpose of the workshop was to identify the next steps that need to be taken to fully implement recommended colorectal cancer screening, including steps to be taken at clinic, community, and health system levels.

[1]The Institute of Medicine (IOM) established the National Cancer Policy Forum (NCPF), effective on May 1, 2005, to succeed the National Cancer Policy Board (NCPB), which existed from 1996 to 2005. IOM forums are designed to allow government, industry, academic, and other representatives to meet and confer privately on subject areas of mutual interest. NCPF is the successor to NCPB in providing a focus within The National Academies for the consideration of issues in science, clinical medicine, public health, and public policy relevant to the goals of preventing, palliating, and curing cancer.

The first U.S. Preventive Services Task Force (USPSTF)[2] guidelines recommending colorectal cancer screening were made in 1996, based on research documenting that colorectal cancer screening using fecal occult blood tests (FOBTs) and sigmoidoscopy effectively reduced the numbers of deaths from this cancer (USPSTF, 1996). In 2002, colonoscopy and double-contrast barium enema were added to the USPSTF-recommended colorectal cancer screening arsenal (USPSTF, 2002). Researchers also found a number of interventions in medical practices/health systems and in communities that were effective in increasing screening rates, including client reminders and recalls, provider reminders, reduced structural barriers, provider assessment and feedback, and small media. Yet colorectal cancer screening rates remain relatively low in the United States.

Encouraged by the Centers for Disease Control and Prevention (CDC) to recognize the need to make colorectal cancer screening more widespread, the NCPF convened the workshop "Implementing Colorectal Cancer Screening," which was held February 25 and 26, 2008, in Washington, DC. After the natural history and epidemiology of colorectal cancer were described, speakers identified major barriers to implementation of screening and described effective strategies to increase screening, based on available research and on their own experience as leaders in the field. These strategies included not only interventions to increase rates of screening, but also analysis of current screening technologies that could be used to increase screening effectiveness. The speakers represented a broad spectrum of contexts in which issues of implementation are encountered, from primary care or gastrointestinal (GI) specialty practices to community-, state-, or national-based programs. Health insurers and providers of employment-based programs also gave their perspective, as well as health economists and epidemiologists. The presentations were followed by a session in which participants discussed the relative value of actions needed to increase recommended colorectal cancer screening services. This document is a summary of the workshop proceedings.

Moving Evidence-Based Recommendations into Practice

Dr. Ralph Coates, associate director for science in the National Office of Public Health Genomics at the CDC, began the morning presentations by summarizing the purpose of the workshop and detailing how colorec-

[2]Across the complete range of clinical preventive health services, the U.S. Preventive Services Task Force (USPSTF) provides the gold standard in evidence-based recommendations. USPSTF recommendations are equally respected by physicians, patients, payers, and policy makers; because of this, the USPSTF has been instrumental in establishing the standard of care for preventive health services in the United States since its creation in 1984 (Eisenberg and Kamerow, 2001).

tal cancer screening often is "lost in translation" on the continuum from discovery of benefit to clinical implementation in communities throughout the United States. He noted that the genesis of the workshop stemmed from the 2003 NCPB report, *Fulfilling the Potential of Cancer Prevention and Early Detection* (NRC, 2003).[3] The report concluded that because evidence-based prevention and screening interventions are not widely implemented, thousands of avoidable deaths occur each year.

Although the 2003 report made several recommendations related to colorectal cancer—such as providing resources for state-based comprehensive cancer control programs, conducting timely reviews of cancer prevention interventions, providing insurance coverage of preventive services recommended by the USPSTF, and supporting a public health colorectal cancer screening program for low-income, uninsured populations—its broad focus precluded outlining detailed suggestions for how to boost implementation of cancer preventive services for specific cancers, Dr. Coates said. Consequently, the NCPF decided to take this report further by focusing on one cancer—colorectal cancer—and discern what steps need to be taken to improve screening implementation. As Dr. William Lawrence of the Agency for Healthcare Research and Quality (AHRQ) and the CDC added later, both agencies recently prioritized clinical preventive services. Colorectal cancer screening was ranked number four on the list of all preventive services, and number two for the screening services, mainly because of the preventable disease burden linked to such screening, and the fact that optimal colon cancer prevention is not being achieved with current levels of screening (Maciosek et al., 2006).

Until recently, fewer than half of Americans aged 50 and older received recommended colorectal cancer screening (Seeff et al., 2004). The limited implementation of this screening in the face of such strong evidence that it is effective is a conundrum. One reason that might explain this puzzling finding is that there is limited research on implementation that might indicate effective ways to improve it. Dr. Coates showed in a slide that as candidate clinical applications proceed on the continuum from discovery to clinical practice, there is a significant drop in funding beginning just before the development of evidence-based guidelines for using the intervention and continuing through all subsequent steps (Figure 1). The paucity of funding for relevant research on how to implement new clinical interventions may help explain why so many effective interventions are not more widely used in the clinic. "The bench-to-bedside continuum

[3]A subsequent NCPB workshop addressed cost-effectiveness of colorectal cancer screening. The workshop is summarized in *Economic Models of Colorectal Cancer Screening in Average-Risk Adults: Workshop Summary* (IOM, 2005b).

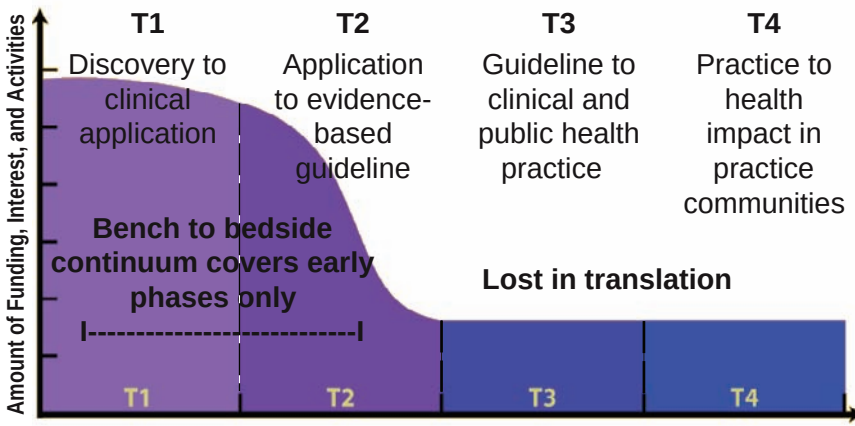

FIGURE 1 The research community's interest in implementation processes wanes along the continuum of cancer translational research. SOURCES: Coates presentation (February 25, 2008) and IOM (2002), Khoury et al. (2007), Sung et al. (2003), and Woolf (2008). Adapted from Khoury, M. J., M. Gwinn, P. W. Yoon, N. Dowling, C. A. Moore, and L. Bradley. 2007. The continuum of translation research in genomic medicine: How can we accelerate the appropriate integration of human genome discoveries into health care and disease prevention? *Genetics in Medicine* 9(10):665–674. Copyright 2007 by the American College of Medical Genetics. Reprinted with permission of Lippincott Williams & Wilkins.

covers only the early phases of this continuum, and therefore some applications are lost in translation," Dr. Coates said.

This seems to be especially true for colorectal cancer screening, Dr. Coates noted. Good biomedical research findings support the USPSTF evidence-based recommendations for such screening, and social science and health services research supports guideline recommendations of the Task Force on Community Preventive Services (TFCPS). But there is limited research on implementation of screening services, and even less on implementing *Guide to Community Preventive Services (Community Guide)* recommendations (TFCPS, 2008a). There also is limited assessment of what the health benefits are when those guidelines and services are effectively in the general population. The IOM tried to bridge that gap with its 2001 report *Crossing the Quality Chasm: A New Health System for the 21st Century* (IOM, 2001) and its 2005 report *Building a Better Delivery System: A New Engineering/Health Care Partnership* (IOM, 2005a). In those reports, the IOM recommended increasing the use of systems tools, such as tracking and reminder systems, and information technologies to increase quality and delivery of recommended services. But questions remain on how to

implement those recommendations, and colorectal cancer was not specifically addressed in either report.

Consequently, in addition to presentations related to the natural history and epidemiology of colorectal cancer, as well as evidence-based guidelines for screening for this cancer, the workshop was planned to bring together the expertise of workshop participants with presentations on strategies for improving the implementation of colorectal cancer screening in health care settings, including both primary care practice and gastrointestinal specialty practices, Dr. Coates noted. But recognizing that the health care delivery system does not operate in isolation, the workshop planners also aimed to gather expert advice on ways that other sectors of society, such as employers, health insurers, and state and federal public health agencies, have fostered successful implementation of colorectal cancer screening. Thus, the workshop includes presentations on those topics, as well as on the costs of implementation and performance monitoring.

NATURAL HISTORY AND EPIDEMIOLOGY

Dr. Bernard Levin, professor emeritus of the M.D. Anderson Cancer Center and chair of the American Cancer Society's (ACS's) National Advisory Task Force on Colorectal Cancer, and Dr. Michael Pignone, associate professor of medicine and chief of the Division of General Internal Medicine at the University of North Carolina at Chapel Hill, presented the natural history and epidemiology of colorectal cancer. Dr. Levin revealed the latest trends in colorectal cancer incidence, mortality, and screening, and he discussed the natural history of the cancer and how screening can affect it. Dr. Pignone mainly focused on factors that influence the implementation of colorectal cancer screening.

Dr. Levin reported that colorectal cancer is the third most common cause of cancer in men and women, and the second leading cause of cancer death in the United States (ACS, 2007a). African Americans have higher incidence and death rates, as can be seen in Figure 2, and are more likely to develop colon cancer at an earlier age than white people (NCI, 2007). Remarkably, Japan, which previously had a low incidence of the cancer, is now the country with the highest incidence in men (Parkin et al., 2005), and Japanese who have emigrated to Hawaii have the highest incidence in the world (Sakamoto et al., 2006), Dr. Levin noted. This probably reflects, at least in part, the environmental influences on the development of colorectal cancer. The incidence in China and Hong Kong is also increasing rapidly, perhaps due to the adoption of a Western lifestyle and diet (Hospital Authority, 2008; Sung et al., 2005; Vainio and Miller, 2003). Environmental factors linked to colorectal cancer include obesity, physi-

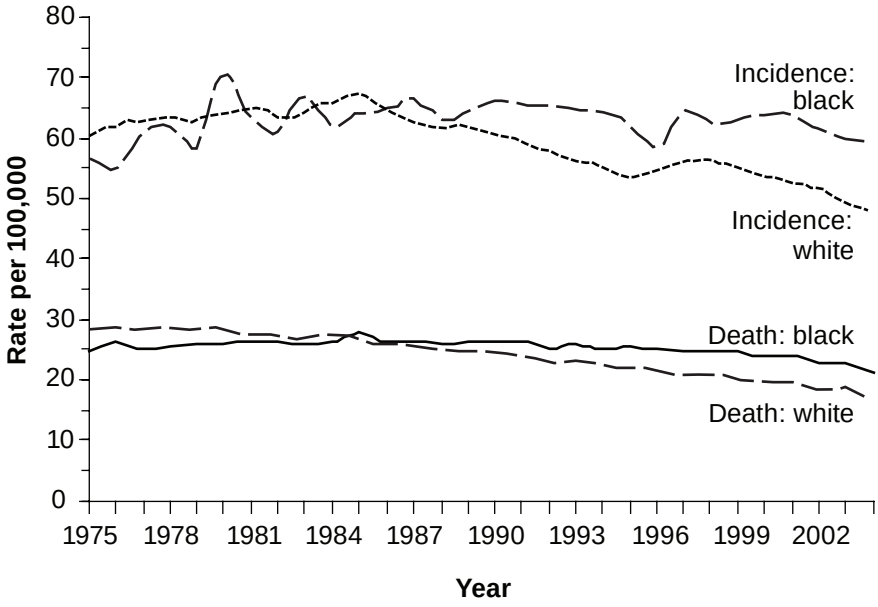

FIGURE 2 U.S. incidence and death rates by race from invasive colon and rectal cancers from 1975 to 2004. Rates are per 100,000 and are age-adjusted to the 2000 U.S. standard population. SOURCES: Levin/Pignone presentation (February 25, 2008) and *SEER Cancer Statistics Review, 1975–2004* (NCI, 2007).

cal inactivity, intake of red and processed meat, tobacco use, and heavy alcohol intake, Dr. Levin pointed out (Koushik et al., 2007; Wolin et al., 2007).

In contrast to what is being seen in Asian countries, colorectal cancer incidence and mortality are declining in many Western nations. In the United States between 1973 and 1995, incidence declined by 7 percent and continued to decline between 1995 and 2003, while mortality declined by 20 percent (NCI, 2004) between 1985 and 2002 and even more steeply from 2002 to 2004, Dr. Levin reported (NCI, 2007). He attributed this decline to increased screening, detection, and removal of adenomas. As he noted, it is now well known that colorectal cancers begin as adenomas that may progress to invasive cancer over 5 to 15 years (Rozen et al., 2002). This slow progression enables physicians to identify and remove adenomas before they progress to invasive cancers. Colorectal adenomas are found in up to 40 percent of people by age 60, he indicated in the background paper he and Dr. Pignone provided (Appendix C; Eide, 1986; Kim and Lance, 1997; Peipins and Sandler, 1994). Although hereditary factors can heighten the risk of developing colorectal cancer, about 70 percent of

these cancers arise sporadically (Pignone et al., 2002). Consequently, colon cancer screening strategies cannot be directed solely to high-risk patients, Dr. Levin said.

Colorectal cancer screening not only enables the detection and removal of adenomas before they progress to invasive cancers, but also fosters the detection of colorectal cancer at an earlier stage when it is more curable. Survival rates at 5 years are more than 80 percent for patients diagnosed with local disease, and higher than 60 percent for regional disease (Appendix C; NCI, 2004). Encouragingly, comparing data collected between 1975 and 1979 with data collected between 1998 and 2003, reveal that people are being diagnosed at an earlier stage, with an increasing fraction of them being diagnosed with localized disease (Table 1; NCI, 2004). Data from the most recent *Cancer Statistics Review*, produced by the Surveillance Epidemiology and End Results (SEER) group of the National Cancer Institute (NCI), indicated that 40 percent of colorectal cancers in this country are localized when diagnosed, about 37 percent have spread regionally, and 19 percent have metastasized to distant sites, Dr. Levin reported (NCI, 2004).[4] Dr. Pignone noted that the improvement in the stage of diagnosis might be attributable to the heightened amount of screening that has occurred recently, as two national studies reveal (CDC, 2008; Meissner et al., 2006). One study conducted by the CDC found that in 2007, more than 60 percent of age-eligible adults reported being up to date with screening, which compares with only 40 percent in 1997 (CDC, 2006). The recent increases in screening rates are due predominantly to increasing use of colonoscopy (Meissner et al., 2006).

Dr. Pignone also reported what factors appear to increase a person's likelihood to undergo colorectal cancer screening. These factors include being between 65 and 85 years of age, having a higher educational achievement or income, belonging to a health maintenance organization (HMO), having a belief that cancer is preventable, and lacking a strong fear of cancer. Receiving a physician recommendation for screening has

[4]The TNM classification system is used to stage colorectal cancer (ACS, 2008; NCI, 2008). T refers to the characteristics of the primary tumor, N refers to the involvement of regional lymph nodes, and M refers to the extent of metastasis, if any. The TNM stages are then grouped into familiar numbered stages, 0–4. Stage 0 refers to highly localized cancers that have not grown beyond the inner layers of the colon or rectum. Stage 1 refers to cancers that have penetrated the inner layers of the colon or rectum, but not to the outer layers. Stage 2 refers to cancers that have penetrated all layers of the colon or rectum, may or may not have reached adjacent tissues, but have not reached lymph nodes or distant sites. Stage 3 refers to cancers that have spread to one or a few nearby lymph nodes, and they may or may not have spread to nearby organs. Stage 4 refers to cancers that have spread to distant sites. For more information, see http://www.cancer.org/docroot/CRI/content/CRI_2_4_3X_How_is_colon_and_rectum_cancer_staged.asp or http://www.cancer.gov/cancertopics/pdq/treatment/colon/HealthProfessional/page4.

TABLE 1 Stage at Diagnosis Improving Over Time

	1975–1979			1985–1989			1996–2003		
	All	White	Black	All	White	Black	All	White	Black
Percent localized	33%	33%	30%	38%	38%	33%	40%	40%	35%
Percent regional	37%	37%	35%	37%	37%	36%	37%	37%	35%
Percent distant	22%	22%	26%	19%	19%	24%	19%	18%	24%
Percent unstaged	8%	8%	9%	6%	6%	7%	4%	4%	6%

SOURCE: Levin presentation (February 25, 2008).

been one of the strongest factors linked to screening that has been identified across studies, Dr. Pignone observed. Access variables, such as having a usual source of care, and the number of physician visits have been consistently linked to higher screening rates (Meissner et al., 2006). Dr. Pignone stressed that there is nearly a 30 percentage point difference in colorectal cancer screening rates between those who are insured and those who lack insurance, recent data show (Meissner et al., 2006). "I want to highlight that colorectal cancer screening is becoming a health disparity and an access issue, and our efforts need to be thought of in that context," Dr. Pignone said. He summarized both his and Dr. Levin's presentation by noting that although screening is an effective means of reducing colorectal cancer incidence and mortality, it is underused. "Things are getting better, but we are still not doing quite as well as we would like," he said.

Following Dr. Pignone's presentation, a discussion focused on the disparities between black and white people in the incidence and mortality statistics that Dr. Levin presented. Due to its complexity, Dr. Levin was not willing to ascribe the differences to one specific factor, but noted several factors that may contribute to those differences in incidence and outcome. These factors include access to treatment and obesity, he said. Dr. Patricia Ganz of the University of California, Los Angeles, Schools of Medicine and Public Health asked whether any studies had been conducted to examine the lower incidence of colorectal cancer among black Africans; she noted that comparisons between black Africans and black North Americans or Europeans could provide valuable information.[5] Dr. Levin responded that he was unaware of any such studies, but that there was some evidence of an increasing prevalence of adenomas in Southern Africa (Angelo and Dreyer, 2001; Walker and Segal, 2002). Dr. Edward Benz of Harvard Medical School suggested that lower levels of vitamin D circulating metabolites in several of these groups may explain the increased incidence of colorectal cancer, which, several studies suggest, protect people from developing various cancers. Although Dr. Levin said he has seen data to support the notion that black North Americans have lower levels of Vitamin D circulating metabolites, he was not aware of convincing data that this was causally related to the increased incidence of colon cancer they experience compared to white people. Dr. Robert Fletcher of Harvard Medical School and the University of North Carolina at Chapel Hill School of Medicine added that environmental risk factors, such as smoking, diet, or obesity, may not individually account for the differences seen between black and white people. However, collectively the risk factors might explain much of the disparity in the colorectal cancer incidence statistics seen between these two populations.

[5]For example, see O'Keefe et al. (2007).

Referring to Dr. Levin's report that black people tend to develop colorectal cancer at an earlier age than white people, Dr. Ann Zauber of the Memorial Sloan-Kettering Cancer Center mentioned a microsimulation model she used that showed screening black people at age 45 rather than 50 would generate a 15 to 20 percent increase in life-years saved, assuming it did not decrease current adherence to screening. Dr. Coates pointed out that, in addition to racial variations in incidence, "it is also important to keep in mind that if we plotted variations in incidence by age for any risk factor, those groups at higher risk, that is those who are physically inactive or overweight or have a poor diet, would have higher incidence at an earlier age. So any potential recommendation for screening one group early could also apply to those who are physically inactive, overweight, have a poor diet, etc."

EFFECTIVENESS OF COLORECTAL CANCER SCREENING

The next presenter, Dr. Evelyn Whitlock, senior investigator at The Center for Health Research at Kaiser Permanente Northwest and associate director of the Oregon Evidence-based Practice Center (OEPC), summarized the findings from the 2007–2008 updated evidence synthesis on colorectal cancer screening that the OEPC did for the USPSTF. The synthesis is the basis for the USPSTF's updated recommendations on colon cancer screening (Whitlock et al., 2008).[6] She began her talk by noting that in 2002, based on the evidence review done at that time, the USPSTF strongly recommended that clinicians screen men and women 50 years of age or older for colorectal cancer, but gave no preference for the type of screening done—whether it was home FOBT, flexible sigmoidoscopy, colonoscopy, double-contrast barium enema, or some combination of these options. The updated review Dr. Whitlock and her colleagues conducted focused on assessing the following factors:

- Mortality impact of colorectal cancer screening;
- Effectiveness of optical colonoscopy and flexible sigmoidoscopy in community practice;
- Efficacy of newer screening technologies such as high-sensitivity FOBTs (Hemoccult SENSA), fecal immunochemical tests (FITs), fecal DNA, and computed tomography (CT) colonography; and
- Harms of screening tests.

For this review, the OEPC researchers combed the literature for studies of the use of the various colorectal cancer screening technologies on people

[6]See also http://www.ahrq.gov/clinic/uspstfix.htm.

aged 40 and older who had average risk for developing the cancer. The OEPC review focused on evidence that was not available at the time of the 2002 recommendation and evidence that might justify changes to the 2002 recommendation.

One review published after 2002 found that biennial FOBT was linked to a 15 percent reduction in colorectal cancer mortality in four randomized controlled trials (Kerr et al., 2007), but there was no additional evidence since the previous recommendation on the effects of other fecal screening tests, flexible sigmoidoscopy, optical colonoscopy, or CT colonography on mortality, Dr. Whitlock reported.

The OEPC researchers used three studies to assess the effectiveness of optical colonoscopy in community practice (Johnson et al., 2007; Kim et al., 2007; Pickhardt et al., 2003). But estimates from these studies were hampered, to some degree, by the small number of colorectal cancers that occurred during the study interval. Although one study showed only 50 percent sensitivity in detecting colon cancer, only two colon cancers in total occurred in the study population (Pickhardt et al., 2003). No colon cancers occurred in the second study (Kim et al., 2007), while in the third study (Johnson et al., 2007), 20 percent of colon cancers were detected. Sensitivity for detecting adenomas 10 mm or larger ranged from 88 to 100 percent. Only one study documented its sensitivity for detecting adenomas 6 mm or larger (Pickhardt et al., 2003). This sensitivity was 92 percent. Another meta-analysis found miss rates in tandem colonoscopy in non-screening populations to be only 2 percent for larger lesions, and 13 percent for lesions 5 to 10 mm (van Rijn et al., 2006).

The OEPC researchers used four studies, including an American College of Radiology Imaging Network (ACRIN) study (Johnson, 2007), whose results are not yet published, to assess the efficacy of CT colonography in comparison to optical colonoscopy (Johnson, 2007; Johnson et al., 2007; Kim et al., 2007; Pickhardt et al., 2003). They found that the sensitivities of the two tests were comparable, although CT colonography appeared to be less sensitive at detecting adenomas 6 mm or greater. The specificity was either lacking or ranged substantially in the studies reviewed, which made comparisons difficult, Dr. Whitlock noted. "In general, although not completely true, the specificity of CT colonography worsens as the lesions are smaller," she said. Her group used three studies to estimate that between 1 in 10 and 1 in 13 patients who received CT colonography would subsequently receive optical colonoscopy if the threshold for referral was presence of a 10-mm or larger lesion. With a lower threshold of 6 mm or greater, between one in three and one in five persons would need to have optical colonoscopy.

The OEPC researchers assessed the efficacy of newer fecal tests, such as high-sensitivity FOBTs, FITs, and fecal DNA tests, by comparing them

to optical colonoscopy or to registries allowing estimation of colorectal cancer. The efficacy for these tests is shown in Tables 2 and 3. Both the Hemoccult SENSA FOBT (Beckman Coulter, Fullerton, CA[7]) and the PreGen Plus fecal DNA test (EXACT Sciences, Marlborough, MA[8]) showed improved sensitivity in comparison to the Hemoccult II FOBT (Beckman Coulter, Fullerton, CA). But there is a sizable difference in the Hemoccult II sensitivities reported between the two studies used in the comparison, Dr. Whitlock noted. The OEPC researchers determined the comparative efficacy of several types of fecal immunochemical tests and reported a wide range of sensitivities, which reflects the wide variety of technologies that underlie these tests, Dr. Whitlock pointed out. The sensitivities of these newer tests were generally better than that for Hemoccult II and the specificities were generally slightly lower (Table 3). Dr. Whitlock noted that "there are some disconnects between test performance and whether tests are FDA approved and available in the U.S. market. The better studied MagStream FIT [Fujirebio, Tokyo, Japan[9]], for example, which has some of the best test performance characteristics, is not currently FDA approved nor in the U.S. market" (B. Levin et al., 2008).

As for the harms of colonoscopy and CT colonography, the OEPC researchers did a meta-analysis of 12 studies and found 28 serious complications per 10,000 colonoscopy procedures, including perforations and major bleeding. Most of the serious harms appeared to stem from polypectomies, she pointed out. Procedure-related harms for CT colonography were absent in three of four studies, whereas another study suggested there are a few perforations, but most of them tend to occur in symptomatic patients. Radiation-related harms from CT colonography have been estimated to be one person per 1,000 for developing leukemia or a solid cancer of the abdomen from an excessive exposure to 10 mSv (Jensch et al., 2006). But the exposure range for this procedure is from 1.6 to 24.4 mSv, depending on the kind of technology used, she noted, so this estimate could vary by a factor of two or three. Newer technologies may decrease the dose of radiation needed, she added. Another potential effect of CT colonography that the researchers did not know whether to classify as a harm or benefit is the detection of extra-colonic findings. They determined that, from the limited data available, between 7 percent and 16 percent of those undergoing CT colonography were recommended to have additional diagnostic evaluation for extra-colonic findings. No harms were found to be linked to the use of fecal tests.

Dr. Whitlock concluded her presentation by noting that certain FITs

[7]See http://www.beckmancoulter.com/products/rapidtestkits/hemoccultsensa.asp.
[8]See http://005d4d1.netsolhost.com/applied/index.html.
[9]See http://www.fujirebio.co.jp/english/product/immunological.html.

TABLE 2 Efficacy of High-Sensitivity FOBT and Fecal DNA

	Two Cohort Studies for High-Sensitivity FOBT		One Cohort Study (Subgroup) for Fecal DNA Test	
	Hemoccult SENSA	Hemoccult II (Reference)	PreGen Plus	Hemoccult II (Reference)
N	13,945		2,507	
Sensitivity for CRC	64.3[a]–79.4%	37.1%	51.6%	12.9%
Specificity for CRC	86.7–90.1[a]%	97.7%	92.4[b]%	95.2[b]%
Test positives	10.1[a]–13.6%	2.5%	8.2%	5.8%

NOTES: CRC = colorectal cancer, FOBT = fecal occult blood test, Hemoccult II = Hemoccult II FOBT from Beckman Coulter (Fullerton, CA; see http://www.hemoccultfobt.com/), Hemoccult SENSA = Hemoccult SENSA FOBT from Beckman Coulter (Fullerton, CA; see http://www.beckmancoulter.com/products/rapidtestkits/hemoccultsensa.asp).

[a]Left-sided lesions only.

[b]Specificity for minor polyps.

SOURCES: Whitlock presentation (February 25, 2008) and Allison et al. (1996, 2007); Imperiale et al. (2004).

TABLE 3 Efficacy for Fecal Immunochemical Tests

	Hemoccult II (Reference)	MagStream (Quantitative)	FlexSure	MonoHaem	OC–Hemodia
N	26,335	37,330	5,841	7,976	35,351
Sensitivity for CRC	25–38%	61–85%	82%[a]	56–91%	67–88%
Specificity for CRC	98%	94–98%	97%	94–97%	83–95%
Test positives	2%	2–6%	3.2%	4.7%	5–9%
FDA approved	Yes	No	Yes	Yes	No
U.S. market	Yes	No	Yes	No	No

NOTES: CRC = colorectal cancer, FlexSure = FlexSure fecal immunochemical test, now sold as Hemoccult ICT (Beckman Coulter, Fullerton, CA; see http://www.beckman.com/products/RapidTestKits/hemoccult_ict.asp; Allison et al., 2007), Hemoccult II = Hemoccult II FOBT from Beckman Coulter (Fullerton, CA; see http://www.hemoccultfobt.com/), MagStream = MagStream fecal immunochemical test (Fujirebio, Tokyo, Japan; see http://www.fujirebio.co.jp/english/product/immunological.html), MonoHaem = MonoHaem fecal immunochemical test from Millipore (Billerica, MA; see http://www.millipore.com/catalogue/item/991040995), OC–Hemodia = OC–Hemodia fecal immunochemical test from Eiken (Tokyo, Japan; see http://www.eiken.co.jp/en/product/index.html).

[a]Left-sided lesions only.

SOURCES: Whitlock presentation (February 25, 2008) and Soares-Weiser et al. (2007).

may substitute for standard FOBTs in a screening program to improve sensitivity without losing specificity. But many of these tests have tradeoffs between sensitivity and specificity, she added. She also noted that CT colonography may be ready for population screening if publications of the ACRIN data conform to data presented at meetings (Johnson, 2007), if there is consensus that only lesions 10 mm or greater require detection and referral for optical colonoscopy, and if the unknowns about harms and community performance are judged to have minimal impact. Her final conclusion was that "optical colonoscopy is not a perfect test, which confirms what others have found previously." She added that she did not discuss flexible sigmoidoscopy because the best evidence on this is about to be revealed from four randomized controlled studies.

In the discussion following Dr. Whitlock's presentation, Dr. David Lieberman of Oregon Health and Science University pointed out that the stool testing studies the OEPC analyzed were for single-test performance, but the implementation of fecal testing programs involve viewing it programmatically, not as a one-time test. "One-time testing is a very misleading way to look at it," he said, "because the performance of that one-time test may not reflect how many patients actually get colonoscopies for positive tests. It may not reflect how many patients come back for repeat testing, as is recommended by the USPSTF."

Dr. Fletcher raised the highly debated issue of whether smaller adenomas are considered worth detecting and/or removing. Dr. Pignone responded that the Pickhardt research group showed via modeling that there would be a very poor or high cost per life-year gained for lesions less than 5 mm, a very good one for the 10-mm and larger polyps, and an intermediate one for mid-sized polyps within the range of $50,000 to $75,000 per life-year gained (Pickhardt et al., 2002).

SCREENING STRATEGIES

The most efficient strategies for colorectal cancer screening were explored by the next speaker, Dr. Ann Zauber, associate attending biostatistician in the Department of Epidemiology and Biostatistics at Memorial Sloan-Kettering Cancer Center. Dr. Zauber reported on an analysis she and her colleagues did for the USPSTF as part of the Cancer Intervention and Surveillance Modeling Network (CISNET), which is supported by the National Cancer Institute (Zauber et al., 2008).[10] CISNET does population-

[10]See also a report using the same methodology on the Centers for Medicare and Medicaid Services (CMS) website (Zauber et al., 2007); a paper using the microsimulation model to project future trends of colorectal cancer mortality considering different intervention strategies (Vogelaar et al., 2006); and an NCI-sponsored website on colorectal can-

based microsimulation modeling to aid health policy decisions. The aim of the CISNET analysis Dr. Zauber reported on was to assess the best age to begin and end colorectal cancer screening with the various tests available, and how frequently that screening should be done. The CISNET study did not have a cost analysis as part of its purview. This analysis will be used by the USPSTF to decide whether to change its current recommendations on screening, which are that colorectal cancer screening should begin at age 50, and that the screening interval should be every year for stool FOBT, every 5 years for flexible sigmoidoscopy, and every 10 years for colonoscopy. Current recommendations do not give an age when screening may be discontinued.

The CISNET analysis was for the general population and not specific for sex or race. This analysis assumed the average time from when an adenoma first develops and until colorectal cancer is first clinically detected is 10 years or 22 years, depending on which of two models is used. The analysis also assumed 100 percent adherence to the screening regimens, although it did assess the effectiveness of screening at various suboptimal levels of adherence. The analysis also made assumptions about the sensitivity and specificity of the various tests, which can be seen in Table 4.

The researchers considered screening strategies to be most effective if they gave the greatest life-years gained relative to no screening. But the researchers also weighed the effectiveness against the resources required, and exposure to procedure risks, such as perforation. Resources required for this analysis were determined by the total number of colonoscopies required for a given screening strategy. They evaluated 145 screening strategies to see which came closest to the efficiency frontier, which is the point at which the most life-years are gained for the least amount of resources used to achieve those gains. "If a strategy requires more colonoscopies with fewer life-years gained, it is less effective than another strategy," Dr. Zauber explained.

The CISNET analysis found that the current recommended guidelines are at or near the efficiency frontier. Beginning screening at age 50 balances the life-years and the number of colonoscopies required and associated risk of perforation. Starting at an earlier age did not give much additional benefit. However, the analysis found that the efficiency of current guidelines could be increased by stopping screening after age 75. With this scenario, a person would have three colonoscopies at ages 50, 60, and 70, assuming that no findings from those colonoscopies suggested more frequent screening. Additional colonoscopies after age 75—that is, more than three colonoscopies after beginning screening at age 50

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cer mortality projections based on modeling different strategies (see http://cisnet.cancer.gov/projections/colorectal).

TABLE 4 Test Characteristics Base Case Assumptions Used for the Simulations

Test Characteristics	Hemoccult II	Hemoccult SENSA	FIT	Sigmoidoscopy[a]	Colonoscopy
Specificity	98%	92.5%	95%	100%	100%
Sensitivity				Sensitivity within reach:	
Adenomas ≤0.5 mm	2%	7.5%	5%	75%	75%
0.6 mm–0.9 mm	5%	12%	10%	85%	85%
≥1.0	12%	24%	22%	95%	95%
Cancers	40%	70%	70%	95%	95%
Reach	Whole colorectum	Whole colorectum	Whole colorectum	80% reach the sigmoid–descending colon junction[b]	95% reach cecum

[a]The assumed sensitivity for colorectal cancer screening by sigmoidoscopy for the whole colon was comparable to the evidence review.

[b]It was assumed that 80 percent of the flexible sigmoidoscopies would reach the junction of the sigmoid and descending colon and that 40 percent of the flexible sigmoidoscopies would reach to the beginning of the splenic flexure.

SOURCE: Zauber presentation (February 25, 2008).

with 10-year intervals—did not give much benefit. Equally efficient is a strategy whereby patients have an annual high-sensitivity FOBT or FIT between the ages of 50 and 75, or flexible sigmoidoscopies every 5 years and FOBT every 3 years. As for colonoscopy, after age 75, there is not much additional benefit in such screening, the researchers found. Their analysis also showed that screening for cancer using only flexible sigmoidoscopies every 5 years or only conducting annual FOBT with the less sensitive guaiac test did not lead to as many life-years saved as the other screening measures.

In addition, it is important to note that the effectiveness of the stool test screening depended on 100 percent compliance, which is difficult to achieve. "The best test is the one that gets done," Dr. Zauber pointed out and provided a table and figures that showed how adherence affected the life-years gained for each type of intervention and two different models (Table 5 and Figures 3 and 4). Colonoscopy every 10 years was more advantageous than other screening measures when adherence was 80 percent, but lost its lead on health benefit advantage when colonoscopy adherence was as low as 50 percent compared to other strategies. In general, the life-years gained with colonoscopies declined with decreased adherence, but the researchers' overall conclusions about screening ages and frequency and the screening tests did not change substantially because adherence varied from 100 to 50 percent.

In the discussion following Dr. Zauber's presentation, Dr. Ganz and Dr. Laura Seeff from the CDC's Division of Cancer Prevention and Control suggested ways that maximum benefit to society could be reaped given the reality of less-than-optimal adherence. Dr. Ganz explored the benefit of concentrating effort on ensuring that all new Medicare participants—typically at age 65—will have had at least one colonoscopy. "Maybe as a society," she said, "if we could at least get people to do the first colonoscopy, the burden to society both in terms of incidence of colon cancer and mortality would be greatly reduced, and the additional gains obviously would be very important." Dr. Ganz then suggested modeling to look at which fraction of the population benefits most from the subsequent colonoscopies, to see whether genetic predisposition to adenomas could be determined, effectively simplifying colorectal cancer screening to one-time colonoscopy. Dr. Seeff added that taking the focus off age may be a better strategy when crafting the message to the public, instead making the message, "after three negatives you can stop screening." Dr. Seeff noted that a similar strategy has been successful for cervical cancer screening (USPSTF, 2003).

EFFECTIVENESS OF COMMUNITY- AND OFFICE-BASED INTERVENTIONS

The next speaker was Dr. Shawna Mercer, director of the *Guide to Community Preventive Services* at the National Center for Health Marketing at the CDC. The *Community Guide* provides systematic reviews of the available evidence on community-based preventive health services (TFCPS, 2008a). The TFCPS, a team of renowned researchers, public health practitioners, and representatives of health organizations, conducts the reviews and compiles them into recommendations for policy and practice. To motivate future research, the *Community Guide* also describes areas that lack sufficient evidence. When conducting their reviews, the TFCPS considers both qualitative and quantitative data. "This is extremely important because of the range of study designs and the guidance to look at, and also the fact that randomized controlled trials are often not possible when you are looking, for example, at the effect of a law," Dr. Mercer said.

Unlike the *Guide to Clinical Preventive Services* produced by USPSTF (1996, 2007), which examines interventions at an individual level in clinical settings, the *Community Guide* examines interventions at a group level: community- and population-based interventions, as well as interventions that can support physicians' efforts to effectively treat their patients, such as insurance benefit coverage changes and assisting with access to services. The *Community Guide* tends to focus on behavioral and social types of interventions, as well as environmental and policy changes, including laws, and is used by TFCPS to make recommendations. Once those recommendations are made, the *Community Guide* supports translation of those recommendations into action.

Recently, the TFCPS examined which population-based and health system interventions are effective in increasing colorectal, breast, and cervical cancer screening. Their analysis was based on the reviews of 244 studies that passed their screening and inclusion criteria. These included four studies of sufficient quality on the use of patient reminders for FOBT (Hogg et al., 1998; Myers et al., 1991; Thompson et al., 1986; Vinker et al., 2002). Screening completion was ascertained by either self-report, record review, or returned FOBT kits. All studies reported improvements in screening due to the interventions. The median postintervention increase of FOBT completion was 11.5 percentage points. These studies did not separate the findings by race, socioeconomic class, or other factors, so it was difficult for the reviewers to assess the applicability of the findings across various populations. But, as Dr. Mercer pointed out, a study of client reminders for breast and cervical cancer screening "did suggest there is broad applicability of these data." There were no qualifying studies on the use of patient reminders to boost adherence to other colorectal cancer screening tests or procedures.

TABLE 5 Strategies Varied by Overall Adherence to Screening

	50% Adherence		80% Adherence		100% Adherence	
Strategy	Number of Colonoscopies (per 1,000)	Number of Life-Years Gained (per 1,000)	Number of Colonoscopies (per 1,000)	Number of Life-Years Gained (per 1,000)	Number of Colonoscopies (per 1,000)	Number of Life-Years Gained (per 1,000)
MISCAN Model						
Colonoscopy Ages 50–75, 10-year interval	2,250	140	3,193	184	4,136	230
FOBT—Hemoccult SENSA Ages 50–75, 1-year interval	1,752	149	2,427	177	3,350	230
Fecal immunochemical test Ages 50–75, 1-year interval	1,510	145	2,116	173	2,949	227
FOBT—Hemoccult II Ages 50–75, 1-year interval	962	113	1,395	145	1,982	194
Flexible sigmoidoscopy Ages 50–75, 5-year interval	1,150	128	1,373	155	1,911	203
Flexible sigmoidoscopy plus FOBT—Hemoccult SENSA Ages 50–75, 5-year flexible sigmoidoscopy, 3-year FOBT interval	1,553	147	2,063	178	2,870	230

Sim-CRC Model						
Colonoscopy Ages 50–75, 10-year interval	1,977	168	2,904	227	3,756	271
FOBT—Hemoccult SENSA Ages 50–75, 1-year interval	1,361	182	1,920	217	2,654	259
Fecal immunochemical test Ages 50–75, 1-year interval	1,140	177	1,629	213	2,295	256
FOBT—Hemoccult II Ages 50–75, 1-year interval	666	130	993	172	1,456	218
Flexible sigmoidoscopy Ages 50–75, 5-year interval	544	122	711	158	995	199
Flexible sigmoidoscopy plus FOBT—Hemoccult SENSA Ages 50–75, 5-year flexible sigmoidoscopy, 3-year FOBT interval	770	168	1,153	210	1,655	257

NOTE: FIT = fecal immunochemical test, FOBT = fecal occult blood test, Hemoccult II = Hemoccult II FOBT test from Beckman Coulter (Fullerton, CA; see http://www.hemoccultfobt.com/), MISCAN = a microsimulation model designed to evaluate colorectal cancer screening, SENSA = Hemoccult SENSA FOBT test from Beckman Coulter (Fullerton, CA; see http://www.beckmancoulter.com/products/rapidtestkits/hemoccultsensa.asp), Sim-CRC = a microsimulation model designed to evaluate colorectal cancer screening.

SOURCE: Zauber presentation (February 25, 2008).

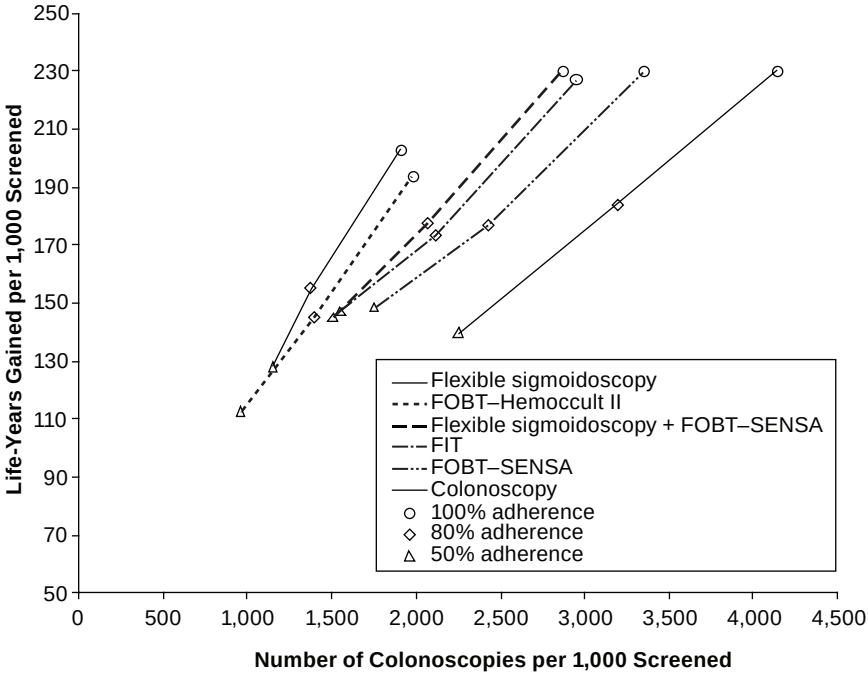

FIGURE 3 MISCAN adherence plot. Data resulting from modeling six screening methods are shown; the models looked at screening between the ages of 50 and 75. For colonoscopy, the test frequency used for modeling was 10 years; for flexible sigmoidoscopy, it was 5 years; and for FOBT tests, it was annual. For flexible sigmoidoscopy combined with FOBT, the frequency was 5 years for the flexible sigmoidoscopy and 3 years for the FOBT. NOTE: FIT = fecal immunochemical test, FOBT = fecal occult blood test, Hemoccult II = Hemoccult II FOBT test from Beckman Coulter (Fullerton, CA; see http://www.hemoccultfobt.com/), MISCAN = a microsimulation model designed to evaluate colorectal cancer screening, SENSA = Hemoccult SENSA FOBT test from Beckman Coulter (Fullerton, CA; see http://www.beckmancoulter.com/products/rapidtestkits/hemoccultsensa.asp). SOURCE: Zauber presentation (February 25, 2008).

The TFCPS review team evaluated whether small media, such as videos, brochures, letters, flyers, or newsletters sent from health care or community settings, boosted community demand for FOBT, based on the results of six studies (Dickey and Petitti, 1992; Hart et al., 1997; Kramish Campbell et al., 2004; Lee, 1991; Powe, 2002; Pye et al., 1988). No studies assessed the use of small media for other colorectal cancer screening techniques. Most studies showed favorable results for this intervention, with the median increase in FOBT use of 12.7 percentage points. Most of

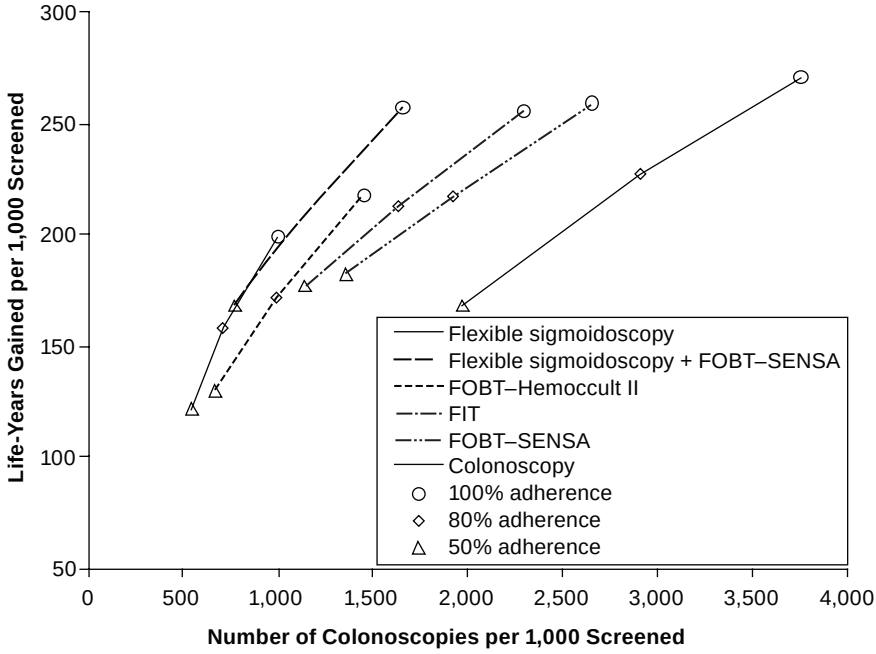

FIGURE 4 Sim-CRC adherence plot. Data resulting from modeling six screening methods are shown; the models looked at screening between the ages of 50 and 75. For colonoscopy, the test frequency used for modeling was 10 years; for flexible sigmoidoscopy, it was 5 years; and for FOBT tests, it was annual. For flexible sigmoidoscopy combined with FOBT, the frequency was 5 years for the flexible sigmoidoscopy and 3 years for the FOBT. NOTE: FIT = fecal immunochemical test, FOBT = fecal occult blood test, Hemoccult II = Hemoccult II FOBT test from Beckman Coulter (Fullerton, CA; see http://www.hemoccultfobt.com/), SENSA = Hemoccult SENSA FOBT test from Beckman Coulter (Fullerton, CA; see http://www.beckmancoulter.com/products/rapidtestkits/hemoccultsensa.asp), Sim-CRC = a microsimulation model designed to evaluate colorectal cancer screening. SOURCE: Zauber presentation (February 25, 2008).

the populations in these studies were white and African American from both urban and rural settings as well as from both clinical and community settings, suggesting broad applicability of the findings.

The TFCPS review team assessed whether various measures aimed at reducing structural barriers to community access to colorectal cancer screening interventions were effective, based on seven studies (Church et al., 2004; Freedman and Mitchell, 1994; King et al., 1992; Mant et al., 1992; M. F. Miller and Wong, 1993; Ore et al., 2001; Plaskon and Fadden, 1995).

These measures included reducing the time or distance to the delivery setting, adjusting hours of service, offering screening in alternative or nonclinical settings such as mobile vans, simplifying administrative procedures, and providing help with translation or scheduling. All the studies showed these measures were effective, with a median increase in FOBT use of 16.1 percentage points. Efforts to reduce structural barriers were more effective if they were also accompanied by an invitation to attend a clinic, a return mailer with prepaid postage, or a follow-up telephone reminder.

The last community-based intervention the review team assessed was the use of provider reminders, which are meant to inform or remind providers or other health care professionals that individual patients are either due or overdue for screening. Reminders were in the form of notes attached to patient charts, memorandums, or letters. The six studies reviewed were on provider reminders given for FOBT and/or flexible sigmoidoscopy and showed a median increase in use of 17.6 percentage points (Becker et al., 1989; McPhee et al., 1989; Tierney et al., 1986; Vinker et al., 2002; Williams et al., 1998). A wide range of populations and settings were included in these studies so the reviewers assumed their findings had broad applicability.

Based on the evidence the *Community Guide* provided, the Task Force on Community Preventive Services (TFCPS) recommended:

- Patient reminders for increasing fecal occult blood testing;
- Small media campaigns directed at patients to increase their use of FOBT;
- Interventions to reduce structural access barriers; and
- Provider reminders on cancer screening measures.

See Table 6 for a summary of the review team's conclusions (TFCPS, 2008b).

Dr. Mercer also pointed out that she and her colleagues did not find multicomponent interventions to be more effective than individual-component interventions when they reviewed the literature. However, within studies, they generally found incremental effectiveness when at least one TFCPS-recommended intervention was included along with at least one other effective component. Next, they plan to assess whether "you are better off doing one or two things well, rather than trying to do a bunch of things at once," she said.

Following Dr. Mercer's presentation, there was a discussion on whether adherence to repeat screening was assessed in the studies reviewed. "That was one of the most discouraging things—we found very little data on repeats—and this was one of our very strong recommendations for future research. In all of these areas, people should identify adherence ver-

TABLE 6 Evidence of Effectiveness for Cancer Screening Interventions

	Breast	Cervical	Colorectal
Community Demand			
Client reminder	Strong	Strong	Sufficient
Client incentive	Insufficient[a]	Insufficient[a]	Insufficient[a]
Mass media	Insufficient[a]	Insufficient[b]	Insufficient[a]
Small media	Strong	Strong	Strong
Group education	Insufficient[c]	Insufficient[b]	Insufficient[c]
One-on-one education	Strong	Strong	Insufficient[b]
Community Access			
Reduce structural barrier	Strong	Insufficient[b]	Strong
Reduce out-of-pocket expense	Sufficient	Insufficient[b]	Insufficient[a]
Provider Role			
Provider reminder	Strong		
Provider assessment and feedback	Sufficient		
Provider incentive	Insufficient[b]		

Reason for conclusion of insufficient evidence:
[a]No studies.
[b]Too few studies.
[c]Inconsistent findings.
SOURCE: Mercer presentation (February 25, 2008).

sus first screen," Dr. Mercer said. Dr. George Isham of HealthPartners added that in his health system in Minnesota, repeat testing adherence is assessed with a single metric—whether patients are up to date on their preventive services. In addition, it was noted that while assessment of adherence data from clinical trials is useful, Dr. Mercer emphasized that "we need to look beyond our clinical trials to community settings as well, where you do tend to see much lower rates of adherence."

A workshop participant pointed out that when Dr. Zauber's group modeled adherence to annual fecal testing, a higher fraction of the benefit was retained at a 50 percent adherence rate than for the longer interval tests. "So I don't think I need 10 FOBTs in the next 10 years to protect me fully," he said. "Fecal testing is basically directing people who need it into colonoscopy, so as long as you have achieved that within a reasonable period of time, you are still accruing almost all of the benefit." The

discussion concluded with Dr. Mercer noting, "It is very important that we think about the messages that we want to go out to people. We need to be very careful when we talk about intervals or incremental benefit. If we say to people, get screened once because that is the best thing you can ever do, we have to be careful about how we follow that. We have to be careful if we have to give a different message for FOBT every year versus colonoscopy every 5," she said.

OVERCOMING BARRIERS TO SCREENING

Dr. George Isham, chief health officer and plan medical director at HealthPartners, gave a presentation on health insurance barriers to colorectal cancer screening, as well as patient-, physician-, and employer-perceived barriers to such screening, as indicated by focus groups. He also provided suggestions for overcoming such barriers. Dr. Isham began his presentation by noting that a recent Government Accountability Office (GAO) report found that 20 states had laws in place as of May 2004 that required private insurance coverage of colorectal cancer tests for screening purposes (GAO, 2004). In addition, most, but not all, health plans reviewed by the GAO covered all four colorectal cancer screening tests (GAO, 2004). He added that a voluntary survey by the American Health Insurance Plans (AHIP) found in 2002 that nearly all the responding health plans covered one or more of the recommended screening tests and more than 90 percent covered all four types.

However, Dr. Isham said that over the past 5 years or so, to reduce the cost of health insurance, there has been a shift from first-dollar HMO coverage to high-deductible copayment plans, coinsurance coverage, and consumer-directed health plans, including health savings accounts (HSAs). A 2007 AHIP survey of health insurance plans that offer high-deductible policies in conjunction with HSAs found that only 83 percent offer first-dollar coverage for colonoscopies, if they offer first-dollar coverage for preventive care. "This is a really critical issue because as we have a decrease in first-dollar coverage [and] the introduction of copayments and large deductibles, then cost becomes a factor in terms of the willingness to get preventive services for those [who] have insurance," he said.

On a more encouraging note, a National Committee for Quality Assurance (NCQA) study reviewed claims data to determine whether screening was up to date on any of four tests: colonoscopy once every 10 years, flexible sigmoidoscopy once every 5 years, FOBT every year, or double contrast barium enema once every 5 years. It was found that colon cancer screening of the recommended population participating in commercial plans increased from 47.4 percent in 2003 to 54.5 percent in 2006 (NCQA, 2007). The same survey found that screening rates went from 49.5

TABLE 7 Colon Cancer Screening HEDIS® Rates Are Increasing in Health Plans

Year	Commercial	Medicare
2006	54.5	53.3
2005	52.3	53.9
2004	49.0	52.6
2003	47.4	49.5

SOURCES: Isham presentation (February 25, 2008) and NCQA (2007). HEDIS® is a registered trademark of the National Committee for Quality Assurance. Reprinted, with permissions, from *State of Health Care Quality, 2007*. © 2007 by the National Committee for Quality Assurance.

to 53.3 percent for those with Medicare (Table 7). "The standardization of measures and the encouragement of reporting by health plans has been a significant factor in health plans encouraging their networks to improve their colon cancer screening rates," Dr. Isham said. But he noted there is considerable variation in screening rates by location, with a 22 percent spread for commercial plans and a 27 percent spread for Medicare plans. He summarized insurance barriers by saying that colorectal coverage of cancer screening by insurance companies "is not a big barrier within those plans today, but I worry about the future. And it certainly is a barrier for those [who] don't have insurance at all."

Dr. Isham then shared the focus group findings of the Institute for Clinical Systems Improvement (ICSI) that related to colorectal cancer screening. This institute found that the main reasons patients gave for not complying with colorectal cancer screening included the discomfort and inconvenience of the colonoscopy bowel preparation, difficulty in scheduling, and ignorance about screening. Another deterrent for women was the negative things they heard from others about colonoscopies (Gendron, 1999).

These patients gave numerous suggestions for increasing colorectal cancer screening, including receiving emotional support during the screening, having access to the test when it is recommended, and receiving information and encouragement from a trusted physician. Training, experience, trustworthiness, and a good attitude from the person doing the test is critically important to patients. Some noted with irony that they get service reminders for their vehicles, but not preventive health service reminders (Gendron, 1999).

Another ICSI focus group examined patient-perceived barriers to primary prevention of chronic disease and how to overcome them. They

listed additional barriers, including lack of time, cost or lack of insurance coverage, their own lack of motivation to sustain a healthy lifestyle, and providers who do not focus on prevention of risk factors or educate them on steps toward prevention. These patients suggested schools provide preventive health care education to children, and that employers and insurers provide benefits that allow more education about and support of prevention efforts (Landin and Vinz, 2007).

The ICSI study also included a provider focus group. Physicians in this group listed a number of barriers to primary prevention of chronic disease, including a lack of time, inadequate reimbursement and payment to support preventive care, limited influence, and the recognition that health behaviors are a community issue. "In other words, doctors don't always feel it is their job to get in there and motivate their patients as far as healthy behaviors, or they feel powerless often with respect to that task," Dr. Isham said. Patient barriers recognized by the provider focus group included cost; lack of contact with the health care system; and lack of education, motivation, and time (Landin and Vinz, 2007).

The ICSI study also convened a focus group of employers on the topic of primary prevention of chronic disease. They found that although most employers believe they are responsible for the health of their employees and families and want to offer an environment that supports prevention of chronic disease, at best only half of employees use the preventive service benefits they provide. Many employers also noted that they are unsure of where to focus their attention and benefits, and most desired advice from the health care system regarding what they should include in their employee benefit contracts and initiatives (Landin and Vinz, 2007).

In response to this finding, Dr. Isham pointed out that the National Commission on Prevention Priorities examined the preventable burden and cost-effectiveness of the USPSTF recommendations and listed colorectal cancer screening as one of the most important to include as a benefit (Partnership for Prevention, 2007). But he added there is a great deal of confusion when numerous preventive health recommendations are published from many sources, some more reputable than others. "Well-meaning advocacy groups of all stripes are making recommendations and we are confusing the public," he said. "We ought to all try to get on the same page and send a consistent message."

Dr. Isham noted several ways that health plans show their commitment to increasing colorectal cancer screening by providing various incentives. In addition to providing coverage for screening, many health plans do outreach to members and communities with educational initiatives, health fairs, and public service campaigns on the importance of getting screened. Health plans may also send screening reminders to patients and physicians, including telephone reminders via an automated system.

To motivate physicians, many plans provide performance feedback and pay-for-performance initiatives, which include providing feedback on the rate of colorectal cancer screening by a physician compared to his or her peers or the health plan's average. Health plans may also use claims data to identify gaps in care for members in disadvantaged populations, who are less likely to get screening, including Hispanic/Latino members, African Americans, and those living in low-income areas. "Many of our large clinics and hospitals are now collecting those data and showing disparities in performance by race and ethnicity," Dr. Isham said. "So that is a big future opportunity for us, to collect and use the data to try to figure out how to encourage improvement." Some plans fund research on reducing colorectal cancer screening barriers, he added.

Dr. Isham dedicated the remainder of his talk to a series of suggestions on how to overcome some of the barriers that are impeding adherence to screening recommendations. In addition to extending insurance coverage of colorectal cancer screening to all patients, he suggested requiring all health insurance plans to eliminate copayments and coinsurance for covered preventive services. He also suggested requiring all health plans and providers to publicly report their screening rates for colorectal cancer screening because such transparency and accountability for results can improve rates.

Some of Dr. Isham's suggestions were directed at improving primary care physicians' ability to educate their patients on the importance of screening and provide reminders of such screening. This included redesigning payment systems to provide incentives for prevention/education efforts. "The way we pay is a problem, as money is moving toward procedures and away from cognitive and other thoughtful services for patients [who] need help," he said. Unit-based fee-for-service payment is also "a disaster with respect to how it fragments effort," he added. "It tears people apart in terms of focusing on things other than prevention. We need to find ways to not only pay people appropriately and fairly for what they do, but encourage them to do a lot of things they are not doing today, like reaching out and reminding patients to come in for screening and installing systems for education."

In addition to having recommendations based on good science, Dr. Isham suggested that the organizations making evidence-based recommendations craft a consistent message. He also suggested prioritizing preventive efforts for practitioners unsure of where to focus their efforts by estimating preventable burden and cost-effectiveness. Dr. Isham also stressed that well individuals need education and engagement *before* they are patients—in other words, before they are sick and in need of treatment. Standardized care processes supported by automated medical record systems can aid such preventive health care efforts. "We need to make sure

we are making standard use of nurses, nurse practitioners, and physicians, in terms of how they approach the patients, so that things aren't left out," Dr. Isham said. His final suggestion for improving colorectal cancer screening rates was to "listen very, very carefully to our patients. We need to do more focus groups with patients and find out what is getting in the way of their doing screening so we can then design interventions to address those barriers," he said.

During the discussion following Dr. Isham's talk, Dr. Ganz suggested that the annual patient checkup might be a way to address the need to reach out to patients before they become sick, and provide preventive health advice and screening. A study she conducted showed the number of encounters that individuals had with their primary care physician predicted whether they received colorectal cancer screening. Dr. Isham responded that such yearly visits might be beneficial in fostering patients' adherence to preventive health measures, but suggested more may be required, based on the experience of what was needed to foster immunizations in children. Immunization rates improved when physicians were required to make sure their patients were up to date with their immunizations every time they came in for a sick visit. "Offering the opportunity for prevention at every point of contact is absolutely critical to improving rates," he said. He agreed that having a good relationship with a primary care physician is a strong tool for improving patients' preventive services, but added that "medical practices or health plans ought to be tracking patients and encouraging them to get what they need, whether or not they are coming in for a visit."

In the discussion following Dr. Isham's presentation, Dr. Richard Wender of Thomas Jefferson University raised the question of whether federal or state laws requiring insurers to cover all colorectal cancer screening options may not make much of an impact on improving screening rates, based on the evidence Dr. Isham presented. Dr. Isham agreed, noting that a large body of existing health plans is trying to execute USPSTF recommendations. Dr. Kim Ryan of C3: Colorectal Cancer Coalition added that Congress is considering three bills, one which requires Medicaid to cover colonoscopies, one that requires all private insurance companies to cover the procedure, and one that requires Medicare to cover the preoffice visit needed for a colonoscopy.[11]

[11]*Cancer Screening Coverage Act of 2007.* HR 3425. 110th Cong., 1st sess. (August 3, 2007). *Colon Cancer Screen for Life Act of 2007.* S 1164. 110th Cong., 1st sess. (April 19, 2007). *Colorectal Cancer Screening and Detection Coverage Act of 2007.* HR 3060. 110th Cong., 1st sess. (July 17, 2007).

PUBLIC AND PATIENT INTERVENTIONS TO IMPLEMENT SCREENING

The next speaker, Dr. Sally Vernon, Director of the Division of Health Promotion and Behavioral Sciences, Blair Justice Professor in Mind–Body Medicine and Public Health, and Professor of Epidemiology and Behavioral Sciences at the University of Texas–Houston School of Public Health, discussed current research on clinic- and community-based interventions to improve colorectal cancer screening rates and research gaps that need to be addressed. She noted that most community interventions in the United States are conducted through community organizations, such as civic clubs, labor unions, houses of worship, and community clinics.

Dr. Vernon pointed out that evidence from systematic reviews, including the *Community Guide*, shows that client reminders and reducing nonfinancial structural barriers are effective at increasing colorectal cancer screening with FOBT. However, those reviews do not include the most recent data and did not evaluate modalities other than FOBT. Data from more recent intervention studies show that a variety of intervention approaches are effective at increasing FOBT (Figures 5 and 6) and endoscopy (Figures 7 and 8) in both clinic- and community-based settings. "The bottom line from these studies is that doing something, however modest it is, including usual care, is effective," Dr. Vernon said. During discussion, she pointed out that, regarding these data, "Some percentage of the population will do whatever you ask them to do." She added that more data are needed on the relative effectiveness and cost-effectiveness of interventions that vary in intensity. "How much additional bang for the buck do we get beyond the minimal intensity interventions that can be easily and cheaply employed in clinic and community settings?" she asked.

Dr. Vernon also stressed that as we think about implementation of strategies to increase colorectal cancer screening, we need to monitor trends and patterns in screening prevalence and to identify important correlates and predictors of screening. For example, data from the 2005 National Health Interview Survey (NHIS) show that the use of colonoscopy is increasing, but the use of sigmoidoscopy is decreasing (NCHS, 2005). Dr. Vernon and her colleagues also observed a consistent pattern of lower colorectal cancer screening by both African Americans and Hispanics compared with non-Hispanic white people (Shapiro et al., 2008). Fifty-one percent of white people over age 50 had FOBT or endoscopy, compared with 44 percent of African Americans and 34 percent of Hispanics. The same analysis found that only 18 percent of people over age 50 with no insurance had endoscopy within the past 10 years, compared with 39 percent of those with Medicare insurance only, and 44 percent of those with private health insurance. Data such as these help us to identify

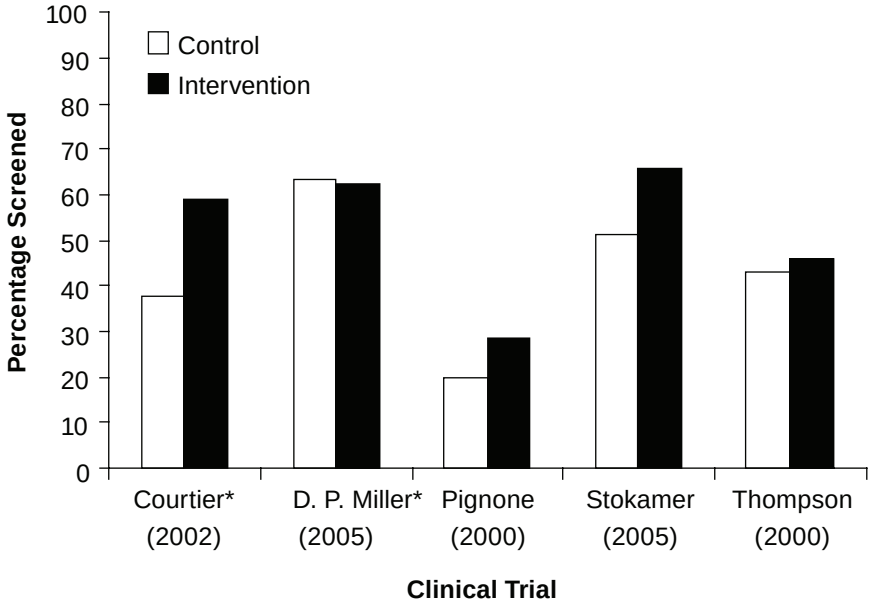

FIGURE 5 Results of FOBT clinic interventions, such as one-on-one education, mailed client reminders, small media, and multicomponent interventions. The purpose of the graph is not to identify which interventions work best, but instead it is to illustrate that efforts to increase screening work. *Note that Courtier et al. (2002) and D. P. Miller et al. (2005a) did not have a control group; both groups in each study received intervention materials. NOTE: FOBT = fecal occult blood test. SOURCES: Vernon presentation (February 25, 2008) and Courtier et al. (2002), D. P. Miller et al. (2005a), Pignone et al. (2000), Stokamer et al. (2005), and Thompson et al. (2000).

subgroups of the population who are underserved and who may need screening so that we can target intervention efforts more effectively.

Dr. Vernon went on to discuss major research gaps that need to be addressed, including monitoring the prevalence of screening behaviors over time and understanding the determinants of screening. She also suggested applying behavioral science theory to develop interventions using new technologies, such as interactive, computer-based educational programs to deliver interventions. She envisions the "bench-to-trench" continuum as a feedback loop, where epidemiologic surveillance plays a key role, as shown in Figure 9. She said the interventions that appear to work well now may not continue to do so as trends change; likewise, correlates and reasons for not completing screening may shift with time.

In the discussion after Dr. Vernon's presentation, Dr. Betty Ferrell of the City of Hope National Medical Center asked if what has been learned

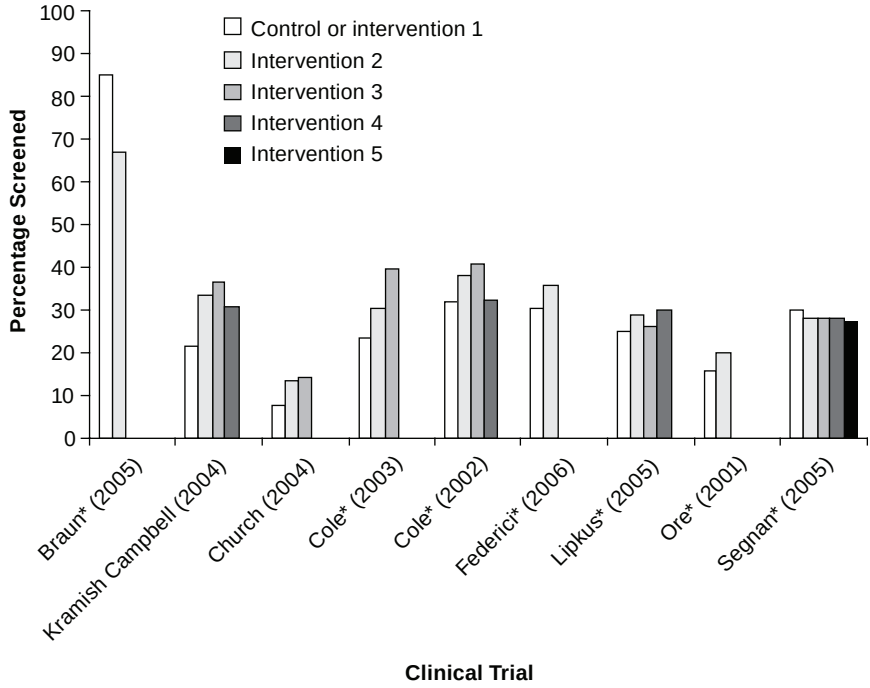

FIGURE 6 FOBT community interventions, such as small media, mailed client reminders, telephone client reminders, and multicomponent interventions. The purpose of the graph is not to identify which interventions work best, but instead it is to illustrate that efforts to increase screening work. *Some studies did not have a control group (Braun et al., 2005; Cole et al., 2002; Cole et al., 2003; Federici et al., 2006; Lipkus et al., 2005; Ore et al., 2001; Segnan et al., 2005); all groups in these studies received some form of intervention. NOTE: FOBT = fecal occult blood test. SOURCES: Vernon presentation (February 25, 2008) and Braun et al. (2005), Church et al. (2004), Cole et al. (2002), Cole et al. (2003), Federici et al. (2006), Kramish Campbell et al. (2004), Lipkus et al. (2005), Ore et al. (2001), and Segnan et al. (2005).

about behavioral strategies that are effective in motivating adherence to preventive efforts for other cancers, such as breast cancer, apply to colon cancer. Dr. Vernon responded affirmatively, but noted that there are important differences. "At this point, hardly anyone, when asked why they didn't have a mammogram, says they didn't know they needed it, for instance," she said. Earlier in the presentation, Dr. Vernon showed data from the 2005 NHIS indicating that lack of awareness of the importance of colorectal cancer screening was the reason most often given by

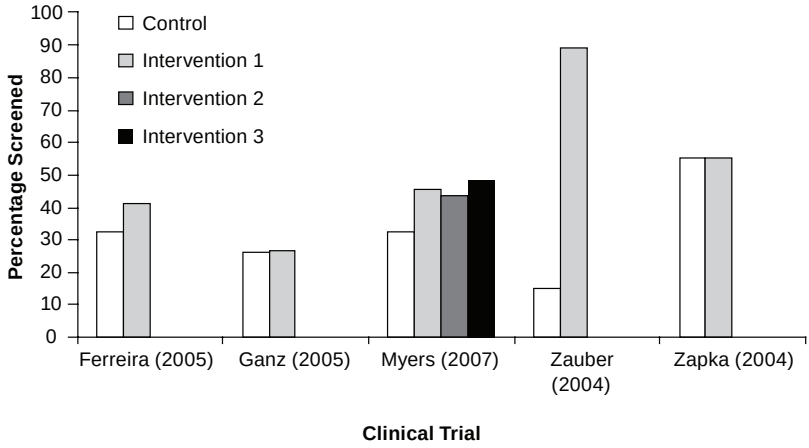

FIGURE 7 Results of endoscopy clinic interventions, such as provider education, mailed client reminders, small media, and multicomponent interventions. The purpose of the graph is not to identify which interventions work best, but instead it is to illustrate that efforts to increase screening work. SOURCES: Vernon presentation (February 25, 2008) and Ferreira et al. (2005), Ganz et al. (2005), Myers et al. (2007), Zapka et al. (2004), and Zauber (2004).

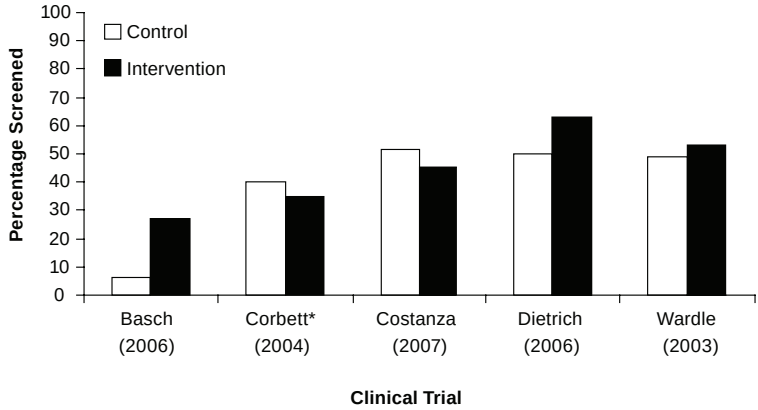

FIGURE 8 Results of endoscopy community interventions, such as small media, mailed client reminders, telephone client reminders, and multicomponent interventions. The purpose of the graph is not to identify which interventions work best, but instead it is to illustrate that efforts to increase screening work. *Note that Corbett et al. (2004) did not have a control group—both groups received invitations in the mail to get colorectal cancer screening from either their general practitioner or a local hospital. SOURCES: Vernon presentation (February 25, 2008) and Basch et al. (2006), Corbett et al. (2004), Costanza et al. (2007), Dietrich et al. (2006), and Wardle et al. (2003).

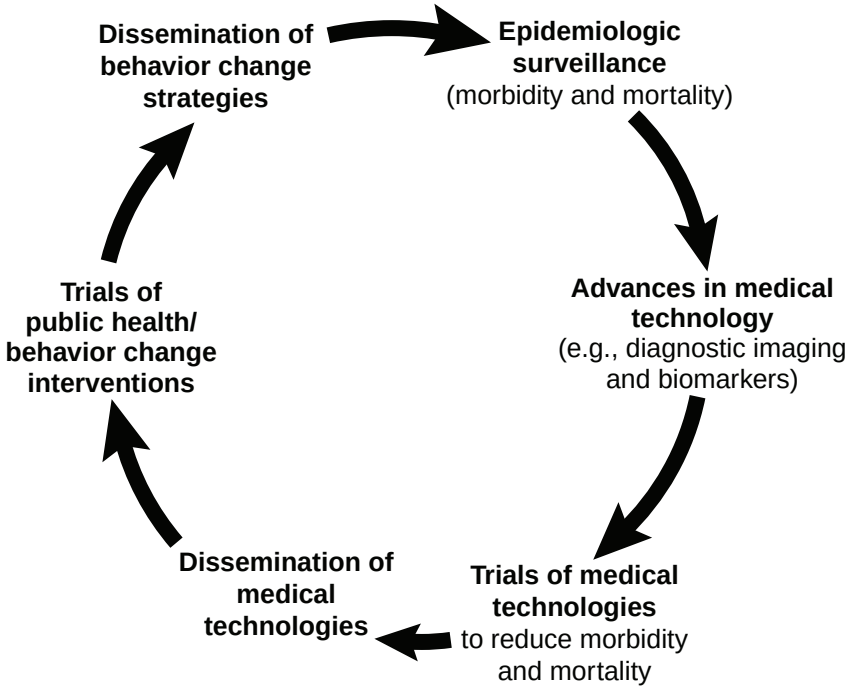

FIGURE 9 Integrating epidemiology and health promotion to improve cancer screening. As populations and screening barriers change, changes will be necessary to maintain the best interventions for maximizing colorectal cancer screening. SOURCES: Vernon presentation (February 25, 2008), Dr. L. Kay Bartholomew, University of Texas–Houston School of Public Health, and Dr. Deborah del Junco, University of Texas Health Science Center at Houston.

nonscreeners for not being tested (NCHS, 2005). Another problem specific to colorectal cancer screening is that several screening modalities can be done, with different screening intervals.

During the discussion, several challenges of data collection were pointed out, including overreporting by patients about their own colorectal cancer screening, underreporting by providers in the medical record, and the incomplete claims data held by insurance programs. Dr. Vernon concluded, "One of the important issues for the field is to try to understand more about the sources of error in all of the datasets that we use to measure the outcomes, including self-report, medical records, and administrative data, because none of them is perfect."

PRIMARY CARE PRACTICE INTERVENTIONS TO IMPLEMENT SCREENING

The next presentation was given by Dr. Robert Fletcher, professor of ambulatory care and prevention at Harvard Medical School and adjunct professor of epidemiology and social medicine at the University of North Carolina at Chapel Hill School of Medicine. Dr. Fletcher began his presentation by discussing the primary care environment and the challenges it poses to ensuring adequate colorectal cancer screening. He noted that such screening is currently constituted as a primary care activity, in that it is initiated and tracked by primary care physicians. But several factors affect the ability of these doctors to carry out such screening in their patients, including a shortage of time, the complexity of colorectal cancer screening algorithms, other competing preventive care measures, and broader societal influences. Dr. Fletcher said one study found that following USPSTF recommendations would require primary care physicians, working under current arrangements, to spend about 7 hours a day providing preventive care (Yarnall et al., 2003). Another study found doctors would have to spend 10 hours a day providing chronic disease care (Østbye et al., 2005). "This is a very big agenda into which we are injecting the prevention of colorectal cancer," Dr. Fletcher said.

Even within the prevention arena, Dr. Fletcher said, more than a dozen other issues besides colorectal cancer have to be addressed (Box 1). The fact that there are several colorectal cancer screening options that have to be explained to patients in conjunction with time constraints further impedes how effectively primary care physicians can educate patients on their screening options. Several people noted in the discussion following Dr. Fletcher's presentation that many physicians are mainly recommending the colonoscopy screening option to their patients because it takes less of the physicians' time. "It is so much easier to send the referral sheet off for a colonoscopy and then wait 10 years for the next one, than to remind people every year for FOBT," said Dr. Scott Ramsey of the Fred Hutchinson Cancer Research Center. Dr. Ganz added that the increasing recommendation for colonoscopy as the screening test of choice stems from time pressures and the fact that colonoscopy is the simplest screening test to convey in comparison to discussing all other options. Dr. Wender concurred that his informal survey of primary care clinicians indicates that the vast majority are recommending colonoscopy as the preferred option to their patients, but that is partly because they cannot ensure their patients adhere to annual FOBT screening.

Societal influences also play a part on colorectal cancer screening implementation at the primary care level. These include insurance, malpractice concerns, and public belief in the value of screening. Although increasingly states are mandating insurance coverage of screening, many

BOX 1
Colorectal Cancer Screening in the Context of Other Preventive Care

Smoking
Obesity
Hypertension
Dyslipidemia
Aortic aneurysm
Breast cancer
Colorectal cancer
Cervical cancer
Prostate cancer
Depression
Immunizations
Chemoprevention
Injury prevention
Physical activity
Sexually transmitted diseases
Substance abuse
HIV infection
Vision and hearing

SOURCE: Fletcher presentation (February 25, 2008).

"affordable" health plans do not cover all options, Dr. Fletcher pointed out. He also noted that because screening for colorectal cancer is now the consensus opinion, failure to screen is becoming an important malpractice problem that is motivating physicians to encourage it among their patients. Also motivating patients to obtain screening are posters, radio segments, magazine articles, and famous people talking about colorectal cancer screening and its importance. "What is possible in the office is heavily dependent on what has taken place in the larger society around us before the patient ever gets there," Dr. Fletcher said.

Despite the competing responsibilities, limited time, and insurance barriers that hamper primary care physicians from fostering colorectal cancer screening among their patients, studies indicate that physicians committed to such screening are able to achieve high screening rates. One unpublished study of a multispecialty group practice in Boston with 14 sites found that screening rates varied extensively by physicians facing the same impediments to implementing such screening. "What this shows is that physicians can screen at very high rates if that is what they want to do," Dr. Fletcher said.

The remainder of Dr. Fletcher's talk focused on interventions that can help primary care physicians promote colorectal cancer screening, including recommending it to their patients and providing screening reminders, and working with office staff and local gastrointestinal physicians to overcome barriers to screening (Figure 10). But Dr. Fletcher prefaced this discussion by pointing out that research studies usually provide evidence that various interventions increase screening rates in ideal circumstances, such as in large and highly organized clinical settings, and that they do not provide evidence about small private practices where the bulk of care is given. "We don't have a lot of effectiveness information on how these things work in ordinary settings," he said.

Several studies have found that physician recommendations for screening strongly influences patients to comply with those recommendations, including one study that found that provider recommendation is strongly associated with being screened regardless of a patient's risk of developing colon cancer related to family history (Palmer et al., 2007),

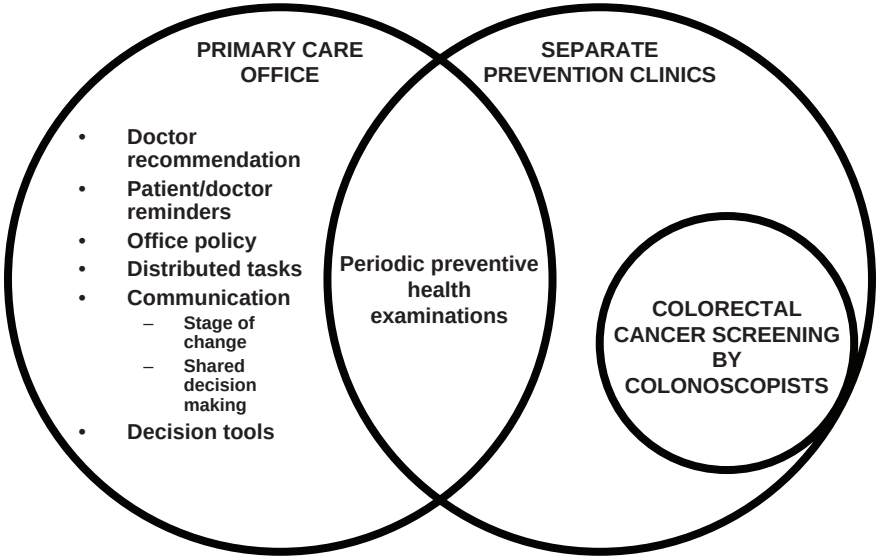

FIGURE 10 Opportunities for improvement inside and outside the current office paradigm. Several factors can be improved within primary care offices to improve colorectal cancer screening rates. Dedicated preventive health visits can improve care both within the primary care office and in separate prevention clinics, and colonoscopists provide an important service in increasing colorectal cancer screening outside the primary care clinics as well. SOURCE: Fletcher presentation (February 25, 2008).

Dr. Fletcher said. Patient reminders for such screening are also critical. He noted that his own dog receives preventive health measure reminders from his veterinarian more consistently than many patients do from their physicians. "If we can do it for dogs, we can certainly do it for people," Dr. Fletcher said. Although effective strategies for encouraging consistency in preventive care reminders exist—such as manual forms, spreadsheets, and flow charts—electronic medical records (EMRs) integrate all of the information within a practice, simplifying the process. The older methods have been used for decades, but EMRs make the process of generating preventive care reminders easier, Dr. Fletcher observed, adding, "to the extent that medical records are fostered, so can the possibilities for reminder systems." But in the discussion that followed, Dr. Ganz pointed out that installing EMRs is not an easy feat because it requires a work flow redesign and office setup. But she added that pay-for-performance might cause physicians to make the leap to EMRs to make their practices more efficient.

Dr. Fletcher suggested that staff in primary care offices work as a team to plan a strategy for encouraging colorectal cancer screening among their patients and commit to carrying out this strategy so that physicians and staff have a shared understanding about what they are trying to accomplish. He pointed out that personalized screening in which patients have a say on which screening test to pursue is often viewed as "the right thing to do," but studies have not shown that honoring patient preferences results in greater patient adherence, and that involving patients in decision-making takes time away from other important discussions and activities that need to take place during a primary care office visit.

Two conflicting messages are being given to patients regarding colorectal cancer screening, Dr. Fletcher asserted. One is that all recommended screening tests are effective, and patients should be screened with the one he or she prefers. The other, which is increasingly being given, is that colonoscopy is the best screening test and the patient should have it. The latter message may be detrimental to adherence, he pointed out, because it may not be affordable or acceptable to many patients.

Dr. Fletcher recommended several "tool kits" for improving colorectal cancer screening rates within practices, including the National Colorectal Cancer Roundtable[12] guide (Safarty, 2006), and a journal article that addresses the issue (Safarty and Wender, 2007). He also suggested that primary care physicians consider innovative ways to improve their patients' colorectal cancer screening rates, including partnering with colonoscopists and separate prevention clinics. Research studies of effective interventions often do not assess the effectiveness of such local solutions,

[12]See http://www.nccrt.org.

Dr. Fletcher said. "If your patients find when they call to make an appointment for a colonoscopy they get a busy signal, nobody calls them back, or the wait time is 9 or 10 months for their procedure, then this is not a research question, but a local problem to solve."

Dr. Wender added during the discussion following Dr. Fletcher's presentation that his university hospital system teamed primary care physicians with local colorectal surgeons and gastrointestinal physicians to discuss barriers to getting colonoscopies and how to overcome them. "Having local, small primary care practices form networks, perhaps linked by a hospital system, and meet with area colonoscopists is a powerful and important intervention," Dr. Wender said. Dr. Fletcher added that the National Colorectal Cancer Roundtable is exploring the relationship between primary care physicians and gastrointestinal specialists and how they can support each other.

Dr. Fletcher ended his talk by noting that interventions to increase colorectal cancer screening rates should support other preventive care. "The last thing we want is for colorectal cancer screening programs to replace and push out other preventive services, some of which are even more important than colorectal cancer screening," he said. During the discussion that followed, Dr. Ferrell commented on the compelling evidence that primary care provider recommendations for screening are highly linked to patient's adherence to such screening. He asked whether, given the limited resources available at NCI or other governmental or state agencies, if those resources should be sunk into encouraging more provider screening recommendations. Dr. Fletcher responded, "when it comes to interventions, it takes several of them together in order to get substantial increases in screening rates. The doctor saying this is important is not good enough if the patient is not insured and everybody around that patient doesn't think it really is important. The central pitch I would make is that you have to do a bunch of things together."

GASTROINTESTINAL SPECIALTY PRACTICE CONCERNS

Dr. David Lieberman, professor of medicine and chief of the Division of Gastroenterology at Oregon Health and Science University, followed Dr. Fletcher's presentation and spoke about the challenges gastroenterologists face with the increasing rates of colon cancer screening. Data from one study revealed that between 2000 and 2002, less than 10 percent of colonoscopies were performed for screening (Lieberman et al., 2005a). In 2007, preliminary data show that about 35 percent were done for screening purposes.[13] The increase in screening reflects, in part, the growing

[13]Personal communication, D. Lieberman, Oregon Health and Science University, May 27, 2008.

evidence that the detection and removal of adenomas can prevent many colorectal cancers, Dr. Lieberman said. This has changed the goals of screening from early cancer detection, first recommended by the American Cancer Society[14] in 1980, to colon cancer prevention.

The increase in the number of colonoscopies performed challenges gastroenterologists to document and improve the quality of the procedure and meet the rising need for colonoscopies with the limited resources at hand. Also, gastroenterologists need to evaluate the risks and benefits of new screening technologies and undergo training for them as they become available. A number of findings raise concerns about colonoscopy quality. Studies show that within 2 to 3 years of having a baseline colonoscopy with all polyps removed, there is a 0.3 to 0.9 percent rate of colon cancer discovered in patients, Dr. Lieberman reported. "We would not expect to see any cancer appearing if colonoscopy was a really perfect test," he pointed out. The interval cancers might be due to new and fast growing lesions. But more likely they are due to either incomplete removal of lesions found in the baseline colonoscopy or missed lesions, evidence from CT colonography studies suggest. These studies found colonoscopy miss rates for polyps greater than 1 cm ranged from 2 to 12 percent (Cotton et al., 2004; Pickhardt et al., 2003; Rockey et al., 2005).

Polyps may be missed because of inadequate colonoscopy bowel preparation, incomplete cecal intubation, or too quick a withdrawal time from the cecum. Dr. Lieberman shared preliminary data from a project funded by the National Institutes of Health called Clinical Outcomes Research Initiative (CORI), which collected endoscopic practice data from 70 diverse clinical practice settings throughout the United States. The project found that a number of sites had 10 to 20 percent of patients with inadequate bowel preparation. Cecal intubation rates appeared to be adequate at most sites. But Dr. Lieberman pointed out that the most important measure of colonoscopy quality is whether significant polyps are being detected (Figure 11). The CORI study found for polyps greater than 9 mm, the detection rate at most sites fell within the expected rate range of between 4 and 10 percent, but the lower volume sites tended to have poorer detection rates. "This just gives us a little bit of a snapshot, but I think it is something that will in the future be expected of the GI community," Dr. Lieberman said. "We are entering a new world where there is going to be pay-for-performance and where patients and payers are going to be demanding information about quality."

Quality of colonoscopies also depends on adverse event rates. Studies indicate the risk of adverse events ranges from 0.03 to 1.1 percent and include perforation, bleeding, and cardiopulmonary complications (Bowles et al., 2004; Ko et al., 2007; Korman et al., 2003; T. R. Levin et al.,

[14]See http://www.cancer.org.

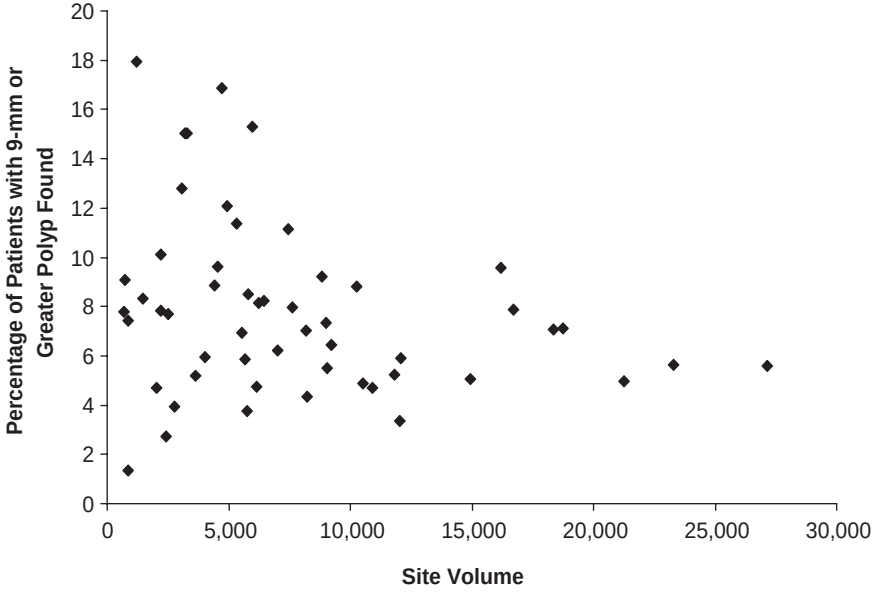

FIGURE 11 Scatterplot of detection rates for polyps 9 mm in diameter and greater plotted against site volume of screening exams. The sites include more than 70 community, academic, veterans', military, and health maintenance organization practices around the country, and the data represent more than 600,000 colonoscopies. The mean detection rate for 9-mm and larger polyps is 6.3 percent. SOURCE: Lieberman presentation (February 25, 2008).

2006; Nelson et al., 2002; Rathgaber and Wick, 2006; Sharma et al., 2007). The CORI study found that the complication rates ranged widely from site to site, depending on the thoroughness of reporting at each site. "Getting more standardized methods of reporting is going to be very important in the future," Dr. Lieberman said.

There is concern that the high demand for colonoscopy services may outweigh the potential capacity. But Dr. Lieberman pointed out that if colonoscopy is used more appropriately, demand may better match capacity. He conducted a study that found that about 20 percent of patients who are receiving colonoscopy are under the age of 50. Of those patients, 9 percent of the women and 12 percent of the men are receiving it for average-risk screening (Lieberman et al., 2005b). Also, 29 percent of the women and 18 percent of the men were being evaluated for irritable bowel syndrome symptoms, even though "there is some question about whether these patients benefit from having these procedures because we

know the [diagnostic] yield here is extremely low," Dr. Lieberman said (Lieberman et al., 2005b). "The point here is that there are a lot of procedures being done in patients under 50. Perhaps they don't all need to be done. That would [free up] capacity," he added.

Colonoscopies also may be overused because of surveillance that may not be necessary or could be avoided, Dr. Lieberman pointed out. About 50 percent of endoscopists recommend surveillance at 3 years or less for small adenomas, despite guidelines that call for surveillance at 5 to 10 years. Many physicians perform surveillance colonoscopies for hyperplastic polyps in the sigmoid and rectum, even though they are not neoplastic and linked to any known increase in risk (Lieberman et al., 2005a; Mysliwiec et al., 2004). Some surveillance is also driven by poor bowel preparation and incomplete exams, Dr. Lieberman added. This was confirmed in the discussion following his talk by Dr. Seeff, whose study found that many endoscopists reported that inadequate bowel preparation required them to see some patients in 5 years rather than 10. "If physicians monitor this kind of information in their practice, and they are not doing well, then they need to look at the process they are using for educating patients about the bowel preparation and try to achieve that 95 percent adequate rate," Dr. Lieberman said.

Another factor that enters into the resource question is whether the use of newer technologies, such as CT colonography and genetic screening, will significantly lower the demand for screening colonoscopies. "With these technologies, a smaller percentage of patients who are average risk may end up getting colonoscopies," Dr. Lieberman said. Other technologies, such as self-propelling scopes, may eliminate the need for colonoscopies in a wider group of patients. Dr. Lieberman pointed out that even given all these factors, there is uncertainty about whether there are enough colonoscopists to meet demand.

With continual entry into the market of new products and technologies, it is important to consider how technology adoption can or should be guided; for example, it is useful to consider how much evidence of new technologies' risks and benefits is needed before widespread use. "There will be new things coming along in the future, and we are going to have to explore how to present those to patients," Dr. Lieberman said. The new technologies also require more training and credentialing. More training may also be required, given the recent finding that flat or depressed lesions are linked to an increased risk of malignancy (Soetikno et al., 2008). Colonoscopists would need to be trained in tissue staining and other techniques to adequately detect flat lesions, Dr. Lieberman noted.

Dr. Lieberman ended his talk by saying, "There is great evidence today that screening can prevent colon cancer, but only if it is done well. The challenge in my specialty today is going to be to document

and monitor quality and appropriate utilization with the goal of quality improvement." In the discussion that followed, Dr. Wender noted that the interval between when a patient agrees to have a colonoscopy and when it is actually performed is an important barrier. It predicts whether the screening occurs or not, he said, and thus should be included in a discussion of quality of colonoscopy screening. He also suggested that primary care physicians partner with colonoscopists to ensure short scheduling intervals, provide patient navigation, and perhaps share responsibility with a registry used to generate patient reminders. Dr. Lieberman agreed that "having that kind of relationship between the primary care provider and whoever is doing the colonoscopy is going to be critical. Providing better service in a more timely fashion is going to be important for any program to be successful."

STATE AND FEDERAL INITIATIVES TO BOOST COLORECTAL CANCER SCREENING

Colorado Screening Initiatives

Dr. Tim Byers, professor in the Department of Preventive Medicine and Biometrics at the University of Colorado Denver School of Medicine and deputy director of the University of Colorado Cancer Center, made the first of three presentations on state or federal initiatives to boost colorectal cancer screening by describing a series of programs he and his colleagues at the University of Colorado instituted to foster more screening within the state. The first of these efforts began in 2000 with an ACS-funded provider and patient survey aimed at assessing their perspectives in regard to colorectal cancer screening. That survey showed that providers and patients were supportive of the idea of colorectal screening, but no active dialogue was underway.

Because colorectal screening by colonoscopy was a new benefit for Medicare recipients at that time, and because most Medicare beneficiaries were not aware of this new benefit, the University of Colorado researchers decided in 2001 to try to promote the benefits of such screening directly to the Medicare population. "We thought, let's do for colorectal cancer what happened for mammography, let's increase consumer demand," Dr. Byers said. In cooperation with the Colorado Foundation for Medical Care,[15] they conducted a randomized, controlled trial that tested brochures mailed to beneficiaries to emphasize the benefits of colorectal endoscopic screening in preventing cancer. The key messages were that colorectal cancer comes from polyps; one of every three adults has polyps; and 80

[15]The Colorado Foundation for Medical Care is the Colorado Medicare quality improvement organization; see http://www.cfmc.org/.

percent of colorectal cancers may be preventable. Some brochures were tailored to gender. They found that the promotion efforts boosted colorectal cancer screening by 5 percentage points, with the gender-tailored brochures producing higher rates than the gender-neutral brochures. Those who received brochures accompanied by their physicians' endorsement with their own personalized letters also had higher screening rates than those who received only the unendorsed brochures. "The main conclusion was that there was low-hanging fruit that got 5 to 10 percent of people to act to have endoscopic screening," said Dr. Byers. "It is not rocket science. If you ask people to do things, some will do it, and the more tailored or intense the intervention is, the better the response."

Given the success of this pilot project, and the fact that in Colorado, Hispanics have a higher rate of colorectal cancer than white people, in 2003 the program was extended to Hispanics within an HMO setting. In collaboration with Kaiser Permanente, they found that brochures tailored to Hispanics were again found to boost screening rates, especially when they were followed up with a phone call. This approach to increasing colorectal screening by increasing consumer demand was then extended into a statewide screening promotion program aimed at people aged 50 to 74. Between 2003 and 2006, brochures were mailed to 75 percent of all households in Colorado that had a Medicare beneficiary, with the same promotional messages given in the pilot project brochures, and accompanied by a Colorado-specific endorsement from television news journalist Katie Couric, who has been active in promoting screening since her husband died of colorectal cancer when he was 42 years old. An evaluation based on telephone calls suggests the widespread mailing boosted colorectal cancer screening rates by 5 percentage points. Many HMOs and Medicaid in Colorado have adopted this approach of direct-to-consumer marketing by mail, adapting and personalizing the same promotional materials, according to Dr. Byers.

In January 2006, Dr. Byers and his colleagues began a program aimed at providing colorectal cancer screening for people in Colorado without health insurance.[16] This program costs about $5 million per year, funded by a state tax on tobacco. The Colorado Colorectal Screening Program, which became statewide in 2007, relies on a partnership with community clinics serving people without health insurance. "Our philosophy is to have the program be very unbureaucratic, as invisible as possible, from the perspective of patients and providers," Dr. Byers said. This program provides free colorectal cancer screening[17] to Coloradans who are without

[16]See www.uccc.info/colonscreen.

[17]Colorectal cancer screenings included in this program are flexible sigmoidoscopy, colonoscopy, and barium contrast enema, according to the program manual (Colorado Colorectal Screening Program, 2007).

health insurance and who are under 250 percent of the federal poverty level.[18] In addition, to qualify, individuals must be 50 or more years of age, have symptoms, or have a family or personal history of colorectal cancer. "For our program, we delegate the judgment about eligibility to the clinics and to the providers so we don't have to implement a system of them having to call in and get permission," Dr. Byers pointed out. "If they meet the eligibility requirements and get the screening done, then we will pay the bill." Between 16,000 and 18,000 people in Colorado are eligible for the program.

A critical component of the program that has made it successful, according to Dr. Byers, is patient navigation. "We heard from our providers that they don't mind providing these services, but what they hate is when someone comes poorly prepped or doesn't show up, thus messing up their schedule," Dr. Byers said. So resources were provided to the community clinics to hire navigators. "Navigation has been key to this—getting people to the appointments, making sure they understand what this is all about, and making sure they are adequately prepped," Dr. Byers said. A dramatic example of how navigators facilitated the program operation was at a clinic that serves homeless people. The homeless patients were put up in hotels to receive the bowel preparation the night before the procedure. The clinic was so successful with its navigation system that the completion rate for the first 40 colonoscopies they scheduled was 100 percent.

Although wait times for colonoscopies were an initial concern, a random survey of providers around the state found that wait times are continuing to be generally short, Dr. Byers said. The program includes monitoring quality by informing providers what their rate is of finding adenomas. "We think that feeding back information on adenoma detection rates to providers is going to be more effective than trying to require a certain withdrawal time or trying to require documentation of what the cecal anatomy looked like," Dr. Byers said.

The program includes follow-up and treatment, including up to $60,000 per patient for treatment of colorectal cancers detected by the screening exams. For some people with colon cancer, that amount is not sufficient, but it is usually enough to carry them over until they can receive funding from Medicaid or another source. Dr. Byers pointed out in the discussion following his presentation that other programs for breast

[18]The federal poverty level refers to the poverty guidelines issued each year by the Department of Health and Human Services. For reference, the 2008 poverty guideline for a family or household of one person is $10,400, and $3,600 is added for each additional family or household member. A full chart and explanation can be found at http://aspe.hhs.gov/POVERTY/08poverty.shtml; this website refers to HHS (2008). For information including other years, see http://aspe.hhs.gov/POVERTY/.

and cervical cancer screening ran into problems if they did not also offer financial support for the treatment of those found to have cancer. "I think the lesson we have to take from that is, if you want to do screening, do it right, which means that you have to put up front some assurance that the institutions, clinics, and providers who are committing to the screening aren't going to get burned from those 1 percent of people who are going to be found to have cancer. Doing it right means you have to have that money up front," Dr. Byers said.

With this program, about 3,000 people are being screened per year, which by 2011 should enable it to reach its goal of screening 75 percent of people without health insurance. The benefits from the first 4,000 colonoscopies conducted with the program include the detection of 35 cancers, and the removal of 1,000 adenomas, including 400 advanced lesions. The Colorado researchers estimate that the program has already prevented 150 future cancers. They conservatively estimate the treatment for those averted cancers to be $100,000 per case, and that figure does not include treatment with newer, more expensive drugs, such as the antiangiogenesis drug Avastin. With that treatment estimate, the program thus far has resulted in an estimated $15 million savings at an estimated cost to date of $10 million.

The success of the Colorado program is based in part on the successes and lessons learned by other state programs, and the Colorado program has served as a test case for other states considering their own programs. Arizona, Connecticut, Maine, Maryland, Minnesota, New York, North Carolina, South Carolina, Texas, West Virginia, and Wyoming have all given advice to or sought advice from Colorado. The funding sources and the stage of development of programs differ for each state, he added, but these state-specific programs should help the planning for similar programs that might be run at the federal level.

Nebraska Screening Initiatives

Next, Dr. Alan Thorson, clinical associate professor of surgery at Creighton University and the University of Nebraska, explained the program he helped initiate in the state of Nebraska to promote colorectal cancer screening. The program has focused on FOBT because it provides low-cost, effective screening that can fit within most communities' budgets, but the educational component includes the entire spectrum of testing recommended by American Cancer Society guidelines. The main reasons for starting this program was Nebraska's low colorectal cancer screening rate—one of the lowest in the nation—and the haphazard way colon cancer screening was being conducted in Omaha, in part because of competition among various health systems and hospitals. "They were

passing out fecal occult blood kits indiscriminately with no follow-up," Dr. Thorson said. "We thought it would make a much better statement to the community if we said that colorectal cancer screening is such an important issue that we are going to rise above the competitive instinct and develop a collaborative program, and that is exactly what we did."

Dr. Thorson compared the guiding principles that informed the creation of the screening program with those developed by ACS "for communities to utilize in developing colorectal screening programs utilizing FOBT," he said. The ACS recommendations are shown in Box 2. The Nebraska program had adopted equivalent guidelines, with the exception of the signed agreement between providers, due to fear that the process of arriving at such an agreement would erode the progress that had been made. Starting in 1999, and beginning within Omaha and extending to other communities in Nebraska, a group of gastroenterologists, colorectal surgeons, oncologists, and family practice physicians established collaborations among hospitals, providers, nonprofit cancer organizations, community organizations, health systems, public health departments, pharmacists, corporate wellness programs, professional medical societies, and

BOX 2
Collaborative Community Screening Model: American Cancer Society (ACS) Guidelines

- Separation of responsibilities between:
  - ACS staff and volunteers, and
  - Sponsors conducting screening, diagnostics, and follow-up
- Inclusion of an educational component that answers questions and explains options
- Informed consent
- Follow-up system for notification and treatment
  - Pretest communication
  - Reporting of results
- Patient
- Physician
  - Follow-up communication with difficult-to-reach patients
  - Follow-up testing for patients with both positive and negative results
  - Follow-up treatment for uninsured and underinsured patients
- Signed agreement between sponsors

SOURCES: Thorson presentation (February 25, 2008) and American Cancer Society (2007b).

the media. These collaborations fostered health care provider outreach, public awareness activities, and structured FOBT distribution during the month of March, which is National Colorectal Cancer Awareness Month, as well as systematic processing and follow-up of the FOBTs.

The health care provider outreach offers information on colorectal cancer screening through presentations by physicians to the lay public as well as to nurses and physician assistants at their professional meetings. Physicians and their office staff are also given information kits and the opportunity to participate in fax quiz competitions. Public awareness activities include public forums, special events, worksite communications and, especially during the month of March, interviews on television news shows and radio programs and inserts in newspapers.

During March, FOBTs are distributed via pharmacies, who participate in an education program about the distribution and follow-up process. The program has a single location where all the kits are returned, then distributed equally to each health system for processing. There is an established communication plan for conveying results to patients and their physicians. The program links to a CDC project through which enrolled individuals are eligible for colonoscopy for a positive test, or if they have a family or personal history that would dictate colonoscopy initially rather than FOBT. The community-based FOBT distribution sites try to identify those individuals who may be candidates for the CDC project, then direct them to that project so they do not lose their eligibility for follow-up colonoscopy for a positive result. On a statewide level, all of the state's American College of Surgeons Commission on Cancer–approved cancer centers have signed letters of intent indicating they would provide treatment for anyone who was found to have cancer within the CDC project. This is an example of expanded statewide networking that has grown with awareness of the community-based programs.

The program has distributed more than 22,000 kits since 1999, and the return rate on the FOBTs is about 50 percent, Dr. Thorson reported. He noted, however, that there have not been as many repeaters in the program as would be expected, given that annual FOBT screening is recommended. But the program has other successes besides boosting FOBT screening, Dr. Thorson noted. "We have seen increased networking and relationship building in other areas, including clinical trials and research between universities and health systems that are involved in clinical trials," he said. In addition, "We have had the establishment of survivorship groups and support groups in Lincoln and in Omaha as a result of the collaborative that we have developed."

The program has also identified educational needs for its physician population base. "Our data show that we still have times when a physician will recommend a repeat FOBT next year to a patient who has had a

BOX 3
Lessons to Be Learned

- Facilitators of effective program establishment
- Number of outcomes by test type and program design
- Changes in screening rates in program population
- Cost and cost-effectiveness by test type and program design
- Treatment?

SOURCE: Seeff presentation (February 25, 2008).

positive stool test in our program. So we can focus our efforts not only on those physicians, because we know who they are, but also the community as a whole that tries to prevent that kind of problem from continuing to occur," Dr. Thorson said. "If nothing else, I think we have educated the health systems about the appropriate way to do colorectal cancer screening, and they like the idea that we transcended competition to do something that is right for patients," he added.

Population-Based Federal Screening Initiatives

Dr. Laura Seeff, associate director for the Office of Colorectal Cancer Programs in the CDC's Division of Cancer Prevention and Control, spoke about the CDC's colorectal demonstration screening program, which is aimed at increasing colorectal cancer screening in underserved populations. Several bills have been introduced in Congress to fund a nationally based colorectal cancer screening program akin to the national breast and cervical cancer early detection program run by the CDC.[19] But no such program exists, so the demonstration project Dr. Seeff described was aimed at determining the feasibility of establishing such an organized federal program and how best to implement it at the community level. Specific issues to be evaluated in the demonstration project are listed in Box 3. "We wanted to be able to inform current and future efforts in organized screening," said Dr. Seeff.

After meeting with stakeholders, the CDC decided that eligible applicants for their demonstration program would be any nonprofit medical entity offering services to low-income persons who are underinsured for

[19]The most prominent of these is *Colorectal Cancer Prevention, Early Detection, and Treatment Act of 2007*. HR 1738. 110th Cong., 1st sess. (March 28, 2007).

colorectal cancer screening. Eligible applicants must also show collaboration with a CDC-funded Comprehensive Cancer Control Program to prevent establishing isolated programs that were not integrated. It was also decided that the focus of the program would be people with average risk of colorectal cancer, and that given the limited funds available, priority would be given to programs ready to begin screening within 6 months.

Because it was a community-driven program, applicants determined how wide an area they would target with their screening, what their priority populations would be among people aged 50 and up who are underinsured for colorectal cancer, and which of the recommended screening mechanisms they would promote. They were given the option of switching their selected tests, if they were having problems with uptake, and applicants set their own screening goals.

In addition to providing screening and diagnostic services, patient support including navigators, and program management, the demonstration program also provided funds for data collection, tracking, and evaluation of program effectiveness, public education and outreach, establishment of quality services standards, and maintenance of relevant partnerships. But the CDC could not provide funding for treatment of those found to have cancer. Consequently, applicants could only be eligible if they stated in their application how they would support such treatment.

The demonstration effort began in 2005 and is still running. It consists of five programs encompassing Suffolk County, NY; the City of Baltimore, MD; the City of St. Louis, MO; three counties in Washington state; and the entire state of Nebraska. Only about $2.5 million is used annually to fund these five programs, Dr. Seeff noted. The recruitment tools for these programs vary and include small referral or client screening incentives, in-reach to women already enrolled in breast or cervical cancer screening programs, and outreach via faith-based programs, phone calls and mailings, community events, health fairs, and the American Cancer Society.

The CDC evaluated each program's start-up phase—the time between when a program is funded and when it initiates screening—and implementation phase—the time between the start of screening and the present. These analyses found that 80 percent of those screened were women, perhaps because many of the programs build on their already established breast and cervical cancer screening programs, and because men are traditionally harder to reach for preventive health measures, according to Dr. Seeff. About 25 percent of the screened population were African American and 20 percent were Hispanic. Only 20 percent were at increased risk for colorectal cancer. High-risk individuals were those with a family or personal history of polyps or cancer; people with inflammatory bowel disease or symptoms of colon cancer were also considered to be high risk, and therefore were excluded from the program.

Half the tests done were colonoscopies and nearly half were FOBTs, with barium enemas, sigmoidoscopies, and other tests comprising only 1 percent of the total. Of the FOBTs distributed across the three programs offering these tests as their primary screening tool, 40 percent were not returned. So far, 75 percent of the tests have been normal, 15 percent detected polyps but with no high-grade dysplasia, 3 percent detected high-grade dysplasia, and five cancers have been detected so far, Dr. Seeff reported.

The CDC evaluation of its own demonstration program found that several factors facilitated program start-up, including a preexisting program infrastructure, partnerships with organizations such as the ACS or the National Comprehensive Cancer Control Program,[20] clinical expertise, and program champions. Start-up challenges included identifying administrative barriers, contracting endoscopists, securing resources for cancer treatment, and the limited resources for the screening programs in general. The CDC's preliminary findings about the first-year operations of the demonstration program were that patient navigation was critical for colonoscopy, recruitment of men was challenging, and in-reach into programs that have a client base is not always sufficient. Dr. Seeff also pointed out that one program began with FOBT as its primary screening tool and then switched to colonoscopy because it was thought to be a more acceptable option to their clients.

Following Dr. Seeff's presentation, much of the discussion focused on how to encourage more men to participate in colorectal cancer screening. Dr. Ganz pointed out that building colorectal cancer screening efforts on other chronic disease treatment efforts might bring in more men (Bloom et al., 2007). She noted that the population aged 50 and older that should do colorectal cancer screening is also likely to have chronic health problems, such as diabetes and high blood pressure. "It's hard to get the men in. But their wives will bring them in for their blood pressure treatment or whatever, and that is a good opportunity," she said. Dr. Seeff responded, "We are very open to other chronic disease models. We explored the breast and cervical model as one model because it is out there, but there is no certainty that this is the way we would go."

Dr. Ferrell suggested adding colorectal cancer screening programs onto successful screening programs for prostate cancer. But Dr. Coates pointed out that because prostate screening is so controversial,[21] and

[20]See http://www.cdc.gov/cancer/ncccp/.

[21]While testing for prostate-specific antigen (PSA) can successfully detect prostate cancer, the test is often positive in patients with benign prostatic hypertrophy (a common condition in which the prostate is enlarged), and many believe that the practice also has led to treatment of small tumors not likely to progress and that this treatment does not lead to decreased mortality from the disease (Lilja et al., 2008).

it is not clear whether it does more good than harm, linking colorectal cancer screening to prostate screening may not be a good pathway to follow. Dr. Byers added that, "making gender-specific appeals is probably still a good idea, particularly for men." There also was some discussion about whether men are truly less likely to participate in colorectal cancer screening than women. Dr. Vernon observed that prevalence data from the National Health Interview Survey showed the prevalence of such screening is about equal between men and women, and Dr. Lieberman said his data showed that 57 percent of those having colonoscopies are women. But both data sources did not focus on the underserved, which was the focus of the CDC demonstration program.

Dr. Ganz also pointed out that people are more likely to follow up on a recommendation for colonoscopy if it comes from a trusted source, such as the clinic where the patient has been going regularly. Dr. Seeff concurred, pointing out that the Suffolk County, NY, program was based on that concept and has been very effective.

Other discussion explored what screening message to give the public. "The battery of tests is long and ever-growing and may be a barrier," Dr. Seeff said. "Are we ready to embrace colonoscopy? I don't know, but I think there are considerations with FOBT, such as the low return rate, the many steps needed to bring people back. Simplifying the message somehow is very important," she added.

EMPLOYER-BASED INITIATIVES TO INCREASE SCREENING

The last speaker of the first day of the workshop was Ms. Ann Skye, a registered nurse and the Quintiles Transnational Corporation Employee Wellness Program Manager. Quintiles is a clinical research organization with 20,000 employees globally in about 50 countries. Nearly 6,000 of its employees are in the United States and affiliated with 16 offices throughout the country, although nearly half of its employees are home based. Ms. Skye spoke about the 2-year-old Quintiles wellness program that was started by Quintiles Chief Executive Officer (CEO) Dennis Gillings, who is committed to early cancer detection. Ms. Skye described the company's efforts to develop strategies to promote colorectal cancer screening among its employees, via participation in groups such as the CEO Roundtable on Cancer and its CEO Cancer Gold Standard™, and via implementation and analysis of the Quintiles wellness program. Both the CEO Roundtable on Cancer and its CEO Cancer Gold Standard informed the creation of the Quintiles wellness program; their objectives are shown in Boxes 4 and 5. Because of the CEO's commitment to early detection of cancer, the program is not completely driven by revenue or cost savings, Ms. Skye noted, and the preventive tests and screening are free for company employees.

BOX 4
CEO Roundtable on Cancer

Mission: To develop and implement initiatives

- Reduce the risk of cancer
- Enable early diagnosis
- Facilitate access to best available cancer treatment

NOTE: CEO = Chief Executive Officer.
SOURCES: Skye presentation (February 25, 2008) and http://www.ceoroundtableoncancer.org.

BOX 5
CEO Cancer Gold Standard™

Five areas of focus: The five "Pillars"

- Tobacco use
- Diet and nutrition
- Physical activity
- Screening and early detection
- Access to quality care and clinical trials

NOTE: CEO = Chief Executive Officer.
SOURCES: Skye presentation (February 25, 2008) and http://www.cancergoldstandard.org.

The wellness program consists of onsite health and wellness events at all offices and at some of the gatherings for home-based employees. These events have a cancer awareness booth and a cancer educator providing age- and gender-specific recommendations and materials. A monthly cancer newsletter is also provided electronically to all employees, who are encouraged to log on to the company's interactive website, which includes videotaped health messages from Quintiles Chief Medical and Scientific Officer Oren Cohen, M.D., and has links to medical library resources, clinical trial search engines, and in-depth content. Those that log on to the site are given the option of having age- and gender-specific

health reminders sent by e-mail. In 2008, the wellness program began offering employees a $50 incentive to complete their health risk appraisal, which includes questions about colorectal cancer screening. The program relied heavily on the Internet to spread the message about colorectal cancer screening because of the decentralized nature of Quintiles, the great expense involved with doing mailings, and the fact that everyone at the company has a laptop and uses their computer regularly.

Since the program began 2 years ago, more than one-third[22] of Quintiles' employees who have access to onsite events[23] have attended a health and wellness event, and about one-third of all employees opened the March 2007 electronic newsletter, which focused on colorectal cancer. During that time, the rate of employee colorectal cancer screening went from 40 to 49 percent. "So we are not really doing any better than anyone else in this area," Ms. Skye said.

The remainder of Ms. Skye's presentation focused on what could help employers at mid- to large-sized companies promote colorectal cancer screening to their employees. "If employers like us just get a little bit of help, we can make a huge impact on screening rates because there are a lot of employed people in this country." Ms. Skye suggested support and guidance for metrics and data collection and analysis aimed at understanding what initiatives are making an impact. She also suggested putting pressure on health care plans to provide employers with prevention-focused plans with no copayments, deductibles, or caps on preventive screening measures, and more transparency and accountability. Ms. Skye also suggested health plans be flexible to quickly accommodate changes in practice guidelines, and to include screening for high-risk individuals. She recommended employers consult the *Purchaser's Guide to Clinical Preventive Services*, which is aimed at employers and put out by the National Business Group on Health (Campbell et al., 2006).

Sharing implementation and promotion ideas and tools, such as best practices and what has worked at other companies, would also be beneficial, Ms. Skye suggested. Guidance is also needed on regulatory compliance with the privacy component of the Health Insurance Portability and Accountability Act (HIPAA) and other regulations. "There is some confusion among wellness managers out there in terms of how far we can go with reminders based on sex and age," she said. In the discussion following Ms. Skye's presentation, Dr. Ganz noted that when the University of

[22]Recent cumulative data suggests about 42 percent. Personal communication, A. Skye, Quintiles Transnational Corporation, May 14, 2008.

[23]This group includes all office-based employees as well as home-based employees who attend annual meetings—about 75 percent of all Quintiles employees. Personal communication, A. Skye, Quintiles Transnational Corporation, May 14, 2008.

California offered employees $75 to fill out a high-risk assessment and get specific health recommendations, there was resistance from employees, particularly unionized employees, who were concerned about privacy issues, even though they were assured the information would not be shared. Ms. Skye noted that when Quintiles employees fill out their health risk appraisals, they sometimes ask who is going to see the data, but most are satisfied when told the data are going to a third party.

Ms. Skye also made a few suggestions on what would help small-sized companies boost colorectal cancer screening rates of their employees. These suggestions included access to or partnerships with community resources for education, awareness, and screening services, as well as tax incentives for providing proactive, evidence-based benefits packages.

In the discussion following Ms. Skye's presentation, she noted that about 65 percent of the participants in a recent wellness program were women, even though the employees at headquarters, where the program was held, are split equally between men and women.

STRATEGIES TO MONITOR PERFORMANCE

Mr. Philip Renner, assistant vice president for quality measurement of the National Committee for Quality Assurance (NCQA),[24] began the second day of the workshop by presenting his agency's mission to improve the quality of health care through measurement, transparency, and accountability, and describing how that applies to colorectal cancer screening. He explained that NCQA accredits health plans using performance data and publicly reports those data. The organization also has physician recognition programs and measures quality in provider groups. Within the objective to improve the quality of health care is to foster movement toward a value-based health care system, which is illustrated in Figure 12. NCQA does not yet have a program centered on prevention or screening, but may in the future, he said. About 84 million Americans are in an accountable health plan that reports data to NCQA, including colorectal cancer screening data.

Many types of measures can be used to assess the quality of colorectal cancer screening, Mr. Renner said, including clinical measures of how many people are screened and how often; patient experience, such as access or waiting times; practice systems, such as the use of registries and reminders; and the following of standards. Such measures given to consumers or providers can be incentives for improvements in quality, Mr. Renner pointed out.

[24]See http://www.ncqa.org.

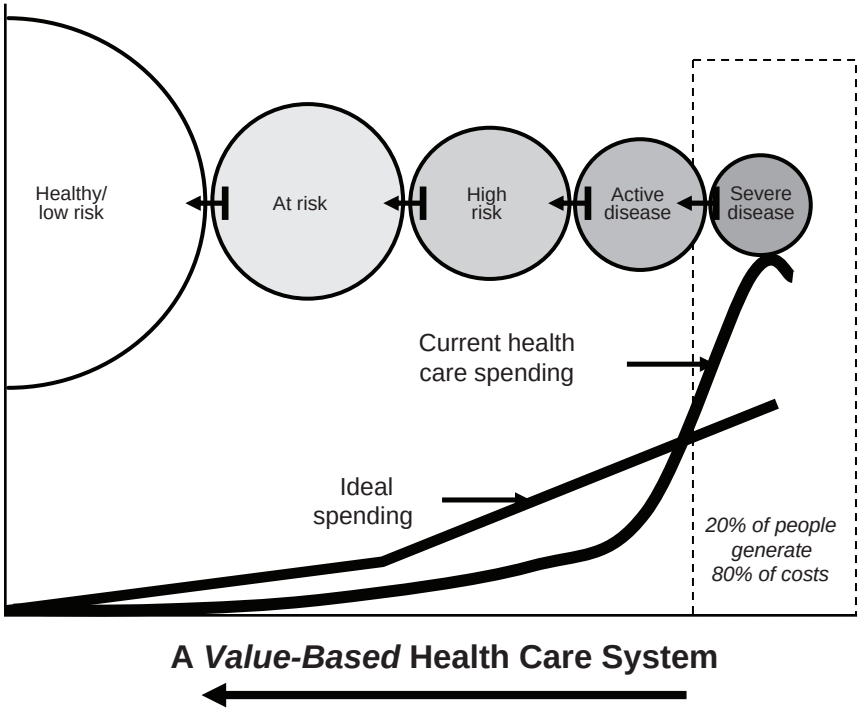

FIGURE 12 Vision for value-based health care. When health care succeeds in providing preventive care, then medical costs are concentrated away from less cost-efficient treatments for active and severe disease. SOURCES: Renner presentation (February 26, 2008), NCQA, HealthPartners, and Halvorson and Isham (2003). Reprinted, with permission, from Nico Pronk, HealthPartners, 1998; George Isham, HealthPartners and Partnership for Prevention, 2002; Halvorson and Isham, 2003; and NCQA, 2005.

The 2008 NCQA Healthcare Effectiveness Data and Information Set[25] (HEDIS) found that about half the people in both commercial and Medicare plans have adequate colorectal cancer screening coverage. Screening frequency within commercial plans has increased about 5 percentage points since the NCQA began collecting these data 3 years ago, with Medicare staying consistent during that time period, for unknown reasons. There is about a 23 percentage point difference between the lower performing and the higher performing plans, Mr. Renner pointed out. If

[25]See http://www.ncqa.org/tabid/536/Default.aspx.

colorectal cancer screening performance was brought up to the optimal 90 percent, which 10 percent of plans have already achieved, 6,000 to 12,000 more lives would be saved, he said (NCQA, 2008a).

NCQA will reassess colorectal cancer screening every 3 years, Mr. Renner said. When the updated recommended screening practice guidelines come out this year, NCQA will convene a workgroup to assess changes in measurements that might be needed to accommodate changes in the guidelines. "We'll assess if the evidence or the health care system has evolved enough that the measure doesn't make sense or it isn't measuring the right thing anymore," he said. But he noted that specifications for the way NCQA measures performance are already frozen in place for the remainder of the year. "So if CT colonography and fecal DNA are added this year to the guidelines, we still won't be able to capture that for this year, although we would be able to potentially add that into the specifications for data that are submitted in 2009 on performance in 2008."

In the discussion that followed Mr. Renner's presentation, Dr. Pignone asked what it takes to develop a program of excellence in prevention and how long it takes to move from idea to implementation. Mr. Renner responded that it takes about a year or more to develop a program of excellence and that all it takes to start such a program is "somebody who wants it. We see organizations like Bridges to Excellence[26] or health plans which are using these as part of their pay-for-performance programs or other tiering or to put a gold star next to a physician's name in a provider directory." Demand and interest in a program of excellence addressing screening for preventive care has not been the same as chronic conditions such as diabetes, he said.

Dr. Byers noted that one of the problems with HEDIS is the narrow type of plans that report to it, and asked how to encourage wider surveillance of clinical preventive services across different types of plans. Mr. Renner responded that the NCQA receives HEDIS data on about 90 percent of the HMO plans because there are state, federal, and purchaser mandates for collection of that data by many managed care plans. The NCQA has just begun collecting data from the preferred provider organization (PPO) plans in the past few years, Mr. Renner said. Such efforts will be aided by federal employee benefits plans, which have begun requiring some of these measures. Many of these federal employee benefits plans are PPOs.

Dr. Coates pointed out that the Washington State Medical Association[27] was working with health plans within the state so that individual-level identifiable data were being shared among health plans to provide

[26]See http://www.bridgestoexcellence.org/.
[27]See http://www.wmsa.org.

reports back to primary care physicians about which of their patients had received recommended preventive services within the interval suggested. He asked Mr. Renner if this was occurring elsewhere as well. Mr. Renner responded that he thought it was happening in a few other places, such as in Minnesota, but "it is definitely not the norm. We have tried to enable some regional collaboration and data aggregation efforts, and the plans have been very uncomfortable with sharing or pooling data."

INTERVENTIONS TO ADDRESS COSTS OF DEVELOPING AND MAINTAINING SCREENING PROGRAMS

Colorectal Cancer Screening in Primary Care

The next speaker, Dr. Carrie Klabunde, epidemiologist in the Health Services and Economics Branch of NCI's Division of Cancer Control and Population Sciences, addressed colorectal cancer screening practices in primary care and what elements encourage such screening. As she pointed out, screening guidelines are largely implemented through the efforts and activities of individual primary care practices. Consequently, NCI, AHRQ, and the CDC undertook a national survey of more than 1,000 office-based primary care physicians, such as family physicians, general practitioners, general internists, and obstetrician-gynecologists, to assess their implementation of screening guidelines for colorectal, cervical, and breast cancers. The results of this survey formed the bulk of her presentation.[28]

The survey results indicated that about two-thirds of U.S. primary care physicians are in small practices of five or fewer physicians and are largely single-specialty practices. About half the physicians routinely recommended two modalities—FOBT and colonoscopy—to their average-risk patients, and nearly 15 percent recommended only colonoscopy. A little over 10 percent recommended three modalities: (1) FOBT; (2) colonoscopy; and (3) another test, which was sigmoidoscopy, fecal DNA test, or CT colonography, depending on the practice. These results contrast to those of a 2000 survey (Klabunde et al., 2003) that found the majority of primary care physicians were recommending FOBT and sigmoidoscopy, and a minority recommended colonoscopy and double-contrast barium enema. Less than 5 percent of primary care physicians reported that they are performing sigmoidoscopy, in contrast to the 29 percent who reported doing so in the 2000 survey. "This really is a procedure that primary care physicians have largely, although not completely, abandoned," Dr.

[28]Because the survey results are not in press yet, the specific data she shared at the workshop could not be part of this summary.

Klabunde said. She also pointed out that only 1 percent of physicians recommended FOBT.

The remainder of Dr. Klabunde's talk focused on office-based systems that helped to improve the colorectal cancer screening rates of their patients, because as she pointed out, the majority of physicians routinely recommend such screening, yet only about half their patients adhere to it. The systems the survey explored were the use of EMRs, reminder systems, nurse practitioners or physician assistants, and feedback reports on screening rates.

EMRs can make it easier to systematically institute patient and provider reminders of needed colorectal cancer screening, assuming the EMR system can easily integrate with other health systems databases, such as those of the specialists providing colonoscopies, Dr. Klabunde noted. But more than half the physicians surveyed were still relying on paper charts. When asked if their practice has implemented colorectal cancer screening guidelines, less than one-quarter of those without EMRs responded affirmatively, but nearly half of those with EMRs answered yes. Less than one-third of practices surveyed had a system for reminders to physicians, and even fewer had a system of reminders to patients.

About half the physicians reported their practices had one or more nurse practitioners. These professionals can help time-burdened physicians carry out discussions about colorectal cancer screening with their patients. Only 10 to 20 percent of physicians were receiving feedback reports on the screening rates of their patients. The larger the practice, the more likely it was to have EMRs, use a nurse practitioner or physician assistant, or provide physicians with reports of their screening rates. But less than 0.5 percent of the physicians surveyed had EMRs, a nurse practitioner or physician assistant, a reminder system, and were receiving reports on the screening rates of their patients, Dr. Klabunde pointed out. "The office systems to support colorectal cancer screening recommendations and activities are really not very well established in primary care physician practices," she said.

Dr. Klabunde then discussed the cost implications of establishing such supportive office systems. The average salary for an office-based physician assistant or nurse practitioner is about $100,000 annually including benefits,[29] whereas the costs to implement an EMR system vary by system functionality and practice size. The initial start-up costs of an EMR system per full-time provider can range from $24,000 to $44,000, and have additional ongoing costs, studies suggest (Table 8; R. H. Miller and West, 2007; R. H. Miller et al., 2005b; Wan and Wang, 2003). A reminder/tracking system can be established in the absence of an EMR system, Dr. Klabunde

[29]U.S. Bureau of Labor Statistics, 2006; see http://www.bls.gov/bls/wages.htm.

TABLE 8 Electronic Medical Record Financial Costs per Full-Time Equivalent Provider, by Health Care Setting

	Initial Costs (software, hardware, lost revenue, etc.)	Ongoing Costs (software maintenance, replace hardware, etc.)
Integrated health care system (2002) (Wan and Wang, 2003)	$24,300	$4,374
Six community health centers (2004–2005) (R. H. Miller and West, 2007)	$53,978	$20,610
Fourteen solo/small-group practices (2004–2005) (R. H. Miller et al., 2005b)	$43,826	$8,412

SOURCES: Klabunde presentation (February 26, 2008) and R. H. Miller and West (2007); R. H. Miller et al. (2005b); and Wan and Wang (2003).

pointed out. Studies estimate the incremental cost-effectiveness ratio to range between $43 to $414 per patient screened for such reminder systems, depending on how intensive the intervention (Lairson et al., 2008; Shankaran et al., 2007). It is also possible to generate feedback reports to providers on colorectal cancer screening rates without an EMR system, at the cost of about $47,000, one study found (Wolf et al., 2005). "Office systems to support colorectal cancer screening activities can be quite expensive, particularly for small practices," Dr. Klabunde concluded. "EMRs are a promising office system component, but they aren't currently widely used in primary care, particularly in solo and small group practices," she added.

Although the biggest barrier to implementing supportive office systems is financial, Dr. Klabunde noted, another key barrier is the information technology interoperability or having access to clinical information that crosses practice or organizational boundaries. This interoperability is particularly important to colorectal cancer screening because much of that screening is done by primary care referral to specialists. One study found that of the 252 Medicare beneficiaries who had an endoscopy procedure recorded in Medicare claims, 19 percent had no evidence of the procedure in the primary care physician's medical record, Dr. Klabunde said (Schenck et al., 2007). "In our decentralized health care environment, incentives and initiatives are needed to promote greater health information exchange," she said. Regional health information organizations are

an example of such needed initiatives. "The idea is that you build the health information exchange at the local and state levels, and that ultimately this would create a national health information network. But there is a long way to go with this," she said.

In the discussion following Dr. Klabunde's presentation, Dr. Byers commented that he thought having EMRs was not key to colorectal cancer screening because EMR-generated reminders are more useful for rarer events. "When half of the people in the practice have the need for screening, you don't really need EMRs," he said. He added that because colonoscopies are being done by referral, patient navigation is critical and does not need to be carried out at the professional level of physician assistants or nurse practitioners. "Pass-off systems of navigation into and through screening is what we ought to look at," he said, and Dr. Klabunde agreed. Dr. Ganz, however, reiterated the importance of nurse practitioners or physician assistants for providing preventive services that physicians often do not have time to provide adequately to their patients. "There is going to be a shortage of physicians. Having other providers who can deliver preventive care to patients as part of a team speaks to an environment that is going to probably be more successful in the health care delivery system," she said. Dr. Pignone added that the decision about whether to hire someone with a lower level of training versus a nurse practitioner to do patient navigation "is one of the things we struggle with in all our disease management programs—do you hire the more expensive person you can bill for, or do you hire the less expensive person you can't bill for? That is a difficult management question," he said.

Cost Considerations in Medical Practice

The next speaker was Dr. Richard Wender, alumni professor and chair of the Department of Family and Community Medicine at Thomas Jefferson University and immediate past president of the American Cancer Society. Dr. Wender addressed the costs of colorectal cancer screening in primary care practices. Dr. Wender prefaced his talk by highlighting research that confirms some of the findings given by previous presenters: most primary care practices have only two to five clinicians, primary care providers are overworked, they must constantly set priorities on what they are going to address, they work on the margins of financial viability, and they have little time for self-reflection (Crabtree, 2003; Green et al., 2001; Grumbach and Bodenheimer, 2002; Stange et al., 1998). In addition, most primary care providers do not have training in quality improvement or organizational management.

Dr. Wender noted that primary care clinicians have two main concerns about costs of colorectal cancer screening: whether the patient can

afford the test and whether the physician can bill for the service (Ubel et al., 2003). He added that because explaining screening options to patients takes up time for which they will not be reimbursed, there is often a financial *dis*incentive to implement such screening. Prevention activities in general are perceived as not reimbursable or, at best, partially reimbursable, Dr. Wender said, and the greater complexity of colorectal cancer screening compared to other prevention screening, such as the simple blood test for prostate-specific antigen (PSA), is an additional impediment to implementation. Perceived payment for in-office digital rectal FOBT and in-office development (analysis of the test) are supporting these non-evidence-based practices, but Medicare and other payers are increasingly not reimbursing for such activities, Dr. Wender added.

Dr. Wender then used the findings from two studies to list some characteristics of high-performing practices (Hung et al., 2006; Orzano et al., 2007). These included leadership, greater staff involvement, and a greater investment in people—as opposed to higher investment in technology, for example. Included under the category of investment in people is involving staff in decision making, which leads to higher staff retention, productivity, and practice satisfaction, and soliciting staff feedback through everyday discussions, as opposed to just regular staff meetings. In addition, Robert Wood Johnson Foundation–funded pilot programs to improve quality health care delivery found that health behavior change resources are enthusiastically received by all; that patients prefer personal contact methods; and that practice extenders, such as nurse practitioners, require extensive training, careful case management, and support, Dr. Wender reported (Cohen et al., 2005). These pilot programs also found that integrating tools requires practice changes, even for small interventions, that are best instituted with the use of a model and specialized expertise. "So if you consider a referral for colonoscopy to be a simple intervention," Dr. Wender said, "to really have practices adopt it and change you still need to study how to make that change happen."

Dr. Wender cited a study which found that the 37 practices *not* using EMRs of the 50 practices studied were generally more likely to meet diabetes outcomes (outcomes measured included glycosylated hemoglobin as a percentage of total hemoglobin, low-density lipoprotein cholesterol level, and blood pressure) than the 13 practices using an EMR system (Crosson et al., 2007). "Just putting in an EMR system will not improve quality," Dr. Wender said. But he added that a new model of EMR implementation is emerging. This new model is enterprise-wide and is centrally managed using business principles and extensive outsourcing, and the practice redesign preceded implementation of the EMR system. Such EMR systems can be quite expensive, but save costs over time, Dr. Wender pointed out. But this high cost was linked to a rapid return on investment: a recent

study (Grieger et al., 2007) showed that a system costing about $18,000 in the first year produced savings of about $14,000 annually. So, this system paid for itself within 16 months and resulted in annual savings of about $10,000 per physician per year (Grieger et al., 2007). However, whether investment in EMR systems will pay off in improved preventive care is undetermined, Dr. Wender noted.

Another new model that has potential to improve prevention in chronic disease management is the patient-centered "medical home," Dr. Wender pointed out. The essential components of a medical home system are that in addition to each patient having an ongoing relationship with a primary care physician, there is a "whole person" orientation: care is coordinated or integrated, and quality, safety, enhanced access, and patient adherence are closely monitored goals that are boosted with pay-for-performance incentives for physicians. The NCQA certifies patient-centered medical homes based on several standards, which are listed in Box 6. For more information about medical homes, see Appendix D. "A medical home is different than a regular source of care," Dr. Wender said in the discussion following his talk. "You must be able to provide patient registries, and include specific infrastructure that will empower and educate patients. You must have a reminder system, and patients must be able to get in any time they want to see you."

The cost of implementing a patient-centered medical home is estimated to be more than $150,000 per primary care clinician, according to Dr. Wender. That cost is generally funded with enhanced up-front payments for the infrastructure, as well as higher reimbursement for episodes of care, and reimbursement is usually linked to quality performance. Employers and insurance companies may agree to pay more to support patient-centered medical homes with an expectation of eventual cost savings. "New medical home models hold promise, but they will demand significant changes in payment," he said. Dr. Wender added that there have been legislative initiatives at the state and federal levels to change payment models to support the implementation of medical homes.[30] He also commented that the incremental benefit gained from a medical home versus having a regular source of primary care that performs well is not that great. Dr. Wender added that the focus to date in patient-centered medical homes has been much greater on management of chronic diseases, such as diabetes and asthma, than on cancer screening. "I think it is a bit of a leap to say that [a] medical home is well designed to deliver cancer screening," he said.

In the discussion following Dr. Wender's presentation, Dr. Pignone

[30]Federal legislation includes HR 676, HR 2351, HR 2584, HR 3162, S 1364, and S 2376, among others. States pursuing legislation include Minnesota and Texas, among others.

BOX 6
Physician Practice Connections:
Patient-Centered Medical Home Content and Scoring

Standards:

1. Access and communication
2. Patient tracking and registry functions
3. Care management
4. Patient self-management support
5. Electronic prescribing
6. Test tracking
7. Referral tracking
8. Performance reporting and improvement
9. Advanced electronic communications

SOURCES: Wender presentation (February 26, 2008) and NCQA (see http://www.ncqa.org/tabid/631/Default.aspx; NCQA, 2008b).

noted that although the vast majority of primary care physicians recommend colorectal cancer screening, such recommendations are given in a rather random fashion, not systematically. "If the more times you go to the doctor, the more likely you are to be recommended to screen, then that suggests there is not a system there for screening recommendations," he said. "What we have seen from our academic detailing is that doctors usually remember it when they either don't have anything else going on, or if something triggers them to think about the GI tract. That suggests you have to have something that moves the screening reminder up in the priority list. Alternatively, you take screening recommendations out of that encounter where there is everything else on the table, including all the chronic diseases, and do it in some other fashion." Dr. Wender added that although most primary care physicians may be recommending colorectal cancer screening, they do not provide patients with any explicit instructions about how to carry out that screening. "So the patients don't follow up because they are waiting for someone to call them or are thinking maybe they will talk about it next time," he said. "Just recommending and perhaps giving a phone number would not qualify as a high-quality, colonoscopy referral-based primary care system."

Costs of Developing and Maintaining Public Health Colorectal Cancer Screening Programs

The last speaker, Dr. Florence Tangka, an economist in the CDC's Division of Cancer Prevention and Control, presented the economic analysis she and her colleagues conducted on the first year of the CDC's colorectal cancer screening development program that Dr. Seeff described in her talk (Tangka et al., 2008). The analysis team collected four main types of cost data: start-up, annual/implementation, reimbursements for screening and diagnostic services, and costs of complications. Their cost data collection approach can be seen in Figure 13.

When the funding sources were averaged for all five awardees in the demonstration program, CDC funds made up 52 percent and in-kind contributions, including labor and supplies, made up 43 percent, with the remaining funds coming from other sources in two of the sites, Dr. Tangka reported. About 42 percent of those funds were spent on screening as opposed to start-up costs, even though screening was only done for 1 to 3 months, with the remaining months being spent on start-up activities.

The distribution of start-up costs among budget categories can be

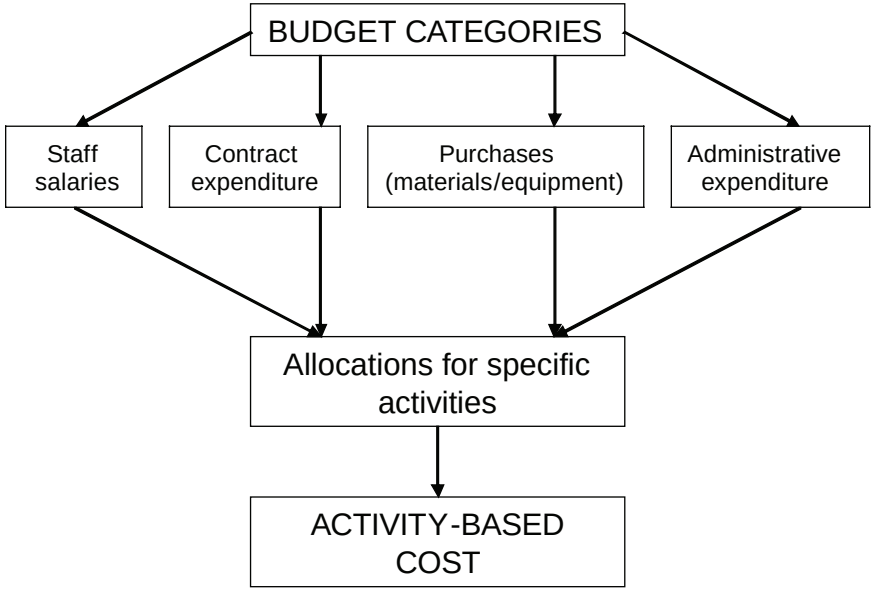

FIGURE 13 Cost data collection approach. SOURCES: Tangka presentation (February 26, 2008) and Tangka et al. (2008).

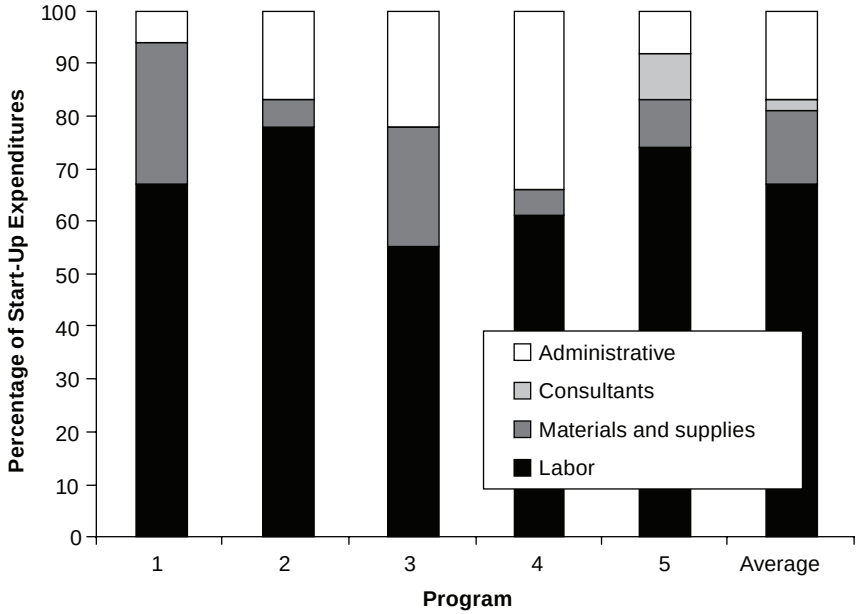

FIGURE 14 Distribution of start-up costs by budget categories for each of the five awardees and averaged across all awardees. Each of the CRCSDP awardees has a different program structure or program model. This graph includes costs from all funding sources (CRCSDP, in-kind, and other). NOTE: CRCSDP = Colorectal Cancer Screening Demonstration Program. SOURCES: Tangka presentation (February 26, 2008) and Tangka et al. (2008).

seen in Figure 14. The largest category was labor, which, on average across the five awardees, accounted for 67 percent of the start-up costs, followed by administrative as well as materials and supplies costs. By activity category, start-up costs varied quite a bit among awardees (Figure 15).

Dr. Tangka then summarized some of the lessons learned from her economic analysis. Start-up costs varied substantially across the five awardees, and the infrastructure available before the beginning of each program and its unique design accounted for some of the differences. She added that in-kind contributions are important sources for programs and should always be included in any economic assessment of the program. She was encouraged that programs can provide detailed activity-based cost information using standardized data collection tools that can then be plugged into economic analyses. Such analyses can be used for planning and for cost projections for a widespread colorectal cancer screening effort. The results from cost analyses or economic analyses can also

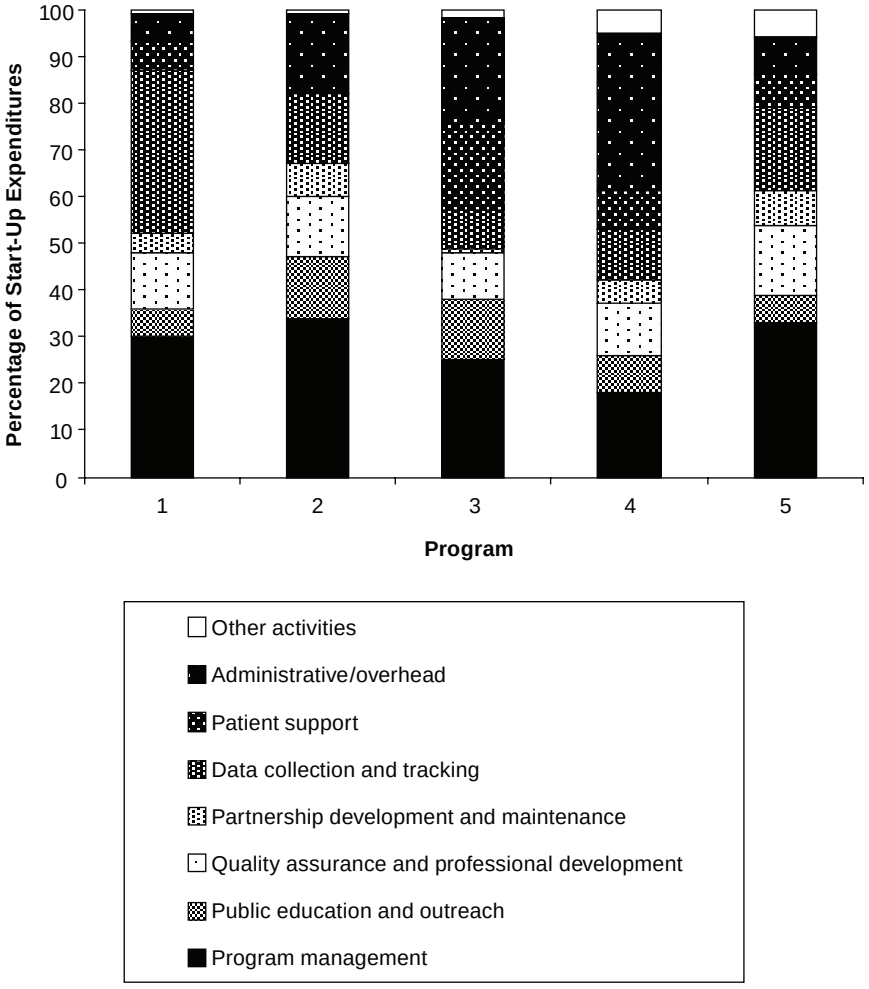

FIGURE 15 Distribution of start-up costs by activity for each of the five awardees. NOTES: Each of the CRCSDP awardees has different program structures/models. This graph includes costs from all funding sources (CRCSDP, in-kind, and other). CRCSDP = Colorectal Cancer Screening Demonstration Program. SOURCES: Tangka presentation (February 26, 2008) and Tangka et al. (2008).

be used for assessing efficiency, setting priorities, and accounting, she concluded.

In the discussion following Dr. Tangka's presentation, Dr. Ganz pointed out that it can be burdensome for staff to report their time by separating it into different activity bins. Although she applauded the

CDC awardees' efforts in this regard, she added that getting staff to comply with providing such detailed records can be difficult. Dr. Tangka responded, "to get high-quality data, there are always tradeoffs. You do this and get high-quality data or you end up with estimates. If we are going to be using this for any expanded effort on colorectal cancer screening, we must try to get as close as possible to the real costs of running this program." She added, in response to another question, that much of this detailed cost information was lacking when the CDC's National Breast and Cervical Cancer Early Detection Program[31] started, although it has been collected for the past 3 years. "What I commend the colorectal cancer team for doing is starting to track the economic costs from the beginning as this really helped inform the program," she said.

GENERAL DISCUSSION AND WRAP-UP

Following the workshop presentations, Mr. Tom Kean, executive director of C-Change, led a discussion among workshop participants on priority actions needed to increase recommended colorectal cancer screening. Mr. Kean first reviewed the workshop by enumerating 10 topics that together encompassed the breadth of issues impacting implementation of screening, as highlighted by workshop presentations and discussions. After Mr. Kean's summary, participants discussed their points of view on methods for increasing screening and how the workshop influenced their opinions on the topic.

Mr. Kean recognized the wide variety of perspectives presented at the workshop, and noted that even so, "there were some threads and themes that wove through many of the conversations during the meeting that I think bear some further attention." The 10 themes highlighted by Mr. Kean were as follows:

- **Colorectal cancer:** The incidence of colorectal cancer has declined since screening was first recommended in 1980. Even so, too many colorectal cancer diagnoses are for late-state disease, and screening rates are still too low. "Every year people are dying from this disease or suffering through more extensive treatment than they might otherwise need," Mr. Kean said.
- **Screening tests:** A fair amount of consensus exists on the current guidelines for colorectal cancer screening. However, the message is complicated by the different tests and intervals at which the tests are performed. Mr. Kean mentioned that even though there seems to be movement toward colonoscopy as the preferred test,

[31]See http://www.cdc.gov/cancer/NBCCEDP/.

this is not necessarily based on evidence of better test sensitivity or specificity. Additional concerns arise as new tests are developed that provide only incremental benefit, but confuse the message to the public about colorectal cancer screening.

- **Quality of screening:** For colonoscopy, in particular, screening often takes place outside the primary care physician's practice. Improving the referral process so that patients are not lost would improve screening rates. Regarding the quality of the testing itself, speakers discussed variability in test results due to different readers for multiple test types and quality of bowel preparation for endoscopic screening. Nonadherence to screening guidelines results in inadequate promotion of screening or the use of non-evidence-based screening tests.
- **Primary care system:** Mr. Kean observed that primary care physicians and their staff are critical to the implementation of colorectal cancer screening. However, the primary care system is under enormous pressure. These physicians deal with significant time constraints due to a large preventive, chronic, and acute care agenda. Financial stability of the practices and incentives for preventive care in primary care practices are also important considerations.
- **Workforce capacity:** It is unclear whether the capacity to fully implement colorectal cancer screening is currently available. On one hand, primary care physicians do not have time to fully implement preventive care in their practices, and there may be long waits for colonoscopy appointments. On the other hand, there may be overuse of colonoscopy. The medical home concept was introduced as a possible route to address workforce issues.
- **Metrics and measurements:** Mr. Kean reiterated a plea from Ms. Skye of Quintiles that "we often hear from community programs and organizations, which is for some advice on what we should be measuring to know whether we are getting where we want to be." Datasets such as HEDIS are helpful in addressing these concerns. Errors and quality of measurements, data standards, and reporting methods were discussed, as well as the apparent spectrum between privacy protections and transparent systems.
- **Costs:** Mr. Kean reported that cost of screening and cost-effectiveness were common themes throughout the workshop: not only the monetary costs of the testing itself, but also the time costs of staff, particularly for small practices. Financial incentives and disincentives to physicians were also seen as affecting colorectal cancer screening implementation.
- **Coverage:** Colorectal cancer screening is generally covered by traditional health insurance plans and Medicare. Beyond lack of

coverage for uninsured and underinsured individuals, however, "we seem to be hearing more and more about the affordability of insurance and the trend to shift more of the cost burden on the employee," Mr. Kean said. This may result in lack of coverage for colonoscopy for more people. "This is at the same time we are seeing increased interest in referrals to colonoscopy," Mr. Kean said. Also, a great deal of variability in screening offerings was highlighted on a state-to-state level, among practice types, and on practice-to-practice and even physician-to-physician levels.

- **Communications:** The content of the message to the public was discussed, as was its place in the general preventive care agenda. Communications between health plans and providers can be improved, as can communications to providers about screening guidelines. Community- and practice-based interventions were shown to be successful, although the data focused on interventions to increase FOBT screening. Data from state and federal demonstration programs showed that large screening initiatives are useful in increasing screening rates and decreasing the incidence of colorectal cancer.
- **Disparities:** During the workshop, several issues of disparities were discussed, including race, gender, age, and insurance coverage. For example, African Americans experience earlier onset of colorectal cancer, suggesting that different screening guidelines might better serve this group. Another topic covered was difference between genders: depending on the setting and types of intervention, there are different screening rates and disease outcomes to be addressed.

After Mr. Kean reviewed the themes that arose from the workshop presentations, he opened the discussion to everyone by posing the question, what are the main ideas that conference particpants had that would help to improve colorectal cancer screening in the United States? Four main topics were discussed: screening implementation, communications, costs and coverage, and the primary care system.

Screening Implementation

The purpose of this workshop was to discuss progress on and how to improve the implementation of colorectal cancer screening. It became evident that, unlike other cancer screening, one of the major barriers is awareness of the need to get screened. Dr. Vernon pointed to the 2005 NHIS (NCHS, 2005) finding that more than 70 percent of the people who have not been screened reported it was due to lack of awareness of the

importance of such screening. "There is a lot of low-hanging fruit out there. I don't think we are going to need a cannon to get a significantly greater number of people into screening," she said. Dr. Ferrell agreed on the importance of paying attention to that finding. "This is strikingly different from other health care concerns I deal with, which are always divided amongst professional, patient, and system barriers. So I don't think we should ignore that," she said. She added that what made cervical cancer screening so effective was the increased awareness of the need for it by patients, which led to them demanding the testing from their providers. "The need is to get the public message out that you should request screening, and that might be a greater return on our investment overall," she said.

Dr. Lieberman reinforced the importance of increasing patient awareness about colorectal cancer screening. He and his colleagues documented the important effect Katie Couric had on boosting screening rates by having a televised colonoscopy (Cram et al., 2003). But Dr. Fletcher and Dr. Seeff pointed out that there already are public campaigns to increase awareness of the importance of colorectal cancer screening. They wondered whether the message needs refinement, but said they believed there was not a lack of awareness efforts. "I think maybe there is just a part of the population that is not hearing the message," Dr. Seeff said.

Dr. Ganz noted that there are two different communities that have to receive messages about colorectal cancer screening—the public and the physicians. For the public, the message should be simple: You should get screened to prevent cancer. The message for physicians as to which test to pursue depends on what might be best in their community. A local organization that has the infrastructure to track FOBTs might do better with that option, for example. "We may not necessarily have the same message to the public as we do to the provider community," she said. Dr. Durado Brooks of the American Cancer Society added that it is important to improve the messaging to the provider community because the second most common reason people give for not undergoing screening is that their doctor never told them they needed it. "We need to try to figure out our messaging to physicians, and also the avenues for providing those messages—we need to know who primary care physicians are listening to and who influences them. Providing incentives is one way to think about it, but some of it is simply raising their awareness of the fact that they have probably got patients who are going to die because they didn't offer this test," he said.

Mr. Kean then pointed out the fair amount of agreement on the importance of boosting the awareness effort aimed at the public that encourages a demand for certain preventive health services, including colorectal cancer screening. There also was agreement, he said, that screening should

be promoted and that there should be integration of all the public messages about preventive health measures. Some segments of the population should not be too difficult to reach, he said, and "we ought to be thinking about identifying these people and how we might reach them. We may be able to get some fairly quick incremental gains, perhaps as much as a 20 percentage point increase in screening with minimal effort."

Communications

Effective interventions to increase screening focus on communication to patients and providers about the need for screening. During the workshop, speakers described screening efforts at many levels, and the discussion led to several common themes. Ms. Skye said, "We are overlooking a fantastic resource, which is an educated and empowered patient base." She noted that it takes six exposures to a message before someone will act on it, on average, "so going to the doctor and hearing it once isn't going to be enough. You have to put it in an e-mail, on a poster, etc." Although she endorsed the idea of a preventive care reminder checklist, she added that to be effective, use of a checklist will require a cultural shift that makes patients take responsibility for their own preventive health. She suggested simplifying current template checklists that are based on gender and age and tailoring them more to the individual. Mr. Kean added that the public is getting multiple messages about preventive care measures from multiple sources, and that messaging must be consistent. "We need to look for ways to make this a more integrated national push. We are out there with our colorectal cancer screening message, but so are the diabetes people and everybody else, not to mention the nonhealth people. Consequently, the public is very confused," he said.

Dr. Coates commented on the conflicting messages about which colorectal cancer screening practices to recommend to the public. "If the U.S. Preventive Services Task Force and the ACS and other groups are coming out with conflicting recommendations, we should focus on where there is agreement, not where there is disagreement," he said. Openness and flexibility are needed when recommending screening tests to accommodate the preferences and capacities of different communities, he said. Dr. Seeff agreed that there needs to be test choice tailored to the community. Dr. Wender noted that his practice changed from recommending all screening modalities to only recommending colonoscopies because "we felt we had a far greater capacity in our community to deliver something that had a longer interval than annually," he said. But not all people have access to and can afford colonoscopies, Dr. Seeff pointed out. Dr. Levin added, "We are dealing with an imperfect menu, and restricting the choices is unwise at this point. It is likely that colonoscopy will continue

to dominate, but excluding the others excludes a significant segment of our population, and that seems unwise and unfair."

Dr. Seeff added that the colorectal cancer screening message to the public does need to be simplified. "This battery of tests has been a persistent barrier, and the test list, which is continuing to grow, is going to further complicate things," she said. Dr. Ferrell agreed that a clear message about colorectal cancer screening is needed. "There's a clear message in saying you need a mammogram—the public and the professional get it. I'm not sure we have a clear message for colorectal cancer screening, and we have all learned over the last 30 years that without the clear message, everything else is not going to work. So I would want to make that the top priority," she said.

Yet there was discussion of the shortcomings of the breast cancer screening message. Several participants brought up the need for clinical breast exam in addition to mammography. Dr. Ganz said, "Once a certain level of compliance or adherence to a recommendation is reached, you then have to backfill if there are ways to enhance the sensitivity of your strategy." Participants discussed ways to apply this lesson to colorectal cancer, to make the message more specific and more effective without sacrificing clarity. Dr. Wender noted that because of the concern about an inconsistent message, the National Colorectal Cancer Roundtable hired a firm to come up with a single message, which was to get screened for colorectal cancer. But this message was not effective because it did not give a specific message about what action to take to get the screening, behavioral experts pointed out.

There was discussion about whether or not it would be helpful to convey that screening can prevent colon cancer. Dr. Lieberman commented that if the message is extended to include the prevention message, there is a potential conflict: a situation where a patient goes to their provider for a test that will prevent colorectal cancer but then are told they are receiving a test to detect early cancer. Mr. Kean added that focus groups have shown that many people do not believe cancer is preventable, but they do believe you can reduce the risk of cancer. "If you talk with them in terms of reducing your risk instead of prevention, they are more likely to listen to exactly the same message," he said.

Dr. Vernon said there is enough evidence that sending patient and provider reminders and reducing non-financial structural barriers to screening can improve screening rates, and pursuing those measures should be a high priority. However, Dr. Fletcher cautioned against trying to do too many interventions at once, and urged considering local issues and doing a few interventions well rather than carrying out multiple interventions poorly. He also suggested publishing the details of interventions that do work. "There are a number of us who are talking

to journal editors and others to try to find ways to allow space to include information on interventions," he said. Dr. Mercer suggested using the Internet to publish this information. Another suggestion from Dr. Fletcher was for researchers to use consistent metrics so there is enough evidence to recommend various interventions or to convince Congress that these interventions are cost-effective.

Costs and Coverage

Costs of screening are important to patients, practices, and payers. Insurance coverage facilitates screening, as do state and federal screening programs. Issues of costs and cost-effectiveness of screening in national screening programs, national health plans such as Medicare, and proposed national health care were also discussed. Dr. Levin observed that Dr. Seeff and others have preliminary data that screening in the pre-Medicare age groups would potentially save billions of dollars in the Medicare population. Dr. Seeff concurred that much of the cost would be deferred or prevented because cancer is prevented. Dr. Levin added that there is a huge differential in cost between treatment of early disease and late disease, with the cost of treating advanced colorectal cancer over one year being about $300,000. But Dr. Thorson added, "We all know that the older we get, the more expensive we get—ultimately we are going to have more expense, so from the entire system standpoint, we may not have as much savings as we anticipate up front." Dr. Vernon added that until there is universal health care, there also should be some system-wide measures to improve screening within HMOs, the Veterans Administration, or other major health care systems.

Dr. Coates suggested improving insurance coverage of screening by having insurers fully cover recommended screening services and making such coverage clear in their plans, and by supporting state and federal community-based programs that pay for such screening in the uninsured and low-income populations. Dr. Byers agreed with the suggestion to provide funding for colorectal cancer screening among the underinsured, and added that when funding a CDC program to address that, such funding should be adequate and not done "in a small token way that takes the heat off the problem but doesn't solve it. We should not repeat the mistake we have made in breast and cervical cancer programs of chronically underfunding the effort." He also suggested creating a single-payer system for clinical preventive services in the United States by lowering the age eligibility requirement for Medicare's clinical preventive services package to age 50 because starting it at 65 is too late. "It would be more efficient, and we would have healthier people going into Medicare where the treatment side is picked up," he said.

Dr. Lieberman endorsed Dr. Byers's suggestion for lowering the age eligibility requirement for Medicare recipients. That suggestion might be supported by a cost argument, he pointed out, because so much of cancer care is deferred to the Medicare-aged population. "If we can develop preventive strategies at a younger age, we end up averting those Medicare costs," he said.

Mr. Kean noted some agreement that there should be a national program to address the uninsured and underinsured, and that this program should be sufficiently funded and evidence based. He mentioned the divergent opinions on whether the program should involve a switch to a national health care system that provides preventive services or more incremental changes that support colorectal cancer screening alone, but added there was agreement that "we need to find some way to provide universal access to screening."

Associated with the issue of universal health care is the need to show that colorectal cancer screening has some cost-effectiveness benefits, Dr. Seeff added. "To make this an acceptable priority, we need to show that there actually is some cost relief," she said. Dr. Zauber added the need to know not only cost-effectiveness, but also actual costs of the various screening measures, including the costs of complications. Dr. Pignone added that updated models are needed that reflect the current costs of colorectal cancer treatment because there will be cost avoidance as a benefit of screening. Dr. Fletcher added that doing a cost–benefit analysis is difficult in the current context of having multiple payers, including private health insurers up to age 65 and Medicare thereafter, because Medicare and not the private insurer benefits from preventive health measures for younger patients covered by private insurers. "If there were a single payer, then all the screening tests have more or less the same cost-effectiveness from society's perspective," he said.

Primary Care System

In addition to the discussion of a national colorectal cancer screening program and the potential benefits of universal health care, there were discussions of changes to the current primary care system that could help improve colorectal cancer screening. Dr. Coates suggested more financial support and incentives for primary care physicians to conduct preventive health counseling and tracking, or hire ancillary staff to perform those activities in their practices. Dr. Thorson built on that by suggesting the development of a system for preventive care that relies less on higher paid primary care physicians, who are trained to be diagnosticians, and more on less expensive nondiagnosticians. "We are talking about telling people to get a colonoscopy and get their blood pressure and blood sugar

checked at a defined frequency. Do we need a diagnostician, who is a very expensive person, to do that? I don't think we do," he said.

Dr. Coates suggested improving, expanding, and making more transparent a system for tracking screening performance. Such a system would operate at the patient/physician level with screening reminders, at the practice level in the form of feedback of screening rates, and at the population level to ascertain demographic characteristics and disparities in screening. This tracking could help to identify individuals to act as champions to increase screening in practices that are at low levels of screening, lead to a culture of improvement, and help to provide incentives for practices with insufficient screening rates that might be motivated to undergo more education and training, Dr. Coates said. Dr. Vernon agreed with Dr. Coates that more integrated systems are needed that allow surveillance of screening and identify those who need screening.

Regarding the use of patient and provider reminders, Dr. Wender pointed out that practices with EMRs that provide regular reminders quickly learn to ignore all those reminders because there are too many of them to monitor, and not enough time to address all of them. Dr. Pignone concurred and said, "There is not just one way to do reminder systems: there are good ways and bad ways." Reducing the number of reminders by prioritizing may be helpful, he said.

Dr. Lieberman advocated for increasing colorectal cancer screening rates by fostering better connections between primary care physicians and gastrointestinal specialists, including more communications and electronic interoperability between the two groups, and improved patient access and navigation so that a primary care physician's recommendation for screening is more likely to be carried out. "These are quite doable, and there are some models for doing them," he said. He also advocated that colonoscopists provide good reports with clear recommendations for how to proceed in the future with surveillance. Dr. Pignone added that gastroenterologists should have a registry for those patients on whom they have done a colonoscopy and be responsible for surveillance reminders, even if those reminders are also being given out by the primary care physician. "If there was dual responsibility there wouldn't be a problem. Both belt and suspenders would probably work pretty well there," he said. Dr. Wender stressed the importance of developing high-quality colonoscopy-based screening strategies, which would include patient navigation, adequate bowel preparation, and quality colonoscopy procedures, reports, and tracking.

Mr. Kean cited the numerous suggestions for supporting primary care, "attempting to shore up the system," as well as connecting the gastrointestinal community with primary care providers in a more integrated fashion that results in good navigation, good communications, and high-

quality reporting. He also reiterated the suggestion that the components of a good system be delineated, beginning with primary care, moving through specialty care and subsequent follow-up. He ended his summary by noting the concern of many for more standardized information about interventions reported in a consistent manner, and more cost data collected and considered in cost-effectiveness analyses.

Final Words

Many workshop presenters and participants believe the implementation of colorectal cancer screening faces several challenges that need to be addressed: awareness of the need for screening, the messages received by patients and providers, costs and coverage of screening, and facilitation of screening within the primary care system. Likewise, many workshop presenters and participants believe that increased screening will save lives through prevention of colorectal cancer, and it will decrease treatment costs and intensity through earlier diagnosis of cancers that do occur. There is reason to move quickly to determine the best paths forward: Dr. Seeff commented that although the general perception has been that systems to encourage and implement colorectal cancer screening were not yet well defined, in reality the field is evolving rapidly. "I think that may have been the case, but I think we are moving fast and furious. There are something like 15-plus states that are now moving toward organizing screening. So I think that makes it all the more important that we help keep the agenda moving forward," she said.

Acronyms

ACRIN	American College of Radiology Imaging Network
ACS	American Cancer Society
AHIP	American Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
CDC	Centers for Disease Control and Prevention
CEO	chief executive officer
CISNET	Cancer Intervention and Surveillance Modeling Network
CORI	Clinical Outcomes Research Initiative
CRC	colorectal cancer
CT	computed tomography
DNA	deoxyribonucleic acid
EMR	electronic medical record
FIT	fecal immunochemical test
FOBT	fecal occult blood test
GAO	Government Accountability Office
GI	gastrointestinal
HEDIS	Healthcare Effectiveness Data and Information Set
HIPAA	Health Insurance Portability and Accountability Act

HMO	health maintenance organization
HSA	health savings account
ICSI	Institute for Clinical Systems Improvement
IOM	Institute of Medicine
NCI	National Cancer Institute
NCPB	National Cancer Policy Board
NCPF	National Cancer Policy Forum
NCQA	National Committee for Quality Assurance
NHIS	National Health Interview Survey
OEPC	Oregon Evidence-based Practice Center
PPO	preferred provider organization
PSA	prostate-specific antigen
SEER	Surveillance Epidemiology and End Results
TFCPS	Task Force on Community Preventive Services
USPSTF	U.S. Preventive Services Task Force

Glossary

Adenoma—a growth in the epithelial layer of the colon. Growths can be flat, pedunculated, or sessile. They result from multiple genetic mutations arising from environmental or inherited causes. Colorectal adenomas can progress to become cancerous.

Adherence—how closely patients comply with recommended medical treatment, therapy, or testing.

Cecum (cecal)—a pouch-like section of the ascending colon, located where the small intestine joins the large intestine (colon). For colonoscopies, this is the farthest point from the rectum observed using the procedure.

Co-insurance—the percentage of medical care costs covered by an insured individual beyond the deductible. In many cases, co-insurance is paid by the insured individual until a predefined limit is reached, after which all costs are covered by the health care plan. Co-insurance also is used to refer to supplemental insurance used to pay the fees not covered by the primary health care plan. Co-insurance is often synonymous with "copayment" which is often shortened to "copay."

Colon—begins at the end of the small intestine. The components of the colon, in order of the anatomy, are: the cecum, ascending colon, hepatic flexure (the turn near the liver), transverse colon, splenic flexure (the turn

near the spleen), descending colon, and sigmoid colon. The colon ends at the rectum.

Colonoscopy—an endoscopic procedure used to detect colorectal polyps and cancers. Colonoscopy uses an imaging scope inserted through the rectum and colon, up to the cecum. Adenomas larger than 1 cm are often removed during the procedure. This is also known as optical colonoscopy.

Copayment—the percentage of medical care costs covered by an insured individual beyond the deductible. Copayment is often shortened to "copay," and is often synonymous with "co-insurance." See also Co-insurance.

Crohn's Disease—a type of inflammatory bowel disease which is characterized by chronic inflammation of the digestive tract. In Crohn's disease, this inflammation is usually located in one or both of the ileum or colon, but it can occur anywhere in the digestive system. In addition, the inflammation may occur throughout all layers of the intestine. Symptoms include abdominal pain, bleeding, or diarrhea.

CT colonography—computed tomography colonography, also known as "virtual" colonoscopy. In this procedure, a 3-D, "fly-through" representation of the colon is created using computed tomography; it can be examined by a radiologist in the same way as an optical colonoscopy. Computed tomography is a radiographic technique that uses a computer to assimilate multiple X-ray images into two-dimensional, cross-sectional images or a 3-D image. Use of this technique can reveal many soft-tissue structures not shown by conventional radiography.

Double-contrast barium enema—an X-ray procedure used to visualize the interior anatomy of the colon. To provide contrast, a barium enema is first administered, followed by insertion of air into the colon. The procedure is called double-contrast due to the contrast-enhancing properties of both the barium and the air. After both contrast agents are in place, an X-ray machine is used to image the colon.

Dysplasia—abnormal cells, possibly precancerous.

Endoscopist—person who performs endoscopies.

Endoscopy—use of a camera inserted into the body to determine the physical appearance of internal organs or tissues. Colonoscopy and flex-

ible sigmoidoscopy are common types of colorectal endoscopy. The term endoscopy also refers to examination of the upper gastrointestinal tract (i.e., mouth, esophagus, stomach) using the same methods.

Fecal DNA test—a test using genetic signature to predict presence of colorectal polyps or cancer. The fecal samples examined contain DNA from exfoliated colorectal cells.

Fecal immunochemical test—FIT. This is a home-administered test to detect blood—specifically hemoglobin—in a patient's stool. Blood in the stool may indicate bleeding colorectal adenomas or carcinomas. The patient prepares the sample and then mails it to the laboratory for development and detection. If a positive result is found, colonoscopy is indicated.

First-dollar health coverage—health insurance that begins paying benefits with the first use of services, not only after payment of a deductible.

Flexible Sigmoidoscopy—an endoscopic screening method for detecting colorectal polyps and cancer. Like colonoscopy, flexible sigmoidoscopy uses an imaging scope inserted through the rectum and colon. Unlike colonoscopy, however, flexible sigmoidoscopy only investigates the rectum, sigmoid colon, and descending colon only.

FOBT—fecal occult blood test. This is a home-administered test to detect blood in a patient's stool. Blood in the stool may indicate bleeding colorectal adenomas or carcinomas The patient prepares the sample, then mails it to the laboratory for development and detection. If a positive result is found, colonoscopy is indicated.

Hyperplastic—pertaining to increased cell proliferation, but where the cells remain essentially normal.

Inflammatory Bowel Disease—a series of diseases affecting the colon and other parts of the digestive system. The two main types of inflammatory bowel disease are Crohn's disease and ulcerative colitis.

Intubation—insertion of an endoscope or other instrument into a bodily orifice. In the case of colonoscopy or sigmoidoscopy, this refers to insertion of the endoscope into the colon.

Medicaid—a state-administered health care program for specified groups of low-income individuals and families. Eligibility criteria vary by state,

and they can include factors such as income, disability status, age, immigration status, and more.

Medicare—a health care program for individuals aged 65 and older. Includes Part A for coverage of hospitalization-related expenses, Part B for coverage of medical care, and prescription drug coverage.

Metastasis—the spread of cancer from its site of origin to other parts of the body. Presence of metastases often indicates more advanced cancer.

Neoplastic—pertaining to abnormal new growth of cells. A neoplasia may be considered precancerous.

Occult—hidden, but possible to discover upon inspection.

Patient navigation—helping a patient work his or her way through a health care system.

Polyp—a colorectal adenoma (see Adenoma).

Polypectomy—removal of a polyp, often during colonoscopy, a procedure that can prevent colorectal cancer.

PSA test—a blood test that detects prostate-specific antigen (PSA). The PSA test was approved by the Food and Drug Administration in 1985 for prostate cancer recurrence, but it is now widely used as a screening test for prostate cancer. While testing for prostate-specific antigen (PSA) can successfully detect prostate cancer, many believe that the practice has led to treatment of small tumors not likely to progress and that this treatment does not lead to decreased mortality from the disease (Lilja et al., 2008).

Screening initiative—a program started by a community, health organization, or another entity to screen certain groups of people for colorectal cancer.

Sensitivity—a measurement of how often a test correctly identifies patients with a specific diagnosis, or the fraction of positive results that are correct. It is calculated as the number of true-positive results divided by the sum of true-positive and false-negative results. In this summary, sensitivities of various colorectal cancer screening tests are discussed.

Sigmoid (sigmoid colon)—the curved portion of the colon between the rectum and the descending colon.

Specificity—a measurement of how often a test correctly identifies the proportion of persons without a previous diagnosis, or the fraction of negative results that are correct. It is calculated as the number of true-negative results divided by the sum of true negatives and false positives. In this summary, specificities of various colorectal cancer screening tests are discussed.

Stage—The TNM classification system is used to stage colorectal cancer (ACS, 2008; NCI, 2008). T refers to the characteristics of the primary tumor, N refers to the involvement of regional lymph nodes, and M refers to the extent of metastasis, if any. The TNM stages are then grouped into familiar numbered stages, 0–4. Stage 0 refers to highly localized cancers that have not grown beyond the inner layers of the colon or rectum. Stage 1 refers to cancers that have penetrated the inner layers of the colon or rectum, but not to the outer layers. Stage 2 refers to cancers that have penetrated all layers of the colon or rectum, may or may not have reached adjacent tissues, but has not reached lymph nodes or distant sites. Stage 3 refers to cancers that have spread to one or a few nearby lymph nodes, and it may or may not have spread to nearby organs. Stage 4 refers to cancers that have spread to distant sites. For more information, see http://www.cancer.org/docroot/CRI/content/CRI_2_4_3X_How_is_colon_and_rectum_cancer_staged.asp or http://www.cancer.gov/cancertopics/pdq/treatment/colon/HealthProfessional/page4.

Ulcerative Colitis—a type of inflammatory bowel disease which is characterized by chronic inflammation of the digestive tract. In ulcerative colitis, this inflammation is usually located in the colon or rectum. In addition, the inflammation occurs only in the lining of the intestine. Symptoms include abdominal pain, bleeding, or diarrhea.

Uptake—the rate at which individuals begin to comply with recommended medical care.

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Appendix A

Workshop Agenda

National Cancer Policy Forum
Workshop on
Implementing Colorectal Cancer Screening

The National Academy of Sciences
2101 Constitution Avenue NW—Lecture Room
Washington, DC 20418

DAY 1: MONDAY, FEBRUARY 25, 2008

8:30 am	**Continental Breakfast**
9:00 am	**Introduction to Colorectal Cancer Screening Workshop: Workshop Advice on How to Move Evidence-Based Recommendations into Practice** *Dr. Ralph Coates, Centers for Disease Control and Prevention* *Dr. William Lawrence, Agency for Healthcare Research and Quality* *Mr. Tom Kean, C-Change*
9:15 am	**Natural History and Epidemiology** *Dr. Michael Pignone, University of North Carolina at Chapel Hill* *Dr. Bernard Levin, M.D. Anderson Cancer Center*
9:45 am	**Evidence for Effectiveness of CRC Screening Technologies** *Dr. Evelyn Whitlock, Oregon Evidence-based Practice Center and Kaiser Permanente Center for Health Research*
10:15 am	**Cost-Effectiveness and Outcomes of Screening Strategies** *Dr. Ann Zauber, Memorial Sloan-Kettering Cancer Center*

10:45 am **Break**

11:00 am **Evidence for Effectiveness of Community and Office-Based Interventions**
Dr. Shawna Mercer, Centers for Disease Control and Prevention

11:30 am **Health Insurance Barriers and Measures to Increase Screening**
Dr. George Isham, HealthPartners

12:00 pm **Lunch**

12:30 pm **Public and Patient Interventions to Implement Screening**
Dr. Sally Vernon, University of Texas–Houston School of Public Health

1:00 pm **Primary Care Practice Interventions to Implement Screening**
Dr. Robert Fletcher, Harvard Medical School and University of North Carolina at Chapel Hill

1:30 pm **GI Specialty Practice Interventions to Implement Screening**
Dr. David Lieberman, Oregon Health and Science University

2:00 pm **Break**

State Initiatives to Implement Screening

2:15 pm **Public State Initiatives**
Dr. Tim Byers, University of Colorado Cancer Center

2:45 pm **Private Initiatives**
Dr. Alan Thorson, Creighton University and the University of Nebraska

3:15 pm **Population-Based Screening Programs**
Dr. Laura Seeff, Centers for Disease Control and Prevention

3:45 pm **Employer Perspectives on Barriers and Measures to Increase Screening**
Ms. Ann Skye, Quintiles Transnational Corporation

4:15 pm **Reflections from Participants Who Will Not Be Present for Day Two: 2–3 Priority Areas**
Meeting participants; Tom Kean (C-Change), facilitator

4:30 pm **Adjourn Day One**

DAY 2: TUESDAY, FEBRUARY 26, 2008

8:00 am **Continental Breakfast**

8:30 am **Effectiveness of Strategies to Monitor Performance and Provide Feedback to Providers**
Mr. Philip Renner, National Committee for Quality Assurance

Interventions to Address Costs of Developing and Maintaining Screening Programs

9:00 am **Practice Models for Delivering Colorectal Cancer Screening in Primary Care and Their Cost Implications**
Dr. Carrie Klabunde, National Cancer Institute

9:30 am **Addressing Costs of Colorectal Cancer Screening Programs in Medical Practice**
Dr. Richard Wender, Thomas Jefferson University

10:00 am **Developing and Maintaining Public Health Colorectal Cancer Screening Programs**
Dr. Florence Tangka, Centers for Disease Control and Prevention

10:30 am **Priority Actions Needed to Increase Recommended Screening Services**
Meeting Participants; Tom Kean (C-Change), facilitator

12:00 pm **Adjourn Workshop**

Appendix B

Workshop Speakers

Tim Byers, M.D., M.P.H., University of Colorado Cancer Center
Ralph J. Coates, Ph.D., Centers for Disease Control and Prevention
Robert H. Fletcher, M.D., M.Sc., Harvard Medical School and University of North Carolina at Chapel Hill
George J. Isham, M.D., M.S., HealthPartners
Carrie N. Klabunde, Ph.D., National Cancer Institute
Bernard Levin, M.D., Ph.D., M.D. Anderson Cancer Center
David Lieberman, M.D., Oregon Health and Science University
Shawna L. Mercer, M.Sc., Ph.D., Centers for Disease Control and Prevention
Michael Pignone, M.D., M.P.H., University of North Carolina at Chapel Hill
Philip Renner, M.B.A., National Committee for Quality Assurance
Laura Seeff, M.D., Centers for Disease Control and Prevention
Ann Skye, R.N., M.P.H., Quintiles Transnational Corporation
Florence K. Tangka, Ph.D., Centers for Disease Control and Prevention
Alan G. Thorson, M.D., Creighton University and the University of Nebraska
Sally W. Vernon, Ph.D., University of Texas–Houston School of Public Health
Richard C. Wender, M.D., Thomas Jefferson University
Evelyn P. Whitlock, M.D., M.P.H., Oregon Evidence-based Practice Center and Kaiser Permanente Center for Health Research
Ann G. Zauber, Ph.D., Memorial Sloan-Kettering Cancer Center

Appendix C

Epidemiology of Colorectal Cancer and Colorectal Cancer Screening: A Background Paper

Bernard Levin, M.D., Ph.D.,
M.D. Anderson Cancer Center, and
Michael Pignone, M.D., M.P.H.,
University of North Carolina at Chapel Hill

BURDEN OF DISEASE

Estimates show that in 2007, there were more than 150,000 new cases of colorectal cancer and over 50,000 deaths from this disease in the United States, making it the second most common cause of death from cancer (ACS, 2007). The estimated lifetime probability at birth of developing colorectal cancer in the United States is approximately 6 percent, and the probability of dying from the disease is about 3 percent (NCI, 2004).

The incidence of colorectal cancer is higher in men than in women, and increases with age for both genders. In the United States, age-adjusted incidence ranges from 48.3 per 100,000 per year in Hispanic men to 72.5 per 100,000 in African American men. In women, it ranges from 32.3 in Hispanics to 56.0 in African Americans per 100,000 per year (NCI, 2004). The age-adjusted mortality rates for all races and genders are 24.8 in men and 17.4 in women per 100,000 per year (NCI, 2004). Mortality is higher for African Americans than for white people (Figures C-1 and C-2, Table C-1).

Worldwide, estimates show that each year nearly 1 million new cases of colorectal cancer occur and nearly 500,000 deaths result from the dis-

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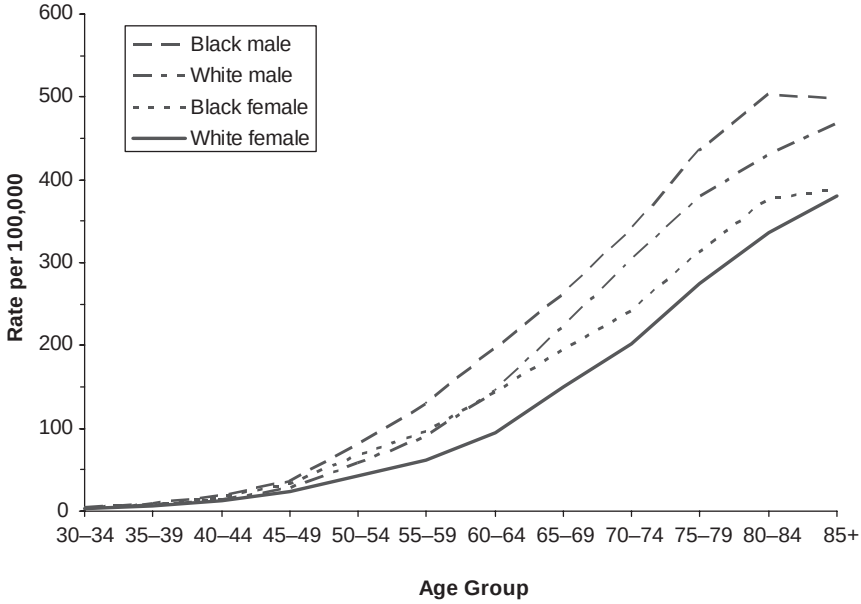

FIGURE C-1 SEER incidence and mortality rates by gender, 1995–1999. SOURCE: NCI (2004).

ease (NCI, 2004). The highest incidence rates occur in North America, Western Europe, and Australia; the lowest incidence rates are found in nonwhite populations of sub-Saharan Africa and India (Figure C-3; Ferlay et al., 2001). However, rates in Asia are increasing in countries adopting Western lifestyle habits (Vainio and Miller, 2003).

Colorectal cancer incidence and mortality are declining in developed countries. In the United States, between 1973 and 1995, mortality declined by 20 percent and incidence declined by 7 percent. Both continued to decline from 1995 to 2003 (NCI, 2006). Colorectal cancer survival and mortality differ according to stage at diagnosis. Survival rates at 5 years are more than 80 percent for patients diagnosed with local disease, and over 60 percent for regional disease. Despite recent advances in chemotherapy, 5-year survival with metastatic colorectal cancer is less than 10 percent. Currently, Surveillance Epidemiology and End Results (SEER) data show that only about 40 percent of colorectal cancers are localized at diagnosis; about 37 percent have regionally spread, and 19 percent have metastasized to distant sites.

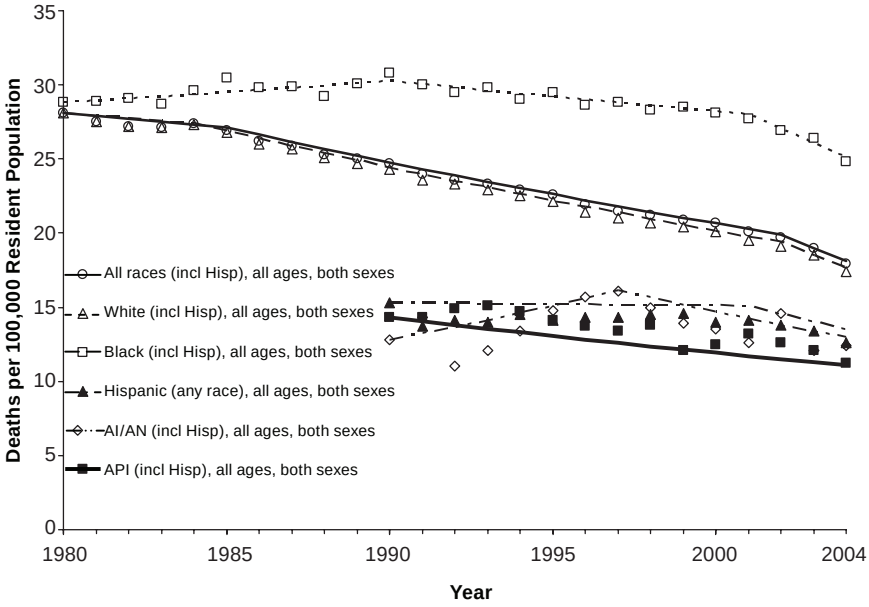

FIGURE C-2 Colon and rectal cancer mortality for both sexes and all ages, by race and ethnicity from 1980–2004. NOTE: Death rates calculated by the National Cancer Institute using SEER*Stat. Death rates are age-adjusted to the 2000 U.S. standard population (19 age groups: <1, 1–4, 5–9, ... , 80–84, 85+). Population counts for denominators are based on Census populations as modified by NCI. Regression lines were calculated using the Joinpoint Regression Program. Due to data availability issues, the time period used in the calculation of the joinpoint regression model may differ for selected racial groups or counties. The regression lines represent annual percent change (APC) over specified time intervals. Rates used in the calculation of the APC are age-adjusted to the 2000 U.S. standard population (19 age groups: <1, 1–4, 5–9, ... , 80–84, 85+). Statistics for minorities may be affected by inconsistent race identification between the cancer case reports (sources for numerator of rate) and data from the Census Bureau (source for denominator of rate); and from undercounts of some population groups in the census. Hispanic mortality data for the United States has been excluded for the following states: Connecticut, Louisiana, Maine, Maryland, Mississippi, New Hampshire, New York, North Dakota, Oklahoma, Vermont, and Virginia. The data on Hispanic and non-Hispanic mortality for these states may be unreliable for the time period used in the generation of the trend (1990–2001) and has been excluded from the calculation of the United States recent trend. This was based on the value of the Hispanic Index. AI/AN = American Indian and Alaska Native, APC = annual percentage change, API = Asian and Pacific Islander, Hisp = Hispanic. SOURCE: Data and notes provided to the State Cancer Profiles website by the National Vital Statistics System public use data file (NCI, 2008). See http://statecancerprofiles.cancer.gov/ and http://statecancerprofiles.cancer.gov/historicaltrend/joinpoint.noimage.html.

TABLE C-1 U.S. Colorectal Cancer Incidence and Mortality Data 2000–2003, based on SEER incidence data and National Center for Health Statistics (NCHS) mortality data

	Men		Women	
	Incidence rate (per 100,000)	Mortality rate (per 100,000)	Incidence rate (per 100,000)	Mortality rate (per 100,000)
All races	61.7	24.0	45.3	16.8
White	61.4	23.4	44.7	16.2
Black	72.9	33.4	56.1	23.4
Asian/Pacific Islander	51.2	15.4	35.7	10.5
American Indian/ Alaskan Native	52.7	15.6	41.9	11.0
Hispanic	47.3	17.3	32.7	11.3

SOURCE: NCI (2006).

NATURAL HISTORY

The natural history of colorectal neoplasia has been well studied at the molecular as well as at the epidemiologic level. Colorectal adenomas, the precursors of nearly all sporadic colorectal cancers, are found in up to 40 percent of persons by 60 years of age. Experimental, epidemiologic, and genetic studies suggest that colorectal adenomas and cancers result from complex interactions between inherited susceptibility and environmental or lifestyle factors (Young et al., 2002). The adenoma–carcinoma sequence consists of the progression from normal-appearing mucosa to small tubular adenoma to larger adenomas and those with more advanced histological features (villous changes, high-grade dysplasia, or both) and then development of cancer. More than 90 percent of adenomatous polyps do not progress to cancer. Some evidence suggests that measures that reduce the incidence and prevalence of colorectal adenomas, such as polypectomy, may result in a subsequent decrease in the risk of colorectal cancer (Winawer et al., 1993).

RISK FACTORS

Individuals with hereditary conditions such as familial adenomatous polyposis and hereditary nonpolyposis colorectal cancer have a significantly increased risk of colorectal cancer, but combined, these two conditions do not account for more than 5 to 6 percent of all cases of colorectal cancer. More common conditions associated with an increased risk include a personal history of colorectal cancer or adenomas; a first degree family history of colorectal cancer or adenomas; a personal history

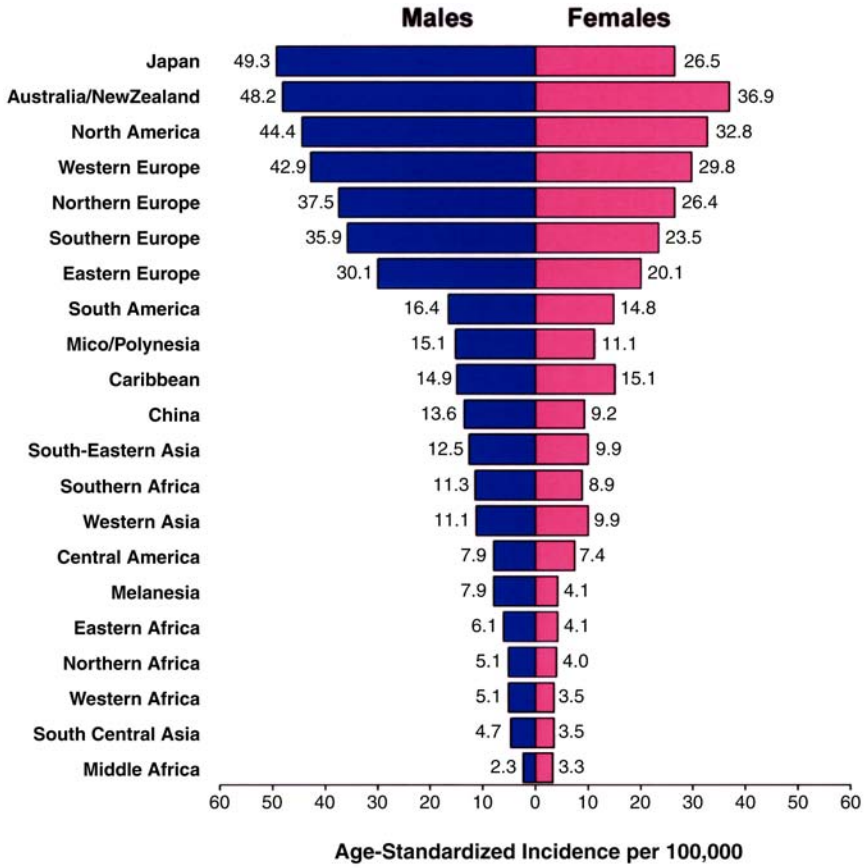

FIGURE C-3 International colorectal cancer incidence rates by gender. Worldwide, there are 945,000 cases of colorectal cancer per year and 492,000 deaths. In the United States, there are 153,760 cases per year and 52,180 deaths. SOURCE: Parkin et al. (2005).

of ovarian or endometrial cancer; and a personal history of long-standing chronic ulcerative colitis or Crohn's disease (Levin et al., 2002). However, estimates indicate that approximately 70 percent of colorectal cancers arise sporadically. Therefore, early detection and treatment strategies cannot be directed solely to high-risk patients if the goal is to substantially reduce associated morbidity and mortality.

A number of other risk factors for colorectal cancer have been identified. Epidemiologic studies have reported that physical inactivity and obesity are associated with an increased risk (Wolin et al., 2007). A high

consumption of red and processed meat and alcohol and low consumption of vegetables and fruit are also associated with increased risk, although not all studies are consistent (Koushik et al., 2007).

SCREENING

Randomized trials have found that screening for colorectal cancer with fecal occult blood testing could reduce the incidence and mortality from colorectal cancer (Mandel et al., 1993, 2000). These findings have been extrapolated to other colorectal cancer screening techniques, including newer occult blood tests, sigmoidoscopy, colonoscopy, and radiological imaging, that have been shown to be accurate for detecting neoplasia, have relatively low rates of adverse effects, and have reasonable costs (Pignone et al., 2002).

Screening Use

Despite the proven effectiveness of screening and the availability of several different tests, overall rates of screening remain low in the United States and other developed countries. Recent data from a national telephone survey conducted by the CDC's Behavioral Risk Factor Surveillance Study (BRFSS) found that only about half (57 percent) of age-eligible adults reported being up to date with screening (CDC, 2006). Screening has become steadily more common over the past 10 years (see Figures C-4 and C-5), with colonoscopy accounting for much of that increase (Meissner et al., 2006). The use of colonoscopy itself has increased fivefold since before 1998, with most of the increase attributable to colorectal cancer screening or surveillance (Gross et al., 2006).

Factors Associated with Colorectal Cancer Screening

Many studies have examined factors associated with screening test completion. Subramanian and colleagues reviewed this literature through 2002 and identified 30 articles that addressed factors affecting screening test completion in average-risk adults, 14 of which used multivariate analysis to identify independent effects (Subramanian et al., 2004). They found that age over 65 and less than 85, level of education, and health maintenance organization membership were all associated with completion of a fecal occult blood test (FOBT) or endoscopy. Insurance coverage itself did not have a consistent relationship with screening. Other demographic characteristics, including sex, race, income, and marital status, also were not clearly or consistently associated with screening. Attitudinal variables associated with screening included the belief that cancer is pre-

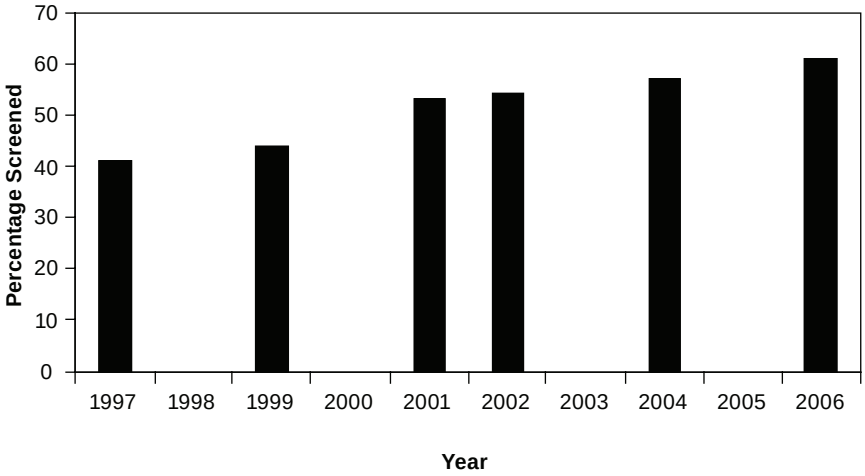

FIGURE C-4 Self-reported colorectal cancer screening levels from the Centers for Disease Control and Prevention's Behavioral Risk Factor Surveillance System. The graph shows the rates at which individuals report being up to date with colorectal cancer screening by any method. SOURCE: http://www.cdc.gov/brfss/index.htm.

ventable or curable; commitment to screening; and lack of significant fear or pessimism/fatalism about cancer.

More recently, Meissner and colleagues examined patient factors associated with screening using data from the 2003 National Health Interview Survey (Meissner et al., 2006). They reported bivariate analyses, stratified by sex. Their findings were similar to those of Subramanian and colleagues (2004), except that having health insurance was strongly associated with screening. Compared with older data from before 2000, recent screening was performed predominantly with colonoscopy (Phillips et al., 2007). It is possible that the use of colonoscopy screening is more closely tied to having health insurance.

Subramanian and colleagues (2004) found that several health care provider or system-related factors—including physician recommendation for screening, more physician visits, having a usual source of care, and having preventive visits—were also positively associated with screening. Other analyses have found that most patients who have not been screened report never receiving a recommendation to do so (Klabunde et al., 2005). Few studies have examined practice-level factors, but limited evidence suggests that use of reminder systems, and possibly use of multidisciplinary teams, are associated with more frequent colorectal cancer screening (Hudson et al., 2007).

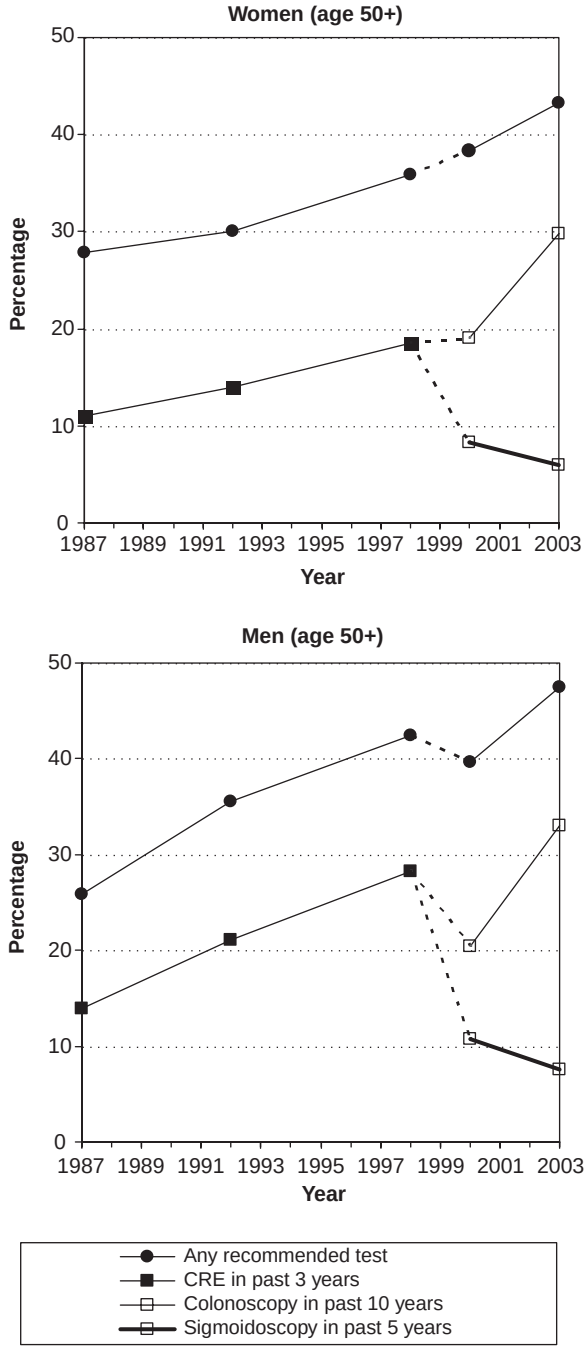
Women (age 50+)
Percentage
50
40
30
20
10
0
1987 1989 1991 1993 1995 1997 1999 2001 2003
Year
Men (age 50+)
Percentage
50
40
30
20
10
0
1987 1989 1991 1993 1995 1997 1999 2001 2003
Year
Any recommended test
CRE in past 3 years
Colonoscopy in past 10 years
Sigmoidoscopy in past 5 years

FIGURE C-5 Self-reported colorectal cancer screening levels from the National Health Interview Survey 1987–2003. NOTE: Percentages are standardized to the 2000 projected U.S. population by 5-year age groups. The relevant survey questions were redesigned after 1998; broken lines represent these changes. Before 1998, recommended tests included home or office FOBT, colonoscopy, proctoscopy, and sigmoidoscopy, because it was not possible to adequately distinguish between tests during these years. After 1998 the recommended tests include home FOBT, sigmoidoscopy, and colonoscopy. NOTE: CRE = colorectal endoscopy. SOURCE: Figure and note reprinted, with permission, from "Patterns of colorectal cancer screening uptake among men and women in the United States," 2006. Copyright American Association for Cancer Research (Meissner et al., 2006).

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Appendix D

The Medical Home

TABLE D-1 The Major Differences Between the Current State of Chronic Care Management and a Future-State Medical Home Model

	Current State	Future State
Primary provider	Primary care physician	Primary care clinician with health coaches
Primary incentive	Visits (volume)	Increased patient adherence to self-care regimen
Infrastructure investments	None	Electronic medical record with registry function and knowledge management tools, and personal health records for patients; required infrastructure investments in practice operations that support coaching platforms, including patient classroom facilities, websites with blog and social networking capabilities, and redesigned educational materials reflecting customized self-care regimen for discrete patient groups (total one-time investment costs of approximately $80,000 to $120,000)
Incremental costs	None	$100,000–$115,000 per primary care clinician, $78,000 per health coach; 56 percent load[a] for coaching tools (data collection, telephones, information technology [IT] systems, etc.); 33 percent full-time equivalent data manager at $65,000 per data manager; and $5,000–$20,000 for health IT and website technical support annual maintenance

TABLE D-1 Continued

	Current State	Future State
Panel size	5,000–7,000 charts (1,500–2,500 active patient records)	1,000–2,000 patients, depending on prevalence and intensity of chronic care management requirements (does not include case-managed population)
Net revenues (annual, per physician)	$350,000–$600,000[b]	$500,000–$1 million ($500/patient in panel) inclusive of performance bonus

[a]Internal Deloitte references.

[b]Cleverley and Cameron (2007).

SOURCE: Deloitte Center for Health Solutions (2008). Reprinted, with permission, from *The Medical Home: Disruptive Innovation for a New Primary Care Model*, http://www.deloitte.com/us/medicalhome and http://www.deloitte.com/dtt/cda/doc/content/us_chs_MedicalHome_w.pdf. Copyright 2008 by the Deloitte Center for Health Solutions, part of Deloitte LLP.

BOX D-1
Critical Features of the Medical Home:
A Platform for Guided Self-Care Management

- Personal physician: Each patient has an ongoing relationship with a Primary Care Physician, as well as clinician health coaches, who are trained to provide first-contact, continuous, and comprehensive care. These clinicians are competent in the use of active listening, health coaching, evidence-based holistic medicine, clinical information technology, population-based outcome improvement and measurement, care team recruitment, and leadership.
- Physician-directed primary care professional organization: A physician leads a team of health coaches who collectively take responsibility for the ongoing care of patients. The day-to-day operation of the practice is focused on managing population-based outcomes and maximizing individual patient adherence to a distinct, customized self-care management program that leverages information technology. Note: A health coach is an allied professional (nurse/patient educator) with specialized training in patient behavior modification and motivational interviewing to match patient values, preferences, and triggers to specific, measurable, short-term, self-care lifestyle modifications.
- "Whole person" orientation toward adherence, not compliance, incorporating holistic methods with conventional allopathic interventions: The primary care team is responsible for providing all of the patient's health care needs and appropriately arranging care with other qualified professionals. This includes care for all stages of life: acute care, chronic care, preventive services, and end-of-life care, with strong consideration for the individual's value system, personal preferences, and level of engagement in decision making. A key focus is the dispensation of directives (prompts, alerts, reminders) in teachable moments to patients and family members/significant influencers to expedite adherence to self-care suggestions (not just compliance to directives). In these clinical models, holistic therapeutic interventions, such as mindful daily practices, are integrated with traditional therapeutic interventions.
- Monitored, coordinated and, integrated care using electronic medical records and personal health records: Care is facilitated across all elements of the complex health system (e.g., subspecialty care, hospitals, home health agencies, nursing homes) and the patient's community (e.g., family, public and private community-based services) by registries, health information exchanges, and other electronic means to ensure that patients get the indicated care when and where they need and want it, in a culturally and linguistically appropriate manner. The information exchanges among members of the patient's care team are synchronized and real-time. These technologies are also used to reduce unnecessary visits, tests, and referrals. Sharing information among medical homes and other providers in the local and regional care system is indicative of an advanced medical home model.
- Measured and managed adherence to evidence-based practices by the care team and the patient: Results measured are hallmarks of the medical home. They range from measures of processes and outcomes to patient satisfaction and success rates in changing behavior:

  - Evidence-based medicine and clinical decision-support tools guide decision making. Nonadherence by the care team and/or the patient is monitored and measured, and root-cause analysis is conducted to assess errors and near-misses.
  - Physicians in the practice accept accountability for continuous quality improvement by voluntarily engaging in performance measurement and improvement.
  - Patients actively participate in decision making, and feedback is sought to ensure patients' expectations are being met.
  - Information technology is used to appropriately support optimal patient care, performance measurement, patient education, and enhanced communication.
  - Patients and families participate in quality improvement activities at the practice level.

- Enhanced accessibility: Care anywhere, anytime: Care is available via open scheduling, expanded hours, and new communications options among patients, their personal physician, and practice staff. Innovations such as group visits, cybervisits, robust customized educational tools, and self-monitoring devices are available through the practice.

- Emphasis on physician incentives for improvements in self-care management: Physician reimbursements appropriately recognize the added value provided to patients who have a patient-centered medical home. The payment structure should:

  - Reflect the value of patient-centered care management work that falls outside of the face-to-face visit.
  - Pay for services associated with care coordination within a given practice and among consultants, ancillary providers, and community resources.
  - Support adoption and use of health information technology for quality improvement.
  - Support enhanced communication access such as secure e-mail and telephone consultation.
  - Recognize the value of technology-based physician work associated with remote monitoring of clinical data.
  - Allow for separate fee-for-service payments for face-to-face visits. (Payments for care management services that fall outside of the face-to-face visit, as described above, should not result in reduced payments for face-to-face visits.)
  - Recognize case-mix differences in the patient population being treated within the practice.
  - Allow physicians to share in savings from reduced hospitalizations associated with physician-guided care management in the office setting.
  - Allow additional payments for achieving measurable and continuous quality improvements.

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