

NIH State-of-the-Science Conference:

Enhancing Use and Quality of Colorectal Cancer Screening

Program and Abstracts

February 2–4, 2010

**William H. Natcher Conference Center
National Institutes of Health
Bethesda, Maryland**

Presented by

National Cancer Institute, NIH
Office of Medical Applications of Research, NIH

Cosponsors

National Institute on Aging, NIH
National Institute of Diabetes and Digestive and Kidney Diseases, NIH
National Institute of Nursing Research, NIH
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Centers for Disease Control and Prevention

The Agency for Healthcare Research and Quality and the Centers for Disease Control and Prevention provided additional conference development support.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



NIH Consensus Development Program

About the Program

The National Institutes of Health (NIH) Consensus Development Program has been organizing major conferences since 1977. The Program generates evidence-based consensus statements addressing controversial issues important to healthcare providers, policymakers, patients, researchers, and the general public. The NIH Consensus Development Program holds an average of three conferences a year. The Program is administered by the Office of Medical Applications of Research within the NIH Office of the Director. Typically, the conferences have one major NIH Institute or Center sponsor, with multiple cosponsoring agencies.

Topic Selection

NIH Consensus Development and State-of-the-Science Conference topics must satisfy the following criteria:

- Broad public health importance. The severity of the problem and the feasibility of interventions are key considerations.
- Controversy or unresolved issues that can be clarified, or a gap between current knowledge and practice that can be narrowed.
- An adequately defined base of scientific information from which to answer conference questions, such that the outcome does not depend primarily on subjective judgments of panelists.

Conference Type

Two types of conferences fall under the purview of the NIH Consensus Development Program: State-of-the-Science Conferences and Consensus Development Conferences. Both conference types utilize the same structure and methodology; they differ only in the strength of the evidence surrounding the topic under consideration. When it appears that there is very

strong evidence about a particular medical topic, but that the information is not in widespread clinical practice, a Consensus Development Conference is typically chosen to consolidate, solidify, and broadly disseminate strong evidence-based recommendations for general practice. Conversely, when the available evidence is weak or contradictory, or when a common practice is not supported by high-quality evidence, the state-of-the-science label is chosen. This highlights what evidence about a topic is available and the directions future research should take, and alerts physicians that certain practices are not supported by good data.

Conference Process

Before the conference, a systematic evidence review on the chosen topic is performed by one of the Agency for Healthcare Research and Quality's Evidence-based Practice Centers. This report is provided to the panel members approximately 6 weeks prior to the conference, and posted to the Consensus Development Program Web site once the conference begins, to serve as a foundation of high-quality evidence upon which the conference will build.

The conferences are held over 2½ days. The first day and a half of the conference consist of plenary sessions in which invited expert speakers present information, followed by "town hall forums," in which open discussion occurs among the speakers, panelists, and the general public in attendance. The panel then develops its draft statement on the afternoon and evening of the second day, and presents it on the morning of the third day for audience commentary. The panel considers these comments in executive session and may revise its draft accordingly. The conference ends with a press briefing, during which reporters are invited to question the panelists about their findings.

Panelists

Each conference panel comprises 12–16 members who can give balanced, objective, and informed attention to the topic. Panel members:

- Must not be employees of the U.S. Department of Health and Human Services.
- Must not hold financial or career (research) interests in the conference topic.
- May be knowledgeable in the general topic under consideration, but must not have published about or have a publicly stated opinion on the topic.
- Represent a variety of perspectives, to include:
 - Practicing and academic health professionals
 - Biostatisticians and epidemiologists
 - Clinical trialists and researchers
 - Individuals representing public-centered values and concerns (ethicists, economists, attorneys, etc.)

In addition, the panel as a whole should appropriately reflect racial and ethnic diversity. Panel members are not paid a fee or honorarium for their efforts. They are, however, reimbursed for travel expenses related to their participation in the conference.

Speakers

The conferences typically feature approximately 21 speakers; 3 present the information found in the Evidence-based Practice Center's systematic review of the literature. The other 18 are experts in the topic at hand, have likely published on the topic, and may have strong opinions or beliefs. Where multiple viewpoints on a topic exist, every effort is made to include speakers who address all sides of the issue.

Conference Statements

The panel's draft report is released online late in the conference's third and final day. The final report is released approximately 6 weeks later. During the intervening period, the panel may edit its statement for clarity and correct any factual errors that might be discovered. No substantive changes to the panel's findings are made during this period.

Each Consensus Development or State-of-the-Science Conference Statement reflects an independent panel's assessment of the medical knowledge available at the time the statement was written; as such, it provides a "snapshot in time" of the state of knowledge on the conference topic. It is not a policy statement of the NIH or the Federal Government.

Dissemination

Consensus Development and State-of-the-Science Conference Statements have robust dissemination:

- A press telebriefing is held on the last day of the conference to assist journalists in preparing news stories on the conference findings.
- The statement is published online at consensus.nih.gov.
- Print copies are mailed to a wide variety of targeted audiences and are available at no charge through a clearinghouse.

The conference statement is published in a major peer-reviewed journal.

Contact Us

For conference schedules, past statements, and evidence reports, please contact us:

NIH Consensus Development Program
Information Center
P.O. Box 2577
Kensington, MD 20891

888–NIH–CONSENSUS (888–644–2667)
consensus.nih.gov



Upcoming Conferences

- NIH Consensus Development Conference: **Lactose Intolerance and Health**
February 22–24, 2010
- NIH Consensus Development Conference: **Vaginal Birth After Cesarean: New Insights**
March 8–10, 2010
- NIH State-of-the-Science Conference: **Preventing Alzheimer’s Disease and Cognitive Decline**
April 26–28, 2010
- NIH Consensus Development Conference: **Inhaled Nitric Oxide Therapy for Premature Infants**
October 27–29, 2010

To receive registration notifications and updates about conferences and other program activities, please join the NIH Consensus Development Program Information Network at consensus.nih.gov/alerts.htm.

Recent Conferences

- NIH State-of-the-Science Conference: **Diagnosis and Management of Ductal Carcinoma In Situ (DCIS)**
September 22–24, 2009
- NIH State-of-the-Science Conference: **Family History and Improving Health**
August 24–26, 2009
- NIH Consensus Development Conference: **Management of Hepatitis B**
October 20–22, 2008
- NIH Consensus Development Conference: **Hydroxyurea Treatment for Sickle Cell Disease**
February 25–27, 2008
- NIH State-of-the-Science Conference: **Prevention of Fecal and Urinary Incontinence in Adults**
December 10–12, 2007
- NIH State-of-the-Science Conference: **Tobacco Use: Prevention, Cessation, and Control**
June 12–14, 2006
- NIH State-of-the-Science Conference: **Multivitamin/Mineral Supplements and Chronic Disease Prevention**
May 15–17, 2006
- NIH State-of-the-Science Conference: **Cesarean Delivery on Maternal Request**
March 27–29, 2006
- NIH State-of-the-Science Conference: **Manifestations and Management of Chronic Insomnia in Adults**
June 13–15, 2005
- NIH State-of-the-Science Conference: **Management of Menopause-Related Symptoms**
March 21–23, 2005

To access previous conference statements, videocasts, evidence reports, and other conference materials, please visit consensus.nih.gov.

General Information

Continuing Education

The NIH Consensus Development Program aspires to offer continuing education credits to as many conference attendees as possible. If your preferred credit type is not listed, please check to see if your credentialing body will honor other credit types.

Please note that continuing education credits are not available for Webcast viewers.

Continuing Medical Education

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). The CDC is accredited by the Accreditation Council for Continuing Medical Education (ACCME[®]) to provide continuing medical education for physicians.

The Centers for Disease Control and Prevention designates this educational activity for a maximum of 13.0 *AMA PRA Category 1 Credits*[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Continuing Education Designated for Non-Physicians

Non-physicians will receive a certificate of participation.

Continuing Nursing Education

The Centers for Disease Control and Prevention is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity provides 12.8 contact hours.

Continuing Education Contact Hours

The Centers for Disease Control and Prevention is a designated provider of continuing education contact hours (CECH) in health education by the National Commission for Health Education Credentialing, Inc. This program is a designated event for certified health education specialists (CHES) to receive 13.0 Category I contact hours in health education, CDC provider number GA0082.

Financial Disclosures

The Centers for Diseases Control and Prevention, our planners, and our presenters wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters, with the exception of the following:

Planning committee members	Company	Financial relationship
Supriya Janakiraman, M.D., M.P.H.	Johnson & Johnson	Stock dividend
C. Daniel Johnson, M.D.	Pfizer GE Healthcare	Stock dividend Software license

Speakers	Company	Financial Relationship
David H. Kim, M.D.	Viatronix	Consulting fee
Jennifer Elston Lafata, Ph.D.	Medicsight VirtuoCTC Abbott	Consulting fee Ownership, Cofounder Honorarium, participation on Health Policy Advisory Board
David A. Lieberman, M.D.	GENENEWS	Scientific Advisory Board
Robert Madoff, M.D.	SoftScope Medical Technologies	Consultant

Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use, with the exception of Dr. Mary Barton's discussion on fecal immunochemical tests that are not yet licensed for use in the United States, but only in regard to published evidence regarding the characteristics of the tests.

There is no commercial support for this activity.

Policy on Panel Disclosure

Panel members signed a confirmation that they have no financial or other conflicts of interest pertaining to the topic being addressed.

Videocast

Live and archived videocasts may be accessed at videocast.nih.gov. The archived videocast will be available approximately 1 week after the conference.

Dining

The dining center in the Natcher Conference Center is located on the main level, one floor above the auditorium. It is open from 6:30 a.m. to 2:30 p.m., serving hot breakfasts and lunch, sandwiches and salads, and snack items. An additional cafeteria is open from 7:00 a.m. to 3:30 p.m., in Building 38A, Level B1, across the street from the main entrance to the Natcher Conference Center.

Online Content

All materials issuing from the NIH Consensus Development Program are available at consensus.nih.gov. In addition, remote participants will have the opportunity to provide comments on the panel statement by visiting consensus.nih.gov/comments.htm from 8:30–11:30 a.m. on Thursday, February 4, 2010.

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Julietta Patnick, CBE, FFPH

Background

Colorectal cancer is the second-leading cause of cancer-related deaths in the United States. Approximately 50,000 people in the United States are expected to die from colorectal cancer in 2009. Colonic polyps—abnormal growths of tissue on the inner lining of the colon—are relatively common findings in men and women 50 years and older. Most of these growths are not cancerous, but one type of polyp, known as an adenoma, can develop into colorectal cancer. Screening tests for colorectal cancer generally are performed to identify and remove adenomas or examine the stool for signs of early cancer in people who have no symptoms. A range of colorectal cancer screening tests are available in the United States. The U.S. Preventive Services Task Force currently recommends that average-risk adults age 50 to 75 years undergo screening for colorectal cancer with annual fecal occult blood testing, sigmoidoscopy (internal examination of the lower part of the large intestine) every 5 years, or colonoscopy (internal examination of the entire large intestine) every 10 years. Additional tests that may be used for colorectal cancer screening include computed tomography (CT) colonography and fecal DNA testing.

Although colorectal cancer is an important cause of mortality in the United States, screening for this disease is currently underutilized among eligible individuals. Despite evidence supporting the value of screening, in 2005, only 50% of U.S. adults age 50 and older had been screened according to guidelines. Rates of screening for colorectal cancer are consistently lower than those for other common cancers, particularly breast and cervical cancer. Reasons for this disparity are complex. Unlike most other preventive services, in colorectal cancer screening, there are multiple test options from which to choose, and patients and providers may have varying preferences for or access to the tests. Successful completion of colorectal cancer screening requires effort on the part of the patient to obtain stool samples for testing or to clean the colon in preparation for endoscopic examination. Test options may also differ in cost and availability for a given community. Patient, provider, and healthcare system characteristics may each play a unique role in influencing the use and quality of colorectal cancer screening.

Adding to the complexity of this issue, colorectal cancer screening may be overused or misused in certain situations. Despite uncertainty regarding the benefit of removing small polyps, many people undergoing sigmoidoscopy or colonoscopy have all identified growths removed. This may put them at increased risk for possible complications from these procedures, which can include rectal bleeding or colonic perforation (a tear in the wall of the intestine that can cause a serious abdominal infection). In addition, follow-up testing of individuals who have previously had polyps removed may occur more frequently than available evidence supports, which, again, may put people at risk for complications and have both cost and capacity implications for the healthcare system.

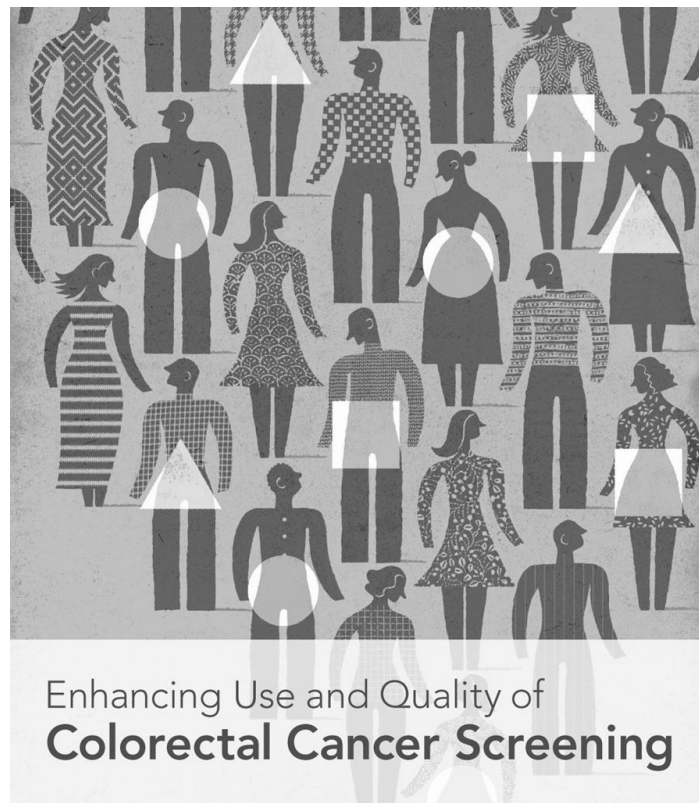
To provide healthcare providers, patients, policymakers, and the general public with a comprehensive assessment of how colorectal cancer screening and surveillance are most appropriately implemented, monitored, and evaluated for average-risk populations in the United States, the National Cancer Institute and the Office of Medical Applications of Research of the National Institutes of Health convened a State-of-the-Science Conference on February 2–4, 2010, to assess the available scientific evidence related to the following questions:

- What are the recent trends in the use and quality of colorectal cancer screening?
- What factors influence the use of colorectal cancer screening?
- Which strategies are effective in increasing the appropriate use of colorectal cancer screening and follow-up?
- What are the current and projected capacities to deliver colorectal cancer screening and surveillance at the population level?
- What are the effective approaches for monitoring the use and quality of colorectal cancer screening?

About the Artwork

The illustration on this volume's cover, and used on a variety of materials associated with the conference, depicts men and women interacting with each other about their experiences and plans, with regard to colorectal cancer screening. The squares, circles, and triangles on some of the figures indicate the variety of screening options available.

The image was created by Timothy Cook, an artist from Kensington, Maryland, working with a team from NIH's Division of Medical Arts and the conference sponsors, and is in the public domain. No permission is required to use the image. Please credit "Timothy Cook/NIH Medical Arts."



Agenda

Tuesday, February 2, 2010

- 8:30 a.m. Opening Remarks
Robert T. Croyle, Ph.D.
Director
Division of Cancer Control and Population Sciences
National Cancer Institute
National Institutes of Health
- 8:40 a.m. Charge to the Panel
Jennifer M. Croswell, M.D., M.P.H.
Acting Director
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
- 8:50 a.m. Conference Overview and Panel Activities
Donald M. Steinwachs, Ph.D.
Panel and Conference Chairperson
Professor and Interim Director
Johns Hopkins Institute for Policy Studies
Director
Health Services Research and Development Center
Department of Health Policy and Management
Bloomberg School of Public Health
The Johns Hopkins University
- 9:00 a.m. The Importance of Colorectal Cancer Screening and Its Public Health Impact
David A. Lieberman, M.D., FACP
Professor of Medicine
Chief
Division of Gastroenterology
Oregon Health and Science University
Veterans Affairs Medical Center
- 9:20 a.m. U.S. Preventive Services Task Force and Colorectal Cancer Screening: Current Recommendations and Supporting Evidence
Mary Barton, M.D., M.P.P.
Scientific Director
U.S. Preventive Services Task Force
Center for Primary Care, Prevention, and Clinical Partnerships
Agency for Healthcare Research and Quality

Tuesday, February 2, 2010 (*continued*)

I. What Are the Recent Trends in the Use and Quality of Colorectal Cancer Screening?

- 9:40 a.m. Trends in the Use and Quality of Colorectal Cancer Screening in the United States
Carrie N. Klabunde, Ph.D.
Epidemiologist
Health Services and Economics Branch
Applied Research Program
Division of Cancer Control and Population Sciences
National Cancer Institute
National Institutes of Health
- 10:00 a.m. Why Disparities Matter in Colorectal Cancer Screening
Electra D. Paskett, Ph.D., M.P.H.
Marion N. Rowley Professor of Cancer Research
College of Public Health
Ohio State University
- 10:20 a.m. Ensuring Quality in Colorectal Screening: Avoiding Misuse and Overuse
David F. Ransohoff, M.D.
Professor of Medicine
Clinical Professor of Epidemiology
Schools of Medicine and Public Health
University of North Carolina at Chapel Hill
- 10:40 a.m. Evidence-based Practice Center Presentation I: Systematic Review Methodology and Recent Trends in the Use and Quality of Colorectal Cancer Screening
Russell Harris, M.D., M.P.H.
Professor of Medicine
University of North Carolina School of Medicine
Cecil G. Sheps Center for Health Services Research
- 11:00 a.m. **Discussion**
Participants with questions or comments for the speakers should proceed to the designated microphones and wait to be recognized by the panel chairperson. Please state your name and affiliation. Questions and comments not heard before the close of the discussion period may be submitted on the computers in the registration area. Please be aware that all statements made at the microphone or submitted later are in the public domain.
- 11:40 a.m. **Lunch**
Panel Executive Session

Tuesday, February 2, 2010 (*continued*)

II. What Factors Influence the Use of Colorectal Cancer Screening?

- 12:40 p.m. Evidence-based Practice Center Presentation II: Factors Influencing the Use of Colorectal Cancer Screening
Debra J. Holden, Ph.D.
Community Health Psychologist
Senior Director
Community Health Promotion Research
RTI International
- 1:00 p.m. Patient Preferences, Patient-Physician Communication, and Shared Decision-making
Jennifer Elston Lafata, Ph.D.
Professor
Department of Social and Behavioral Health
School of Medicine
Virginia Commonwealth University
- 1:20 p.m. Patient and Physician Barriers to Colorectal Cancer Screening
Steven H. Woolf, M.D., M.P.H.
Director, VCU Center on Human Needs
Professor of Family Medicine
Virginia Commonwealth University
- 1:40 p.m. Primary Care Practice and Health System Influences
John Z. Ayanian, M.D., M.P.P.
Professor
Medicine and Health Care Policy
Harvard Medical School
Professor
Health Policy and Management
Harvard School of Public Health
- 2:00 p.m. **Discussion**

III. Which Strategies Are Effective in Increasing the Appropriate Use of Colorectal Cancer Screening and Follow-Up?

- 2:40 p.m. Evidence-based Practice Center Presentation III: Effective Strategies in Increasing the Appropriate Use of Colorectal Cancer Screening and Surveillance
Debra J. Holden, Ph.D.
Community Health Psychologist
Senior Director
Community Health Promotion Research
RTI International

Tuesday, February 2, 2010 (*continued*)

III. Which Strategies Are Effective in Increasing the Appropriate Use of Colorectal Cancer Screening and Follow-Up? (*continued*)

- 3:00 p.m. Intervention Strategies in Diverse Populations
Roshan Bastani, Ph.D.
Professor of Health Services
Associate Dean for Research
School of Public Health
University of California, Los Angeles
- 3:20 p.m. Primary Care Practice-Based Interventions
Allen J. Dietrich, M.D.
Associate Director for Population Sciences
Norris Cotton Cancer Center
Professor, Departments of Community and Family Medicine
Dartmouth Medical School
- 3:40 p.m. Quality Improvement Initiatives and Programs
Elizabeth M. Yano, Ph.D., M.S.P.H.
Adjunct Professor of Health Services
School of Public Health
University of California, Los Angeles
Senior Social Scientist and Co-Director
U.S. Department of Veterans Affairs Center
for the Study of Healthcare Provider Behavior
U.S. Department of Veterans Affairs
Greater Los Angeles Healthcare System
- 4:00 p.m. **Discussion**
- 4:40 p.m. **Adjournment**

Wednesday, February 3, 2010

IV. What Are the Current and Projected Capacities To Deliver Colorectal Cancer Screening and Surveillance at the Population Level?

- 8:30 a.m. CT Colonography Capacity in U.S. Hospitals
Megan C. McHugh, Ph.D.
Director of Research
Health Research and Educational Trust
American Hospital Association

Wednesday, February 3, 2010 (*continued*)

IV. What Are the Current and Projected Capacities To Deliver Colorectal Cancer Screening and Surveillance at the Population Level? (*continued*)

- 8:50 a.m. CT Colonography: Training Issues, Quality Control, and Potential Certification
C. Daniel Johnson, M.D.
Professor of Radiology
Mayo Clinic Arizona
- 9:10 a.m. Endoscopy Capacity
Laura C. Seeff, M.D.
Acting Branch Chief, Comprehensive Cancer Control Branch
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention
- 9:30 a.m. National Estimates of Resource Requirements for Delivering Colorectal Cancer Screening
Ann G. Zauber, Ph.D.
Associate Attending Biostatistician
Department of Epidemiology and Biostatistics
Memorial Sloan-Kettering Cancer Center
- 9:50 a.m. Evidence-based Practice Center Presentation IV: Current and Projected Capacity To Deliver Colorectal Cancer Screening and Surveillance and Effective Approaches for Monitoring Use and Quality of Colorectal Cancer Screening
Russell Harris, M.D., M.P.H.
Professor of Medicine
University of North Carolina School of Medicine
Cecil G. Sheps Center for Health Services Research
- 10:10 a.m. **Discussion**

V. What Are the Effective Approaches for Monitoring the Use and Quality of Colorectal Cancer Screening?

- 11:00 a.m. Achieving Population-Based Performance Measurement for Colorectal Cancer Screening in the United States
Eric C. Schneider, M.D., M.Sc.
Senior Scientist and Director
RAND Boston
Associate Professor
Department of Health Policy and Management
Harvard School of Public Health

Wednesday, February 3, 2010 (*continued*)

V. What Are the Effective Approaches for Monitoring the Use and Quality of Colorectal Cancer Screening? (*continued*)

- 11:20 a.m. Implementing and Monitoring Colorectal Cancer Screening Performance Improvement in an Integrated Healthcare System
Theodore R. Levin, M.D.
Clinical Lead for Colorectal Cancer Screening, TPMG
Physician Site Leader
Associate Chief of Gastroenterology
Kaiser Permanente Medical Center
- 11:40 a.m. Implementing and Monitoring Colorectal Cancer Screening Performance in the National Health Service
Julietta Patnick, CBE, FFPH
Director
National Health Service Cancer Screening Programmes
- Noon **Discussion**
- 12:30 p.m. **Adjournment**

Thursday, February 4, 2010

- 9:00 a.m. **Presentation of the Draft State-of-the-Science Statement**
The panel chairperson will read the draft statement to the assembled audience.
- 9:30 a.m. **Public Discussion**
The panel chairperson will call for questions and comments from the audience on the draft statement, beginning with the introduction and continuing through each subsequent section, in turn. Please confine your comments to the section under discussion. The chairperson will use discretion in proceeding to subsequent sections so that comments on the entire statement may be heard during the time allotted. Participants with comments should proceed to the designated microphones and wait to be recognized by the panel chairperson. Please state your name and affiliation. Questions and comments not heard before the close of the discussion period may be submitted on the computers in the registration area. For participants viewing the remote Webcast, comments may be submitted online at consensus.nih.gov/comments.htm. Comments will not be accepted after 11:30 a.m. Please be aware that all statements made at the microphone or submitted later are in the public domain.
- 11:00 a.m. **Adjournment**
Panel Meets in Executive Session
The public portion of the conference ends at 11:00 a.m. The panel meets in its last executive session to review public comments on the draft statement.

2:00 p.m.

Press Telebriefing

*The panel will provide a summary of its findings to the press and will answer questions from reporters via telebriefing. Only members of the press are permitted to ask questions of the panel during this time. Interested conference participants who are not members of the press may call in (from a remote location) to listen to the live telebriefing. Please go to **consensus.nih.gov** for instructions on joining the call.*

*The panel's draft statement will be posted to **consensus.nih.gov** as soon as possible after the close of proceedings, and the final statement will be posted 4 to 6 weeks later.*

Panel

Panel Chairperson: Donald Steinwachs, Ph.D.
Panel and Conference Chairperson
Professor and Interim Director
Johns Hopkins Institute for Policy Studies
Director
Health Services Research and Development Center
Bloomberg School of Public Health
The Johns Hopkins University
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Department of Health Care Policy
Harvard Medical School
Boston, Massachusetts

Paula Kim
Chief Executive Officer
Translating Research Across Communities
Green Cove Springs, Florida

Judith R. Lave, Ph.D.
Professor and Chairperson
Health Policy and Management
Director
Pennsylvania Medicaid Policy Center
Graduate School of Public Health
University of Pittsburgh
Pittsburgh, Pennsylvania

Thomas A. LaVeist, Ph.D.
Professor
Director
Center for Health Disparities Solutions
William C. and Nancy F. Richardson
Professor in Health Policy
Department of Health Policy and
Management
Bloomberg School of Public Health
The Johns Hopkins University
Baltimore, Maryland

Roberta B. Ness, M.D., M.P.H.

Dean and M. David Low Chair in
Public Health
The University of Texas
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Vice President
Mid-South Imaging and Therapeutics, P.A.
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Beth A. Virnig, Ph.D., M.P.H.

Professor
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Abstracts

The abstracts are designed to inform the panel and conference participants, as well as serve as a reference document for any other interested parties. We would like to thank the speakers for preparing and presenting their findings on this important topic.

The organizers would also like to thank the Planning Committee, the panel, the RTI International–University of North Carolina Evidence-based Practice Center, and the Agency for Healthcare Research and Quality, as well as the National Institute on Aging, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Nursing, and the Office of Behavioral and Social Science Research and our partners, the Centers for Medicare & Medicaid Services, the Health Resources and Services Administration, and the Centers for Disease Control and Prevention. We appreciate your continued interest in both the NIH Consensus Development Program and the area of enhancing use and quality of colorectal cancer screening.

Please note that where multiple authors are listed on an abstract, the underline denotes the presenting author.

The Importance of Colorectal Cancer Screening and Its Public Health Impact

David A. Lieberman, M.D., FACG

Importance of Problem

Colorectal cancer (CRC) is the second leading cause of cancer deaths in the United States. In 2009, there were more than 145,000 new cases and nearly 50,000 deaths. Approximately 5–6% of Americans develop CRC in their lifetime. Worldwide, there were more than 1 million new cases of CRC in 2009.¹

Epidemiology

There are differences in incidence, mortality, and cancer location associated with age, sex, and race. Cancer rates increase with advancing age (Table 1). With advancing age, CRC tends to appear more commonly in the proximal colon compared to the distal colon. Women have a lower age-related risk compared to men (Table 1). The rate of increase with advancing age is parallel in men and women. This apparent delay in the onset of CRC in women has been attributed to protective effects of hormones such as estrogen and progesterone until menopause.² In the United States, blacks have higher age-adjusted rates of cancer precursors³ and CRC,¹ and increased mortality compared to whites. Most studies have found that Asian Americans and Hispanics have lower rates of CRC compared to whites. Compared to other countries, CRC rates in the United States are among the highest. Worldwide, CRC incidence and mortality also are high in Canada, Europe, Australia, and Japan. More recently, rates have been increasing in Asia, particularly among populations of Chinese ethnicity.⁴

Table 1. Probability of Invasive Colorectal Cancer by Age and Gender¹

Age (Years)	Male (%)	Female (%)
<40	0.08 (1/1,296)	0.07 (1/1,343)
40–59	0.92 (1/109)	0.72 (1/138)
60–69	1.55 (1/65)	1.10 (1/91)
70+	4.63 (1/22)	4.16 (1/24)
Lifetime	5.51 (1/18)	5.10 (1/20)
Risk of Death in Lifetime	2.45 (1/41)	2.45 (1/41)

Etiology of CRC

The etiology of CRC is complex and multifactorial. Most cancers are preceded by the development of neoplastic colon polyps. It is likely that genetic factors plus environmental and lifestyle factors play a role. Hereditary syndromes have enhanced our understanding of the molecular genetics. There are several genetic pathways. The *chromosomal instability pathway* accounts for about 80% of CRC. A second pathway results in *microsatellite instability*, accounting for 15–20% of CRC. *Lifestyle factors* associated with increased risk of CRC include the following: dietary factors (diets with high fat, low fiber, low calcium); obesity; low levels of physical activity; tobacco smoking; and high alcohol intake. Although lifestyle choices may contribute to the risk of CRC, there is little evidence that modification of lifestyle will reduce risk.⁵ Several drugs may reduce the risk of CRC, resulting in *chemoprevention*. In randomized trials, the regular use of aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs) and the use of hormone replacement therapy have reduced the risk of developing new adenomas or cancer.^{2,6} However, these agents have potential adverse effects which may offset any potential benefit for CRC prevention and are not recommended for CRC prevention.⁷

Trends in Incidence and Mortality

In the United States, there has been a slow but steady decline in CRC incidence and mortality over the past decade. It is noteworthy that this trend has occurred during a time period when the average lifespan and obesity have increased, since age and body mass index may be associated with increased risk of CRC. There are several possible explanations for this favorable trend, including a significant increase in the population which has received screening over the past 20 years. During this same time period, the use of aspirin for cardiovascular diseases and other NSAIDs for joint complaints has increased, many women received hormone placement therapy, and there has been a national decline in tobacco smoking. In addition, dietary changes (such as lower consumption of red meat) also may play a role, although studies have failed to demonstrate that modification of diet modulates risk of adenomatous polyps. These factors may reduce the risk of CRC and could have contributed to the decline in incidence during this time period.

Identification of Individuals With Higher Than Average Risk

The most common indicator of high risk is having a first-degree relative with CRC. Individuals with first-degree relatives who developed CRC before age 50 should be considered at risk for one of the hereditary syndromes associated with CRC (Table 2). Familial risk accounts for 20% of patients with CRC.⁸ Epidemiologic studies suggest that if there is one index relative with CRC, the personal risk of cancer is increased almost two-fold, compared to individuals with no family history. Screening, preferably with colonoscopy, should be initiated at age 40, or 10 years younger than the age of the index family member, whichever comes first.⁹ Patients with chronic ulcerative or Crohn's colitis are at increased risk for CRC and also should receive surveillance with colonoscopy.

Table 2. CRC: Risk Stratification

	Genetic Mutation	Lifetime Risk of CRC	% of All CRC	Screening Recommendation
High Risk: Inherited Risk				
Familial adenomatous polyposis (FAP)	APC	100%	1%	Sigmoidoscopy in teenage years Genetic screening can be considered Colectomy if phenotype confirmed
Hereditary nonpolyposis colorectal cancer (HNPCC)	Mismatch repair genes	80%	2%	Colonoscopy beginning in 3rd decade at 2-year intervals Genetic screening can be considered Awareness of extracolonic cancers
MYH-associated polyposis (MAP)	MYH	Uncertain	Uncertain	Should be considered in polyposis syndrome if testing for FAP negative
Peutz Jehers	STK11	2–13%	<1%	Colonoscopy in teen years High risk for gastric and pancreatic malignancy
Juvenile polyposis	SMAD4 DPC4	Up to 50%	<1%	Colonoscopy in teen years

Table 2. CRC: Risk Stratification (continued)

	Genetic Mutation	Lifetime Risk of CRC	% of All CRC	Screening Recommendation
Moderate Risk				
Chronic ulcerative colitis or Crohn's colitis	—	Up to 30%	<1%	Colonoscopy every 2 years beginning at 8–10 years after onset of disease
Familial risk	—	10% or more	15–20%	Begin screening 10 years younger than age of index family member; colonoscopy preferred
Personal history of breast, uterine, ovarian cancer	—	Uncertain	<1%	No specific recommendation
Average Risk				
Age >50 years with no family history of CRC	—	5–6%	70–75%	Begin screening at age 50

Rationale for Screening Average-Risk Individuals

Individuals are considered average risk if they have no family history of CRC or suggestive symptoms of CRC (such as rectal bleeding). There is substantial evidence from randomized controlled trials that if cancers are diagnosed in average-risk asymptomatic individuals who undergo screening, the stage of cancer is more favorable and mortality lower than cancers diagnosed in unscreened controls.^{10–12} In addition to early cancer detection, screening may result in reduced cancer incidence.¹³ The National Polyp Study found that individuals who had colonoscopy with removal of adenomatous polyps had a lower than expected incidence rate of CRC over the next 6 years, an effect attributed to removal of precursor lesions.¹⁴ Indirect evidence in several case-control and cohort studies supports the hypothesis that screening can reduce the burden of disease. The primary goals of CRC screening are early cancer detection and cancer prevention.

Screening asymptomatic populations can be a costly and inefficient use of medical resources. Criteria applied to any screening test include key elements (Table 3). CRC satisfies most of these criteria: it is common; screening can identify early lesions; there is evidence of acceptance in the U.S. population, when education is provided; and treatment is effective when the disease is detected at early stages. CRC screening is among the highest-ranking preventive

services in terms of potential impact on quality-adjusted life years saved and cost-effectiveness.¹⁵ Over the past 15 years, screening guidelines in the United States have been revised several times, based on new information. Each program has advantages, limitations, and uncertainties. Patients should understand the “downstream” benefits and risks of the various screening tests. Each program has issues of quality and patient preference, which will be discussed in this State-of-the-Science Conference. Around the world, there is considerable variation in screening recommendations. However, virtually all Western countries now endorse some form of CRC screening for their average-risk populations.

Table 3. Criteria for Screening

Criteria	Colorectal Cancer
Disease is common.	5–6% lifetime risk
Early detection can prevent mortality.	<u>5-year survival</u> : Stage I: near 100% Stage II: 80% Stage III: 30–70% Stage IV: 10%
Treatment modalities are available.	Surgery, radiation therapy, and chemotherapy are available at specialized centers.
Screening methods are shown to be effective.	<u>FOBT</u> : Randomized controlled trials <u>Sigmoidoscopy and colonoscopy</u> : Case-control studies
Resources are available to provide screening in the United States.	<u>FOBT</u> : Yes; primary care setting <u>Sigmoidoscopy</u> : Yes; limited availability in primary care or specialty clinic <u>CT Colonography</u> : No; limited centers and fully trained radiologists <u>Colonoscopy</u> : Uncertain
Resources are available to provide diagnostic tests for patients with positive screening.	Colonoscopy resources are generally available if initial screening test positive.
Screening is cost-effective.	Models demonstrate cost-effectiveness
Screening methods are accepted by patients and providers.	Yes: 50% adherence in United States

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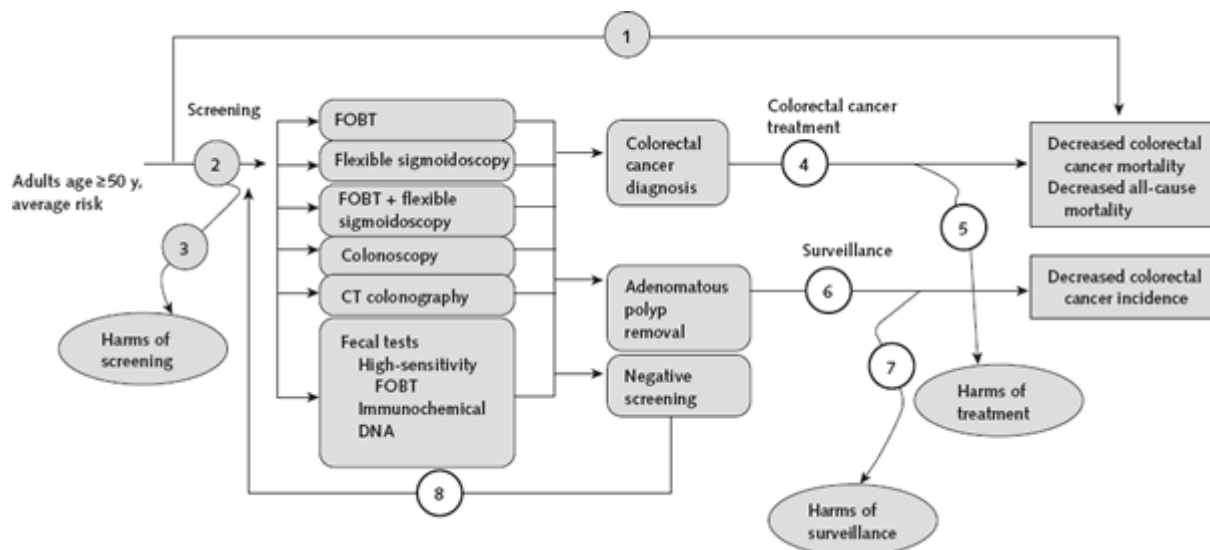
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U.S. Preventive Services Task Force and Colorectal Cancer Screening: Current Recommendations and Supporting Evidence

Mary Barton, M.D., M.P.P.

Screening for colorectal cancer has been shown to prevent colorectal cancer deaths and has been prioritized by the National Commission on Prevention Priorities as an important service with high public health value. The Agency for Healthcare Research and Quality commissioned a systematic evidence review of literature on the effectiveness of available colorectal cancer screening methods to support a 2008 recommendation from the U.S. Preventive Services Task Force (USPST). This session will include evidence from that review for the following colorectal cancer screening modalities: standard and high-sensitivity fecal occult blood testing (hemoccult II and SENSА), immunochemical fecal testing, fecal DNA testing, flexible sigmoidoscopy, optical colonoscopy, and computed tomographic CT colonography. Information on the benefits and harms, or risks, of each modality will be summarized. Figure 1 below displays the analytic framework for the systematic evidence review and lists the key questions used.

Figure 1. Analytic Framework and Key Questions



Key Questions

1. What is the effectiveness of the following screening methods (alone or in combination) in reducing mortality from colorectal cancer?
 - 1a. Flexible sigmoidoscopy
 - 1b. Colonoscopy
 - 1c. Computed tomographic (CT) colonography

1d. Fecal screening tests:

- i. High-sensitivity guaiac fecal occult blood test (FOBT)
- ii. Fecal immunochemical test
- iii. Fecal DNA test.

2a. What are the sensitivity and specificity of (1) colonoscopy and (2) flexible sigmoidoscopy when used to screen for colorectal cancer in the community practice setting?

2b. What are the test performance characteristics of (1) CT colonography and (2) fecal screening tests (as listed in 1d) for colorectal cancer screening, as compared to an acceptable reference standard?

3a. What are age-specific rates of harm from colonoscopy and flexible sigmoidoscopy in the community practice setting?

3b. What are the adverse effects of newer tests, including (1) CT colonography and (2) fecal screening tests (as listed in 1d)?

The presentation also will include a description of the 2008 recommendation on screening for colorectal cancer from the USPSTF, summarized in the following table.

Table 1. Screening for Colorectal Cancer: Clinical Summary of U.S. Preventive Services Task Force (USPST) Recommendation

This document is a summary of the 2008 recommendation of the USPSTF on screening for colorectal cancer. This summary is intended for use by primary care clinicians.

Population	Adults Age 50 to 75*	Adults Age 76 to 85 Years*	Adults Older Than 85*
Recommendation	Screen with high-sensitivity fecal occult blood testing (FOBT), sigmoidoscopy, or colonoscopy. Grade: A	Do not screen routinely Grade: C	Do not screen Grade: D
<p>For all populations, evidence is insufficient to assess the benefits and harms of screening with computerized tomography colonography (CTC) and fecal DNA testing.</p> <p style="text-align: center;">Grade: I (insufficient evidence)</p>			

Population	Adults Age 50 to 75*	Adults Age 76 to 85 Years*	Adults Older Than 85*
Screening Tests	<p>High-sensitivity FOBT, sigmoidoscopy with FOBT, and colonoscopy are effective in decreasing colorectal cancer mortality.</p> <p>The risks and benefits of these screening methods vary.</p> <p>Colonoscopy and flexible sigmoidoscopy (to a lesser degree) entail possible serious complications.</p>		
Screening Test Intervals	<p>Intervals for recommended screening strategies:</p> <ul style="list-style-type: none"> • Annual screening with high-sensitivity fecal occult blood testing • Sigmoidoscopy every 5 years, with high-sensitivity fecal occult blood testing every 3 years • Screening colonoscopy every 10 years 		
Balance of Harms and Benefits	<p>The benefits of screening outweigh the potential harms for 50- to 75-year-olds.</p>	<p>The likelihood that detection and early intervention will yield a mortality benefit declines after age 75 because of the long average time between adenoma development and cancer diagnosis.</p>	
Implementation	<p>Focus on strategies that maximize the number of individuals who get screened.</p> <p>Practice shared decision-making; discussions with patients should incorporate information on test quality and availability.</p> <p>Individuals with a personal history of cancer or adenomatous polyps are followed by a surveillance regimen, and screening guidelines are not applicable.</p>		
Relevant USPSTF Recommendations	<p>The USPSTF recommends against the use of aspirin or nonsteroidal anti-inflammatory drugs for the primary prevention of colorectal cancer. This recommendation is available at http://www.preventiveservices.ahrq.gov.</p>		

*These recommendations do not apply to individuals with specific inherited syndromes (Lynch syndrome or familial adenomatous polyposis) or those with inflammatory bowel disease.

For a summary of the evidence systematically reviewed in making these recommendations, the full recommendation statement, and supporting documents please go to <http://www.preventiveservices.ahrq.gov>.

Disclaimer: Recommendations made by the USPSTF are independent of the U.S. Government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Trends in the Use and Quality of Colorectal Cancer Screening in the U.S.

Carrie N. Klabunde, Ph.D.

Background and Objectives

Major expert groups in the United States have recommended screening asymptomatic, average-risk adults for colorectal cancer since the mid-1990s,¹⁻³ following publication of randomized controlled trial results demonstrating the efficacy of fecal occult blood testing (FOBT) in reducing colorectal cancer mortality.⁴⁻⁶ Colorectal cancer screening first appeared in guidelines issued by the American Cancer Society in 1980⁷ and has been tracked at the population level in the National Health Interview Survey (NHIS) since 1987. Monitoring trends in the use and quality of colorectal cancer screening is important for understanding how screening is being implemented in practice in the United States; to assess whether the population groups targeted for screening are in fact receiving it, consistent with guidelines; and to minimize potential problems with underuse, overuse, and misuse of screening.⁸ In this talk, I use data from multiple national sources to describe recent trends in the use and quality of colorectal cancer screening. I also describe aspects of colorectal cancer screening use and quality for which data are deficient or lacking.

Data Sources

a. National Health Interview Survey

The NHIS is a multi-purpose health survey sponsored by the National Center for Health Statistics, Centers for Disease Control and Prevention.⁹ It is an in-person interview survey that has been conducted annually since 1957 and is the principal source of information on the health of the civilian, non-institutionalized household population in the United States. The National Cancer Institute (NCI) has sponsored a periodic supplement to the NHIS of cancer control items since 1987. Data from the 2000, 2003, 2005, and 2008 NHIS are presented to show national trends in the overall use of colorectal cancer screening and in fecal occult blood test (FOBT), sigmoidoscopy, and colonoscopy. The data are standardized to the 2000 U.S. population by 5-year age groups. Response rates for the NHIS data presented range from 72% (2000) to 63% (2008).

b. Medicare Claims

Claims' data for the U.S. fee-for-service Medicare population age 65 and older for the time period 1998–2005 have been examined to assess trends in the use of colorectal cancer tests covered by the Medicare program, and in being up to date with Medicare-covered colorectal cancer screening.¹⁰ Medicare claims' data are presented to show national trends in use of double-contrast barium enema (DCBE) and immunochemical versus guaiac FOBT.

c. National Provider Surveys

NCI has sponsored several national surveys of healthcare providers on a variety of cancer control topics.¹¹ Data from two of these surveys are presented to show national trends in primary care physicians' colorectal cancer screening recommendations and practices, and in

screening quality. The *Survey of Colorectal Cancer Screening Practices in Health Care Organizations*, fielded in 1999–2000, was a nationally representative survey of primary care and specialty physicians and health plan medical directors designed to obtain national data on the conduct of colorectal cancer screening in the United States and to identify barriers to screening delivery in community practice. A total of 1,235 primary care physicians responded by mail, secure Web page, telephone, or fax (response rate = 72.0%).¹² The *National Survey of Primary Care Physicians' Recommendations and Practices for Breast, Cervical, Colorectal, and Lung Cancer Screening*, fielded in 2006–2007, was designed to obtain information on primary care physicians' knowledge, attitudes, recommendations, and practices regarding colorectal cancer and three other types of cancer screening. A total of 1,266 primary care physicians responded to this mail survey's colorectal/lung cancer screening questionnaire (absolute response rate = 69.3%; cooperation rate = 75.0%).¹³

Results

a. Trends in Use of Colorectal Cancer Screening

The proportion of average-risk adults age 50–75 who were up to date with colorectal cancer screening by having any of the tests measured in the NHIS (home FOBT in the past year, sigmoidoscopy in the past 5 years, or colonoscopy in the past 10 years) increased from 39% in 2000 to 55% in 2008. Screening rates increased over this time period for most population subgroups, including by age, sex, marital status, educational attainment, income, race/ethnicity, and immigration status. Screening rates did not increase significantly, though, for individuals who had no usual source of care, no physician visits in the past year, or who lacked health insurance coverage. Screening rates were higher for individuals age 65–75, who were married or living with a partner, with greater educational attainment, with higher income, who were born in the United States, who were non-Hispanic, with a usual source of care, with one or more physician visits in the past year, with healthcare coverage, or who had received timely breast, cervical, or prostate cancer screenings.

The proportion of average-risk adults age 50–75 who were up to date with colorectal cancer screening by having a home FOBT in the past year decreased from 17% in 2000 to 11% in 2008, and the proportion up to date by having sigmoidoscopy in the past 5 years decreased from 9% in 2000 to 2% in 2008. In contrast, the proportion of adults who were up to date by having colonoscopy in the past 10 years increased from 19% in 2000 to 48% in 2008. Medicare data show low rates of use of DCBE by fee-for-service enrollees: in 1998, 2% had this test, declining in subsequent years to 0.5% in 2005. Medicare data also show declining use of FOBT among fee-for-service enrollees, from 13% in 2003 to 10% in 2007, and very low rates of use of immunochemical FOBT (iFOBT). In 2004, the proportion of enrollees who had iFOBT was 0.3%, rising to 2% in 2007.

National physician data are consistent with trends reported by the adult population. In 2007, significantly fewer primary care physicians than in 2000 reported that they routinely recommended FOBT, sigmoidoscopy, or DCBE as colorectal cancer screening test options to their asymptomatic, average-risk patients.¹³ In contrast, the proportion of primary care physicians routinely recommending colonoscopy rose from 38% in 2000 to 95% in 2007. In 2000, 29% of primary care physicians reported that they performed sigmoidoscopy in their practices, while in 2007, only 4% did so.

b. Trends in Quality of Colorectal Cancer Screening

Underuse of colorectal cancer screening among adults age 50–75 remains a quality issue, although as previously noted, the trend is toward less underuse, with national screening rates increasing by 16 percentage points during 2000–2008.

Potential overuse is implied by physicians recommending screening for asymptomatic, average-risk patients at younger ages or at intervals more frequent than specified in guidelines. Colorectal cancer screening recommendations were guideline-consistent for 9% of primary care physicians in 2000 and for 19% of primary care physicians in 2007.¹⁴

Other important quality concerns are use of in-office instead of home FOBT (because in-office tests have not shown a mortality benefit) and failure to follow up positive FOBTs with total colon examination. Comparison of data gathered from primary care physicians in 2000 and 2007 showed no decline in their use of in-office FOBT, but a substantial increase in the proportion who recommend colonoscopy following a positive FOBT.^{15,16}

Data Limitations/Gaps

The assessment of national trends in colorectal cancer screening use and quality is hampered by several data limitations and gaps. Much of the available data capture one-time rather than repeat screening. This is an important gap because screening should take place periodically over time rather than as a one-time event. At present, there are no national data on use of computed tomographic (CT) colonography. This limitation will be addressed with the inclusion of CT colonography for the first time in the 2010 NHIS Cancer Control Supplement. Survey respondents may not be able to accurately report whether they had a colorectal cancer test for screening versus diagnostic purposes. Nor can survey data identify whether adults have received iFOBT versus standard guaiac-based FOBT. While Medicare claims are an accurate data source for measuring colorectal endoscopy use in the Medicare population, due to Medicare coding and billing rules they cannot be used to accurately distinguish whether procedures were done for screening versus diagnostic versus surveillance purposes.¹⁷ Medicare claims are a less accurate data source for measuring guaiac-based FOBT¹⁸; it is unknown whether they more accurately capture iFOBT, which is reimbursed at a higher rate than guaiac-based FOBT. Assuring screening quality requires obtaining and monitoring many aspects of test and operator performance, technical quality, and outcomes. This is both complicated and challenging for colorectal cancer screening because of its multiple test modalities. Data for monitoring national trends in colorectal cancer screening quality are highly limited.

Conclusions

Nationally, rates of colorectal cancer screening among average-risk adults age 50–75 are increasing, rising from 39% to 55% over the period 2000–2008. Screening rates increased for most population subgroups, but not for individuals who had no usual source of care, no physician visits in the past year, or who lacked health insurance coverage. Colonoscopy has become the predominant colorectal cancer screening modality. Its use increased substantially during 2000–2008, while use of FOBT, sigmoidoscopy, and DCBE declined. Rates of use of iFOBT, although rising, are quite low. There are no national trend data on use of CT colonography. Primary care physicians have essentially stopped performing sigmoidoscopy, which raises questions about availability of this screening test, even though it continues to be included in guidelines as a colorectal cancer screening test option. National trend data on

colorectal cancer screening quality are quite limited. Selected data show continued use of in-office FOBT by many primary care physicians, modest improvement in the guideline consistency of primary care physicians' colorectal cancer screening recommendations, and more substantial improvement in primary care physicians' recommendation of total colon examination following positive FOBT. There is need for development and support of data systems to evaluate and monitor colorectal cancer screening quality.

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Why Disparities Matter in Colorectal Cancer Screening

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There is evidence that disparities exist in colorectal cancer (CRC) incidence, mortality, and survival rates, as well as in CRC screening rates.^{1,2} CRC rates vary depending on gender, race/ethnicity, socioeconomic status (SES), education level, and geographic residence.²

According to the National Health Interview Survey (NHIS) for 2005, only 51.7% of males and 48.7% of females age ≥ 50 had either a fecal occult blood test (FOBT) within the past year, flexible sigmoidoscopy in the past 5 years, or colonoscopy in the past 10 years.⁴ Data from NHIS also documented that African Americans compared to whites (43.5% vs. 51.1%), individuals with less education compared to those with more education (11th grade or less: 37.0%, high school graduate: 46.9%, and grade 16+: 60.7%), and individuals without health insurance compared to those with health insurance (24.1% vs. 48.7%) were less likely to be within CRC screening guidelines. In addition, adults living in rural regions of the United States, such as Appalachia, also have CRC disparities. For example, CRC incidence rates in Ohio Appalachia are 62.3 per 100,000 compared to 55.2 per 100,000 in non-Appalachia Ohio; CRC mortality rates are higher in Appalachia Ohio compared to non-Appalachia Ohio (25.7 vs. 22.6 per 100,000); and CRC screening rates are lower in Ohio Appalachia compared to non-Appalachia Ohio (sigmoidoscopy/colonoscopy in past 5 years: 31.9% vs. 38.6%).⁵

Since CRC mortality rates are higher and CRC screening rates are significantly lower among minority, low SES, and rural populations, strategies to increase CRC screening rates and thus decrease CRC mortality rates are especially needed among these populations. The reasons for the increased CRC burden among certain populations are multifaceted and include many of the social determinants of health described by Marmot and Wilkinson.³ Factors affecting CRC screening rates are numerous, complex, and occur at multiple levels (patient, provider, organization, community, society).⁶ Thus, a multilevel framework that addresses many of these levels is important to use when examining and intervening on health disparities.

Factors that contribute to low CRC screening rates in general include screening barriers at the (1) patient level, including lack of awareness and knowledge, lack of provider recommendation, cultural attitudes, beliefs, norms, cost, insurance, embarrassment, inconvenience, lack of time, fear of cancer, unpleasantness, and perceived discomfort or pain associated with the test; (2) provider level, including lack of time, forgetfulness, norms, reluctance to order screening due to cost, perception of patient compliance, competing medical priorities, lack of knowledge or disagreement with guidelines, and concern over the efficacy of the screening tests; and (3) system level, including lack of reminder and tracking systems, and patient education and support.^{6,7}

We have addressed reasons for CRC screening disparities by investigating different levels using various methodologies among (1) a triracial rural population,⁸ (2) low-income women,⁹ (3) a rural Appalachia population,¹⁰ and (4) adults presenting at an urban primary care setting.¹¹

In the first study, the Robeson County Outreach, Screening, and Education Project focused on low-income, minority patients from three racial groups (African American, Native American, and white) residing in a rural region of North Carolina.⁸ A total of 171 participants were at average risk for CRC, and only 17.5% were within CRC screening guidelines. The odds of being within

CRC screening guidelines were increased for males (odds ratio [OR]=6.69), having a doctor's recommendation (OR=8.45 for FOBT, OR=7.96 for flexible sigmoidoscopy), and increased CRC knowledge (OR=1.72). Among females, African American participants reported more screening barriers and less positive beliefs about CRC screening than white or Native American females. These findings suggest two areas for intervention: improving provider recommendations for CRC screening and focusing on improving patients' beliefs about the importance of CRC screening.

In the second study, the goal of the Carolinas Cancer Education and Screening Project was to improve CRC screening among low-income women in subsidized housing communities in 11 cities in North and South Carolina.⁹ Intervention components were delivered by trained American Cancer Society volunteers and included outreach strategies (educational classes, direct mailings, brochures, media campaigns by community newspapers and local radio stations) focused on providing messages to the public and inreach strategies (waiting room posters, monthly examination room messages) directed to healthcare providers and clinics. Interviews with 2,098 participants focused on CRC knowledge, beliefs, barriers, and screening behaviors. Participants were African American (78%), 62% were 65+ years of age, and 4% were married. At baseline, physician recommendation was the strongest predictor (OR=21.9) of being within screening guidelines. After the intervention, there was an increase in positive beliefs about CRC screening ($p=0.010$) and in the intention to complete CRC screening in the next 12 months ($p=0.053$). However, the odds of being within CRC screening guidelines were similar for women living in the intervention and control cities.

In the third, the research project, "Get Behind Your Health! Talk to Your Doctor About Colon Cancer Screening," was conducted in partnership with a local community-based cancer coalition in Ohio Appalachia.¹⁰ A community needs assessment focused on CRC screening knowledge, behaviors, and barriers, and a CRC screening media campaign was pilot tested. The CRC screening rate was higher for average-risk participants ($n=170$) who had received a doctor's recommendation (OR=6.09; $p<0.0001$) and had adequate CRC knowledge (OR=2.88; $p=0.013$); it was lower among participants employed full time (OR=0.23; $p=0.034$). Having health insurance (OR=4.20; $p=0.029$) and being married (OR=2.58; $p=0.009$) were associated with a participant reporting that he/she had received a doctor's recommendation for CRC screening.

The fourth study was conducted in three urban primary care clinics. Patients were randomly selected to participate from scheduled medical appointments on random days.¹¹ Among average-risk participants ($n=104$), many (46%) were from a minority population and 16% had less than a high school education. Only 35% ($n=36$) were within CRC screening guidelines. Participants with fewer barriers, better knowledge, and more positive beliefs toward screening were significantly more likely to be within screening guidelines. A physician's recommendation for CRC screening was significantly related to screening among patients <65 years of age but not for older patients. These findings highlight the value of developing educational interventions targeting both patients and providers that address the key role of barriers, beliefs, and knowledge in patients' screening behaviors.

Each of these underserved populations has unique characteristics that contribute to CRC disparities including similar (e.g., poor patient-provider communication) and different (e.g., no public transportation) barriers to CRC screening. Data from the Ohio Appalachia project were used to develop, implement, and evaluate a 2-month CRC screening media campaign in an Ohio Appalachian county that focused on activating adults to talk to their doctor about CRC screening. Based on input from the community, the campaign was tailored to the specific needs of the population and included a billboard, posters, brochures, newspaper articles and ads, and

local television and radio spots. A local CRC survivor was asked to participate in the project by the cancer coalition members, and she was featured in all campaign materials. A survey of a convenience sample of average-risk adults (n=61) revealed that 69% recognized the campaign image and message, with a billboard being the most cited source. Among participants who reported seeing the message, two reported having talked to their doctor about the message and four reported that they were planning to talk to their doctor. A larger study is underway to test the effect of a multipronged intervention (billboards, clinic reminders) to improve CRC screening in this Appalachian population. Conversely, for our urban population, a multilevel intervention consisting of system interventions (posters), physician interventions (CME education), and patient intervention (barriers counseling by navigators) is being tested in a randomized controlled trial. Thus how we address CRC screening barriers among different populations is challenging, and individual strategies must be developed and tested for each population. Finally, to achieve maximum success, community members must be involved to help define effective strategies to reduce CRC disparities in the future.

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Ensuring Quality in Colorectal Screening: Avoiding Misuse and Overuse

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Background and Importance

The quality of screening may be compromised when screening is overused or misused. Examples include preferential use of one test or strategy (like colonoscopy screening) if any of several other tests or strategies (fecal occult blood test [FOBT], sigmoidoscopy plus FOBT) might be satisfactory or even better; use of a test in older persons with little benefit compared to harms; and use of post-polypectomy surveillance colonoscopy more aggressively than guidelines suggest, possibly resulting in small benefit or possible net harm. Misuse refers to when the examination itself is low quality; examples may include poorly conducted in-office FOBT or poorly conducted colonoscopy.

Understanding and controlling overuse is important for several reasons. Overuse may lead to adverse outcomes and possibly net harm including individual harm, when benefit of improved outcome is small compared to effort and risk of screening, or group harm when overuse in a small group leads to a resource shortage for other groups. Misuse can result in individual harm when the benefit of an intervention is decreased.

Guidelines Provide a “Set-Point” for Measuring “Use”; Therefore, Guidelines Themselves Must Be Appropriate

Because practice guidelines provide a kind of starting place or “set-point” often used to judge overuse, underuse, or misuse, consideration of the quality of guidelines themselves is required to assess overall quality. If guidelines were to be overly aggressive by going “beyond” evidence, that could lead to overuse from the very start. Concerns about guideline quality have been expressed in recent literature^{1,2} and will be the subject of an upcoming Institute of Medicine report about developing standard, trustworthy clinical practice guidelines.³ Currently, there are more than 200 guideline-making organizations and more than 2,000 guidelines about many medical conditions. Guidelines may differ not only in their recommendations but also in the process used to generate recommendations. Differences in process may occur in the composition of the groups of persons who assess evidence and make guidelines; in the process by which evidence is weighed; and in the fundamental principles or goals that direct the guideline-making process, for example, regarding whether patient outcome is the main focus.^{1,4}

While guidelines ideally might be intended to “do what is best for the patient,” recent commentary has pointed out that that ideal may be compromised by conflicting interests of physicians or professional groups who participate in making guidelines (who may want to maximize economic outcome or professional activity), or from payer or governmental participation (who may want to minimize economic cost).¹ Because guidelines play such an important strategic role in practice and in overall quality of care, it is necessary to understand and manage the process of guideline making itself.

Perhaps the most elaborate and widely referred-to process of guideline making are those developed by the U.S. Preventive Services Task Force (USPSTF). Many current organizations, including the American Cancer Society–U.S. Multi-Society Task Force (ACS-MSTF), use the

USPSTF principles and process as a kind of “touchstone” or reference point. As outlined by the USPSTF, the principles used to decide whether and when to screen involve addressing four questions: (1) Is burden of disease high? (2) Does disease left untreated lead to bad outcome? (3) Does screening/treatment *reduce* bad outcome? (4) What is *balance*: benefit versus harm? (modified from Harris et al.⁵). The main focus of this conceptual framework is patient outcome—what is it, and can it be improved by screening? The ACS-MSTF uses a less formal and less prespecified process.

Status of Colorectal Cancer (CRC) Screening Guidelines

Currently, the USPSTF^{6,7} and ACS-MSTF guidelines⁸ differ regarding important details about the role of colonoscopy. While the USPSTF makes no preference between colonoscopy and other modalities, the ACS-MSTF guideline prefers colonoscopy because “it is the strong opinion of these 3 organizations that colon cancer prevention should be the primary goal of screening.”⁸ These differences will be discussed in light of considerations of “quality of guidelines” noted above.

Table 1. A Comparison of CRC Screening Recommendations

Strategy	Source (Reference)			
	ACS-MSTF	USPSTF	USPSTF Modeling Findings	Other Modeling Studies
Hemoccult II annually	No	Yes	Suboptimal	Mixed
High-sensitivity hemoccult or fecal immunochemical test annually	Yes	Yes	Yes	Yes
Flexible sigmoidoscopy alone every 5 years	Yes	Yes	Suboptimal	Suboptimal
Computed tomographic colonography every 5 years	Yes	Insufficient evidence	Not evaluated	Yes
Colonoscopy every 10 years	Yes	Yes	Yes	Yes
Stool DNA testing every 5 years	Yes*	Insufficient evidence*	Not evaluated	Suboptimal

ACS-MSTF = American Cancer Society–U.S. Multi-Society Task Force; USPSTF = U.S. Preventive Services Task Force.
 * Interval not stated.

Source: Pignone and Sox, 2008.⁴

Evidence About Overuse

Screening

Colonoscopy may be used as a primary test in screening and, of course, is the main test used to work up any positive other screening test, FOBT, sigmoidoscopy, or virtual colonoscopy. The use of colonoscopy, and whether it is “preferred,” will be discussed in the consideration of quality of guidelines, above.

Surveillance

Colonoscopy also is used in post-polypectomy surveillance, which may be recommended for persons discovered to have adenomatous polyps at screening that indicate an increased future risk of cancer. Regardless of what test(s) are used in initial screening, implementation of any kind of screening program will result in substantial use of colonoscopy, because more than 30% of persons over age 50 have one or more adenomatous polyps which, when colonoscopy is done either as a primary screening test or in workup, may be discovered. The impact of post-

polypectomy surveillance on overall screening programs is dramatic: In modeling exercises assessing long-term implementation of various screening programs (with various initial tests) followed by post-polypectomy surveillance (by colonoscopy), the ultimate outcome, cost, and cost-effectiveness of many programs was remarkably similar because for any initial screening program, the “final common pathway” is discovery of polyps and post-polypectomy surveillance.⁹

For post-polypectomy surveillance, the guidelines themselves have evolved over time, perhaps presenting confusing messages to physicians and patients.¹⁰ There is evidence that physicians tend to recommend at the “most aggressive end” of recommendation, based on physician survey (Table 2)¹¹ and on in-office auditing of records in physicians’ offices. (Data to be shown.)

Table 2. Post-polypectomy Surveillance Recommendations in Clinical Practice

Surveillance Interval Recommended (Gastroenterologists)	Type of Polyp	
	Hyperplastic	Small (<1 cm) Adenoma
q 1–3 years	2%	11%
q 3 years	3%	41%
q 3–5 years	11%	41%
q 5–10 years	8%	3%

Source: From Mysliwiec et al.¹¹

If colonoscopy is overused in some instances in post-polypectomy surveillance, the overall impact on outcome could be considered in several ways in modeling exercises: What is the complication rate, and how does that impact overall outcome (benefit vs. harm) in groups with different characteristics such as age and comorbidity? What reasons might explain why aggressive behavior is happening? Possible reasons include economic incentive to do procedures; fear of legal liability if a cancer is missed; belief that guidelines are wrong (the guidelines may be wrong or incomplete); or patient satisfaction from aggressive treatment.¹² If we could learn more about incentives, it might be possible to develop appropriate interventions.

Suggestions for Future Research

1. Use “Tailored Risk” To Refine Guidelines

If subgroups of persons could be identified with low or average risk, then overly aggressive screening or surveillance might be more easily avoided by tailoring timing or types of tests to fit risk. For example, in primary screening, are there persons who have sufficiently low risk that screening does not need to be done at age 50? Or persons who might have a low enough risk of right-sided lesions (e.g., women under age 60) that colonoscopy could be put on a low-priority list? Or in post-polypectomy surveillance, might persons with adenomatous polyps (e.g., small size, small number) and/or with other clinical, demographic, or family history features, be put in the average-risk category?

Doing tailoring requires some kind of quantitative conceptual framework about what is our risk goal (what level do we want to lower risk to), what is a person's risk at any point in time, and what options are available to lower risk.

2. Understand Motivations To Be Aggressive in Surveillance

Physicians seem to operate at the more aggressive end of surveillance recommendations. What reasons drive that behavior? How might they be understood and managed? One can speculate that the following may be important: income, fear of medical liability, and fear of missing any cancer. On the one hand, it is admirable to try to avoid any cancer. On the other hand, if our expectations are too high, we may push ourselves to be overly aggressive with regard to what is best for the patient. Studying these problems may involve a kind of economic or psychological/behavioral expertise that we do not commonly see in traditional medical research but that has been used effectively in other scientific domains.^{13,14} Can we benefit from this kind of expertise in science about "health"?

3. Guidelines: Consider Their Quality in Implementation; Improve Quality

Consider additional research about quality of guidelines and what features make them trustworthy.

4. Understand Use of Guidelines in Practice

Which guidelines do physicians pay attention to and why? How do physicians implement guidelines when guidelines differ—that is, if they change over time (e.g., in the same organization) or if they differ (e.g., among different organizations) at the same point in time? What are the implications for the process of developing guidelines and for management of practice behavior?

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Evidence-based Practice Center Presentation I: Systematic Review Methodology and Recent Trends in the Use and Quality of Colorectal Cancer Screening

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Background

Colorectal cancer (CRC) is the third most common nonskin cancer among men and women; an estimated 146,970 people in the United States were newly diagnosed with this disease in 2009.¹ The overall age-adjusted incidence rate for CRC has decreased in both men and women and in all ethnic groups since the mid-1980s (well before the introduction of widespread screening), with an overall 3% annual decline between 1998 and 2005. CRC is also the third-highest cause of cancer death among men and women.² Periodic screening of people at average risk for CRC is recommended by two important national guideline groups, the U.S. Preventive Services Task Force and the American Cancer Society–Multi-Society Task Force,^{3,4} and multiple other professional societies.⁵ For CRC screening to contribute to a reduction in CRC mortality without unreasonable harms and costs, however, it must be used appropriately—that is, offered to people who have a reasonable probability of net benefit, with high quality of care.

Methods

We conducted a systematic review for key questions (KQs) 2 (Session II), 3 (Session III), 4 and 5 (Session IV), and used articles from our broad search of the literature (and others found by hand searches) to develop a background section for the review (KQ1). For our systematic reviews, we used standard methodology, guided by Evidence-based Practice Center methods with input from our Technical Expert Panel. We searched three electronic databases: MEDLINE®, the Cochrane Library, and the Cochrane Controlled Trial Register. The period searched was January 1998 to September 2009. We developed detailed eligibility criteria with respect to population, interventions, outcomes, time period, and study design. We limited eligible studies to those conducted in the United States so that the data would reflect domestic healthcare concerns, practices, and guidelines. We excluded studies that (1) were published in languages other than English, (2) did not report information pertinent to the KQs, (3) had fewer than 30 subjects for randomized or nonrandomized controlled trials or fewer than 100 subjects for observational studies, (4) were not original research, or (5) evaluated interventions that were conducted in academic settings that would not be applicable to most practice settings. Abstracts and the full text of articles were dually reviewed to assess for inclusion. To assess the quality (internal validity or risk of bias) of included studies, we used predefined criteria based on those described in the Agency for Healthcare Research and Quality (AHRQ) Methods Guide for Comparative Effectiveness Reviews (ratings: good, fair, poor). We also evaluated the overall strength of evidence for the body of literature (with respect to KQ 3, 4, and 5) based on an approach devised by the AHRQ Effective Health Care Program (grades: high, moderate, low, insufficient).

Results

National surveys show that CRC screening rates have been slowly increasing since 2000, reaching 50% to 60% in 2006.⁶⁻⁸ Screening rates in medical practices are also at about the same level.⁹ There are disparities in screening between white people and other racial and ethnic groups, with Hispanic people having some of the lowest screening rates. Low income, low educational level, and lack of health insurance also are associated with lower screening rates.⁸ States vary greatly in CRC screening rates.¹⁰ The increase in CRC screening since 2001 has come primarily from increasing rates of colonoscopy, with decreasing use of flexible sigmoidoscopy (FS) and fecal occult blood test (FOBT).^{8,11} This national trend toward increased colonoscopy and reduced FOBT is different than trends within the U.S. Veterans Administration program¹² and in other countries,¹³ where FOBT remains the most common screening test. In addition to underuse of CRC screening, good evidence suggests underuse of adequate discussions with providers about CRC screening.¹⁴ For some patients, discussions, if they occur, do not provide comparative information about the benefits and risks of alternative strategies or do not allow patient participation in decision-making.¹⁵⁻¹⁷ Overuse and misuse of screening in certain populations also seems evident. For example, some people are screened who have severe comorbidities and are unlikely to benefit,¹⁸⁻²⁰ older people above an age at which benefits are limited are being screened, and tests are possibly being used inappropriately.²¹⁻²⁴

Discussion

Although CRC screening rates are increasing, they are still suboptimal and fall below screening rates for breast cancer. In addition to this underuse, there are multiple, widespread reports of overuse and misuse of CRC screening.

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Evidence-based Practice Center Presentation II: Factors Influencing the Use of Colorectal Cancer Screening

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Background

While many factors have been shown in the literature to influence both the use and quality of colorectal cancer (CRC) screening tests, no systematic review of findings has been done to assess which factors are consistently associated with reductions or increases in screening. While the patient is ultimately the one to make the decision about whether to obtain screening,¹ this decision can be directly affected by discussions with a clinician about screening needs and options.^{2,3} Both the patient and the provider bring characteristics to this interaction that are immutable yet likely to influence the decision to seek screening. These predisposing factors exert their effects before any behavior occurs, by increasing or decreasing a person's or a population's motivation to undertake that particular behavior.⁴ Predisposing patient characteristics that may influence the ultimate decision related to CRC screening include family history of CRC; education level, income, and other socioeconomic factors;⁵ and location of residence (i.e., proximity to screening facilities and/or providers).⁶ Physician characteristics that have been shown to influence screening recommendations^{2,7} include perceived effectiveness of each type of test; physician demographic characteristics such as age, whether solo or group practice, and location of practice; and medical training and awareness of current screening guidelines. Interactions between the patients and clinicians, as well as factors related to the healthcare system, also can influence the ultimate use of tests. A key question to be answered with this systematic review was to identify the key factors that influence the use and quality of CRC screening.

Methods

We used standard systematic review methodology with additional guidance from a Technical Expert Panel and present additional information on the methods in our first abstract (see conference question 1).

Results

Key question (KQ) 2 focused on the factors that influence the use of CRC screening. We categorized these factors into seven topic areas: patient-level factors; physician characteristics, including connectedness between the physician and patient, and physician recommendations; patient and physician communication; periodic health exams or annual checkups; and system-level factors that may be associated with screening rates. The majority of included studies tested associations between these types of factors and CRC screening. Several factors are consistently and significantly associated with reduced CRC screening (i.e., $p < 0.05$ or confidence intervals that do not overlap or include 1.0). They include:

- Low household income (14 studies)
- No health insurance (8 studies)
- Being Hispanic (11 studies) or Asian (4 studies)
- Not being acculturated into the United States (10 studies)
- Limited access to care (i.e., lack of a regular source of primary care [19 studies] and no visits in previous year to provider [11 studies])
- No recent health maintenance visit (7 studies)
- No physician recommendation to be screened (12 studies).

Factors positively associated with CRC screening include having private insurance, being non-Hispanic white, having a higher education level, participating in regular screenings for other cancers, having a history of CRC or personal history of another cancer, having regular access to care, and having effective provider-patient communication. We found one study each that examined the association between screening and either specific physician characteristics or patient-physician connectedness associated with low screening rates. Thus, evidence was insufficient to draw conclusions about these relationships. We found no studies that examined factors associated with overuse or misuse of CRC screening or surveillance.

Discussion

As evidenced by the number of studies included for KQ2, a considerable array of research has explored screening behavior among both the general public and subgroups of the population (e.g., racial and ethnic groups, uninsured). Several factors, as noted in the results, are consistently associated with either increased or decreased CRC screening rates, but others are less consistent and inconclusive. Some of the inconsistencies in findings can be explained by how different studies operationalized the outcome measures; some studies identified people in the sample as being current with screening whereas others, using the same sample, produced different findings simply because of how the outcome was defined. For this reason, we emphasize the need to standardize the measurement of CRC screening so that studies can more consistently convey common factors associated with increased rates. Even with the issues of defining outcomes taken into consideration, common factors associated with screening are evident and could be used to determine how best to target evidence-based interventions.

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Patient Preferences, Patient-Physician Communication, and Shared Decision-Making

Jennifer Elston Lafata, Ph.D.

Background

The U.S. Preventive Services Task Force has advocated for the use of an informed and joint decision-making process when making preventive service recommendations to individual patients.¹ Although the majority of patients report wanting to share decision-making with their physician or other clinical provider, patient preferences are not uniform and may vary across situations. Furthermore, while the use and benefits of a shared decision-making process have been described for some targeted areas, the use and impact of shared decision-making for colorectal cancer (CRC) screening decisions is not well understood. Using audio-recorded data from primary care office visits, joined with a pre- and post-visit patient survey as well as post-visit claims' data, patient preferences for information and decision-making processes, patient and observer ratings of the decision-making process used during office visits, and the impact of these and the concordances of them with patient preferences on adherence to physician-recommended CRC screening is described.

Methods

Physician and patient samples were drawn from the universe of primary care physicians and patients in an integrated delivery system. This health system includes a large, salaried medical group which staffs 26 ambulatory care clinics in southeast Michigan. The practice uses an electronic medical record, which includes a prompt for evidence-based preventive health services including CRC screening. Between January and October 2007, a total of 77 primary care physicians were recruited for study participation (47% participation rate). Physician participants did not differ from nonparticipants in terms of age, gender, specialty, panel size, or CRC screening rate among their panel but did differ in their race (16% vs. 3% African American).

Patients were recruited for study participation approximately 2 weeks before a scheduled annual physical exam with a study participating physician. Eligible patients were insured via a health system-affiliated managed care organization, age 50 to 80 years, and due for CRC screening at the time of their appointment. Study participation was extended to eligible patients via a letter of study introduction followed by telephone contact. Those verbally agreeing to study participation completed a previsit survey over the telephone and were asked to arrive at their scheduled appointment 15 minutes early to enable written consent prior to their visit. Five hundred patients completed study participation (48% participation rate), which included completion of the previsit survey, audio-recording of the office visit, and a brief postvisit survey. Patient participants did not differ from nonparticipants in race, gender, or marital status but were significantly younger (58 vs. 60 years).

The previsit survey collected information on patient preferences for decision-making processes and information when making preventive health decisions. Patient and physician CRC screening talk captured via the office visit audio-recordings was coded for inclusion of the "5 A's" defined by (1) assessment of CRC screening indication; (2) physician advice for patient to be screened; (3) obtaining patient agreement for service; (4) assistance in obtaining screening; and (5)

arrangement of follow-up¹ and elements of shared decision-making as defined by Charles et al.,² as well as for the provision of information consistent with established criteria for informed decision-making.³ The postvisit survey asked patients to self-report whether the decision-making process used for CRC screening was shared. Survey and audio-recorded data were joined with claims' data to evaluate associations of patient-physician decision-making processes, patient preferences, and their concordances with adherence to recommended CRC screening in the 6-month period following the recorded office visit.

Generalized estimating equation (GEE) methods that accounted for the nonindependence of patients receiving care from the same physician were used to test unadjusted associations between patient adherence and the provision of different types of information, patient and observer-rated decision-making processes, and the concordances of these with patient preferences. Of 500 visits attended, 485 resulted in audible recordings and 95% of these contained a discussion of CRC screening (n=461). Preliminary results are presented for 343 cases for which the coding of audio-recorded data is complete and for which at least 6 months of postvisit follow-up has elapsed.

Results

While the overwhelming majority of patients with a discussion of CRC screening received physician advice for screening (98%), the content of that recommendation varied. For example, while 87% of visits contained a discussion of how to complete or schedule a screening test (assist), 58% of the discussions included an assessment of why the patient was due for screening. Further, under a quarter (21%) included discussion of patient preferences and a negotiated course of action (agree), and only 4% included any discussion of results or follow-up (arrange).

At the time of the previsit survey, 69% percent of patients reported a preference for a shared decision-making process. Yet after the visit, only 45% reported that the CRC screening decision was shared, and patient self-reports of the decision-making process matched their previsit preference only 34% of the time. Observer-rated coding of Charles' four elements of shared decision-making resulted in no visit being categorized as using a shared decision-making process for colorectal cancer screening (i.e., none included all four elements of shared decision-making). Observers coded 28% of visits as containing patient and physician involvement in the decision-making process (element 1), 31% as containing the sharing of information (element 2), and 6% each as including a discussion of treatment preference (element 3) or resulting in an agreement on treatment (element 4). Furthermore, we found no significant association between these elements and patient self-reports of a shared decision-making process.

Fifty percent of patients ranked test accuracy as the most important information wanted when making preventive health screening decisions, but they rated knowing the disease for which they were being tested, the pros/cons of testing, and testing alternatives as equally important (mean 1.2–1.3 on a 7-point rating scale). While 58% of visits were coded as including information on the disease for which the patient was being tested, only 27% contained information on testing alternatives, 7% included discussion of test accuracy, and 6% contained information on testing pros/cons.

Six months following the audio-recorded visit, only 48% of patients were adherent to physician recommendations for CRC screening. Preliminary findings indicate significant associations between 6-month patient adherence to physician-recommended CRC screening and three items evaluated. First, if the patient-physician discussion included an assessment of why the patient

was due for screening, patients were significantly more likely to have been screened (57 vs. 43% odds ratio [OR]=2.49 [1.65–3.75]). Furthermore, if the patient received assistance with screening receipt, either via being given FOBT cards or a colonoscopy referral, he or she was significantly more likely to have been screened (54 vs. 46%, OR=1.58 [1.11–2.26]), or via help in scheduling a screening appointment, the patient was significantly more likely to have been screened (56 vs. 44%, OR=2.12 [1.41–3.20]). Although not statistically significant, a visit in which the patient received information regarding test accuracy also was more likely to result in patient adherence to CRC screening recommendations (60 vs. 40%, OR=1.62 [0.78–3.33]).

Conclusions

While the overwhelming majority of annual check-ups included a discussion of CRC screening and, among these, the overwhelming majority included a physician recommendation for screening (advice), only slightly more than half included discussion of why the patient was due for screening (assess), and less than a quarter included assessment of patient preferences and a negotiated course of action (agree). Such variation may be important to consider, as we found that inclusion of an explanation of why the patient was due for screening was significantly associated with patient adherence to screening.

Consistent with studies in other contexts, we found the majority of patients indicating a preference to share decision-making with their physician when deciding about the use of preventive health services. However, we found the use of shared decision-making for CRC screening decisions during annual physical exams to be rare to nonexistent, depending upon whether patient self-reports or observer-rated shared decision-making criteria are considered. Furthermore, only a third of visits resulted in patients reporting a decision-making process that matched their decision-making process preferences. Neither patient self-reports of a shared decision-making process nor a concordance between this process and patient preferences were associated with screening use following the visit. Notable is the fact that we could not test the impact of a shared decision-making process as defined by observers, as no visits in our sample met this criterion.

Also consistent with other studies, we found patients to place a high importance on information when making preventive health decisions. This included the desire for information on test accuracy, disease for which testing is indicated, testing alternatives, and the pros/cons of testing. Yet just over half of visits that contained a screening discussion contained any mention of the disease of colorectal cancer, and 7% or less contained information on test accuracy or the pros/cons of testing.

Policy Implications

Results here confirm the opportunity to improve patient-physician CRC cancer screening decision-making in primary care. This is true whether the presumed goal of these discussions is helping patients make informed and value-concordant decisions regarding CRC screening or to maximize adherence to evidence-based recommendations for CRC screening. More often than not, patient-physician discussions of colorectal cancer screening do not lead to patient receipt of recommended screening. Furthermore, more often than not, these conversations are void of information patients indicate is important and use a decision-making process that is not consistent with patient-reported decision-making preferences. While results do not support the use of a shared decision-making process as defined by patients to improve adherence to physician-recommended CRC screening, because no visit met the criterion for a shared decision-making process as defined by Charles et al.,² we cannot rule out that a shared

process would not result in an increase in screening use. While additional research is needed to determine this, there may be simple things—such as ensuring the reason a patient is due for screening and test accuracy are discussed or ensuring that the patient receives FOBT cards, a referral for testing, or help scheduling an appointment—that could be done to improve the decision-making process as well as increase the likelihood of patient adherence to physician-recommended CRC screening.

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Patient and Physician Barriers to Colorectal Cancer Screening

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Patients, providers, and systems of care encounter a variety of barriers to screening for colorectal cancer (CRC). The barriers encountered by patients are major impediments and are the focus of this presentation, but the difficulties experienced by providers and systems of care are also important. For example, primary care clinicians encounter difficulties when reminder systems are lacking to systematically identify patients eligible for screening; when time and reimbursement are inadequate to counsel patients properly about screening options; or when follow-up systems are unable to track receipt of screening tests (e.g., colonoscopy), ensure evaluation of abnormal results, and arrange for timely retesting at appropriate intervals. Healthcare systems encounter challenges with matching the supply of endoscopists to patient needs and with the costs and coverage of screening tests.

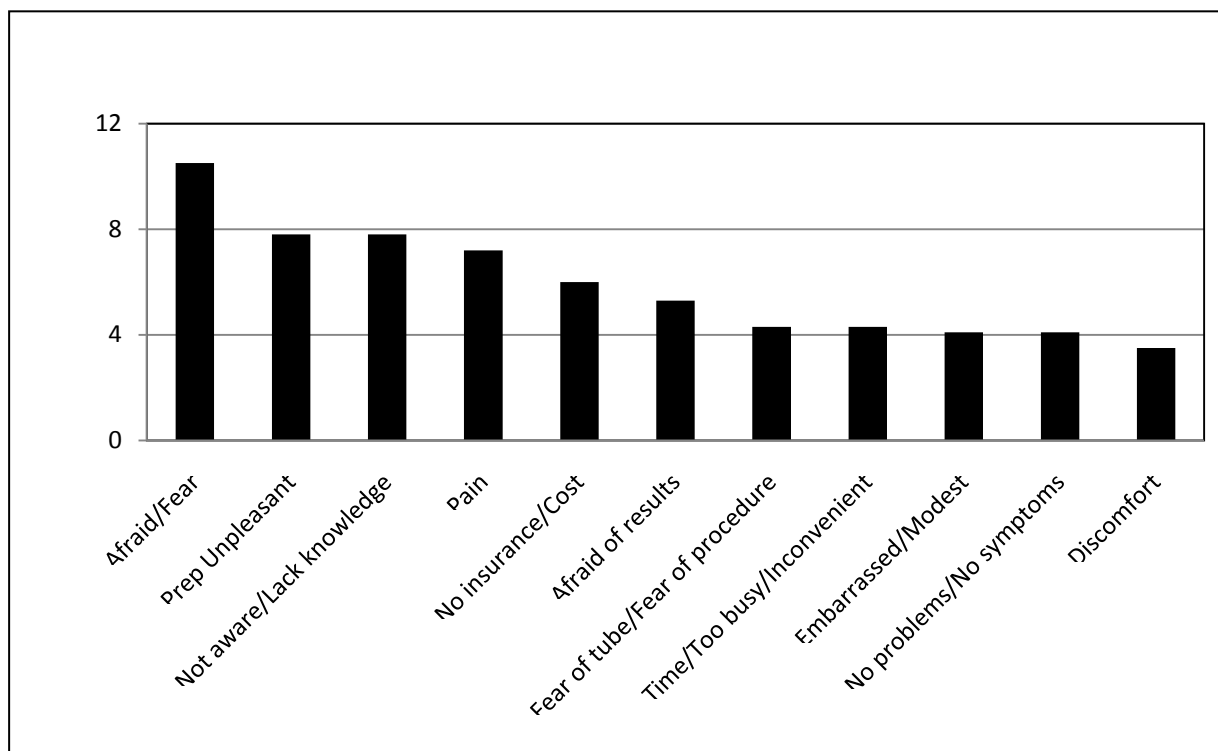
The barriers encountered by patients have been extensively studied.¹⁻¹⁹ Barriers supported by empirical data include the failure of a physician to recommend screening, scheduling difficulties, cost, lack of access to healthcare or insurance coverage, gaps in knowledge, disinterest, fear, embarrassment, perceived pain, and a lack of current symptoms or health problems. Knowledge of what barriers matter most is helpful to prioritize strategies to improve screening rates. However, the relative importance patients assign to CRC screening barriers in general, or to specific recommended tests, has not been adequately studied.

We conducted a mixed-methods study to measure systematically the factors that a diverse group of primary care patients identified for not being screened for CRC and the relative importance. We sought patients' input on all major barriers and the full menu of current screening options recommended at the time. The qualitative study, which was conducted as background for preparing a comprehensive barriers survey, included focus groups and an open-ended question on a regularly administered health assessment questionnaire, which enabled patients to describe barriers in their own words. The quantitative study involved the administration of the comprehensive barrier survey to 6,100 primary care patients to measure systematically the relative importance of factors that they identified for not being screened. Both studies oversampled African Americans.

Open-Ended Question

A total of 317 randomly selected patients, ages 50–75, answered an open-ended survey question about “the most important barrier” to CRC screening. The most important reasons cited for not being screened were fear/being afraid, unpleasant preparation (“prep”), pain, and no insurance/cost (Figure 1). Women were more likely than men to cite fear and an unpleasant prep as barriers

Figure 1. Important Barriers to CRC Screening



Focus Groups

Forty adults, ages 45–75, participated in seven gender-specific focus groups about barriers to, and facilitators of, CRC screening. Focus group participants cited many commonly published barriers that became more nuanced when the details were “unpacked” through discussion (Table 1).

Table 1. “Unpacked” Barriers

-
- Lack of awareness
 - Unawareness of the prevalence of CRC
 - Unawareness of the benefits/harms of CRC screening
 - Unawareness of the arguments for screening that apply to the patient personally
 - Unawareness of what happens when CRC screening is performed
 - Unawareness of how patients should care for themselves before/after screening
 - Unawareness of the pros and cons of each test
 - Unawareness of what insurance will cover
 - Unawareness of what modern early CRC treatment entails, and its success rate
 - Unawareness of survival rates for screen-detected CRC
 - Lack of a recommendation from the physician
 - Lack of clear, direct *advice to get tested*
 - Lack of emphasis of its *importance* or the *rationale* for screening
-

-
- Lack of *personalization* of the argument for the individual patient
 - Failure to present the *options* for screening, or the *details* of what they entail
 - Fear
 - Fear of *cancer* (being diagnosed, being treated)
 - General fear of *medical tests*
 - Fear of *being sedated* by anesthesia
 - Fear of *complications* from screening test procedure (e.g., colonic perforation)
 - Fear of learning of an *abnormal test result* or of *late-stage disease*
 - *Fear of burden on family/friends* (economically, psychologically, physically)
 - Better to find out later
 - Fatalism
 - Time
 - Lack of social support from family and close friends
 - Competing demands
 - Concern that some screening modalities are outdated
-

Patients also mentioned new, previously unreported barriers (Table 2).

Table 2. Previously Unreported General Barriers to CRC Screening Derived From Focus Groups

-
- Bad experience with (or stories of) previous CRC screening tests or insensitive professionals performing them
 - “Para-sexual” issues
 - Inadequate sense of self-worth
 - Mistrust...feeling that cheaper (i.e., lower quality) tests are being recommended or physicians have a conflict of interest (i.e., ordering tests that are beneficial to them given reimbursement)
 - Confusing an in-office fecal occult blood test (FOBT) with recommended home FOBT CRC screening
 - Waiting for a new test that may be easier to undergo (i.e., virtual colonoscopy)
-

Comprehensive Postal Survey

In 2007, we mailed a detailed questionnaire to 6,100 patients, ages 50–75, from 12 family medicine practices in the Virginia Ambulatory Care Outcomes Research Network, a practice-based research network. We oversampled persons ages 65–75 and African Americans. The questionnaire asked patients to indicate how strongly they identified with 19–21 barriers to four recommended tests. The barriers listed on the survey were based on the formative data from the open-ended questions and focus groups (above) and extant literature. The response rate was 55% (n=3,357). The mean age was 61.8 years, 30% of respondents were African American, and 73% were adherent to screening. The failure of a clinician to suggest screening and not knowing testing was necessary were the two most highly ranked barriers to CRC screening (Table 3). The top five barriers for each modality included test-specific barriers (e.g.,

handling stool, bowel preparation), which often outranked generic barriers to screening. Not knowing testing was necessary was a top barrier for all tests but colonoscopy.

Table 3. Barriers Common to the Four Recommended CRC Screening Modalities, for the Entire Sample (N=3,357) and for Screening Status Subgroups

	Rank Order				p-value ⁵
	Total Sample (Adjusted) Rank (n=3,357)	Never Screened (n= 498)	Ever Screened, Overdue per Guidelines ³ (n=412)	Currently Screened per Guidelines ⁴ (n=2,447)	
It would be difficult to have colorectal cancer screening because...					
My healthcare provider has never suggested I get this test.	1	1	1	1	<0.0001
I did not know if I should have this test.	2	2	6	2	<0.0001
This test costs too much.	3	3	2	3	<0.0001
I do not need the test because I feel fine.	4	4	4	4	<0.0001
The test is too embarrassing.	5	7	7	5	<0.0001
My health insurance does not cover this test.	6	6	8	6	<0.0001
No one in my family has had colorectal cancer.	7	5	3	7	<0.0001
I have a high insurance deductible.	8	9	10	8	<0.0001
I have other medical problems that are more important.	9	10	5	9	<0.0001
I am afraid of having this test.	10	8	9	10	<0.0001
I am worried about what this test might find.	11	12	13	11	<0.0001

	Rank Order				
	Total Sample (Adjusted) Rank (n=3,357)	Never Screened (n= 498)	Ever Screened, Overdue per Guidelines ³ (n=412)	Currently Screened per Guidelines ⁴ (n=2,447)	p-value ⁵
It would be difficult to have colorectal cancer screening because...					
I do not have time.	12	11	11	12	<0.0001
I do not feel comfortable talking to anyone about this test.	13	13	12	13	<0.0001
I have had other bad experiences with tests.	14	15	14	14	<0.0001
I do not know anyone who has had colon cancer testing.	15	14	15	15	<0.0001

Although physician advice and awareness of the need for screening are important, we concluded that barriers are heterogeneous across tests. Test-specific barriers warrant consideration in designing strategies to improve screening rates. Evidence that patients are more familiar with colonoscopy than other screening tests suggests an opportunity to improve screening rates by educating patients about alternative tests. Simply recommending screening appears insufficient. Patients need additional information about what each modality entails, attention to target population concerns, and a convincing explanation of the rationale.

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Primary Care Practice and Health System Influences

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Screening for colorectal cancer reduces morbidity and mortality by detecting cancers at an early stage when there is a greater chance of cure and by removing adenomas before they become malignant. In 2006, 71% of U.S. adults age 50 and older reported they had ever been screened for colorectal cancer; 61% reported their screening was up to date by current guidelines, ranging from 52% in Mississippi to 71% in Connecticut.¹ Similar regional differences in the Healthcare Effectiveness Data and Information Set (HEDIS) screening rates were evident for commercial and Medicare health plans in 2007, ranging from 45% in the south central region to 65% in New England.² These widely varying rates of screening underscore the need to understand how and why some regions, health plans, and medical groups are able to achieve higher rates of screening for colorectal cancer. Potential mediators include factors that are internal to primary care practices and those that are external to these practices in the communities and broader healthcare systems in which they operate.

One of the most important internal factors to promote colorectal cancer screening in primary care practices is the availability of high-quality information systems³ such as multifunctional electronic health records.⁴ These systems can identify patients due for screening, provide reminders to primary care physicians and patients, expedite test ordering, and monitor completion of screening tests and follow-up of abnormal tests.⁵ In 2006–2007, however, only one-third of primary care physicians were using partial or full electronic health records, and even fewer physicians were using electronic or paper reminders to physicians (30%) or patients (15%) or reports to physicians on their patients' screening rates (12%).⁶

A second important factor in primary care practices is their structure and staffing devoted to preventive services.³ A physician's recommendation is paramount in most patients' decision to undergo screening.⁷ Nonetheless, team-based approaches in which nonphysicians are trained and supported to monitor and counsel patients about screening have the potential to augment physicians' discussions with individual patients.^{8,9} Enhanced electronic health records and team-based approaches are central features of proposed patient-centered medical homes that may provide a more effective foundation to promote colorectal cancer screening.¹⁰

Factors external to primary care practices in local communities and healthcare systems also are crucial for promoting higher rates of colorectal cancer screening. For example, a city-wide screening program was recently instituted by the New York City Department of Health. Through a newly formed Colorectal Cancer Coalition that promoted widespread public education and use of patient navigators, screening colonoscopy among New York City residents age 50 and older increased from 40% in 2003 to 60% in 2007, and substantial racial and ethnic disparities in use of colonoscopy were eliminated over this 4-year period.¹¹

Public reporting of colorectal screening rates by commercial and Medicare health plans in HEDIS is another important external factor in the healthcare system.^{2,12} In Pennsylvania, nearly half of health plans reported making changes in their clinical guidelines and tracking and reminder systems in response to the HEDIS performance measure focused on colorectal cancer screening.¹³ In Massachusetts, public reporting of colorectal cancer screening rates also has been introduced for primary care groups in the state.¹⁴ With expanded public reporting of colorectal cancer screening, health plans and medical groups have readily available

benchmarks for gauging their performance, and colorectal cancer screening also can be incorporated in pay-for-performance measures.

Because colonoscopy is a relatively expensive procedure, health insurance is another crucial external factor that influences colorectal cancer screening in healthcare systems and communities. Among Medicare beneficiaries, private supplemental insurance is strongly associated with substantially higher screening rates,¹⁵ and increased penetration of managed care is associated with modest spillover effects on screening rates in traditional Medicare.¹⁶ Screening colonoscopy has become more affordable and accessible for Medicare beneficiaries since it became a covered benefit in 2001.¹⁷ Many commercial health plans also have expanded coverage for colorectal cancer screening, but the recent growth of high-deductible health plans may cause some enrollees to forego screening colonoscopy because of its relatively high cost. Furthermore, from 1995 through 2004, communities with high rates of uninsurance and poverty and less access to primary care did not see gains in endoscopic screening or reductions in the incidence of colorectal cancer that were observed in more affluent communities. This lack of improvement disproportionately affected minority communities.¹⁸

Over the next decade primary care practices and healthcare systems will be increasingly important vehicles for efforts to promote colorectal cancer screening.^{3,19} These efforts will mainly focus on raising screening rates, particularly for individuals, medical groups, and communities that have lagged as overall screening rates have risen in the past decade. In this process, clinical leaders and policymakers also must address potential overuse of expensive screening tests²⁰ and ensure that abnormal tests are evaluated appropriately.^{21–23} By focusing on both the quantity *and* quality of colorectal cancer screening, the adverse impact of colorectal cancer on morbidity and mortality can be reduced substantially.

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Evidence-based Practice Center Presentation III: Effective Strategies in Increasing the Appropriate Use of Colorectal Cancer Screening and Surveillance

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Background

Given the variability in screening rates across different subgroups of the U.S. population, and the inconsistencies with which patients tend to receive colorectal cancer (CRC) screening over time, development and testing of effective interventions to improve appropriate CRC screening is critical to reducing related morbidity and mortality. Interventions targeting patients, providers, or systems have been developed to act as “cues to action” for patients and may enhance awareness about the need for screening or otherwise increase screening rates.^{1,2} Patient-level interventions may include those that provide patient reminders, group or individually based education through small media (both with and without the use of decision aids to guide the patient through deciding whether to be tested and which test to obtain), and one-on-one interactions with the patient; they also may include efforts to eliminate structural or cultural barriers to screening. Provider-level interventions may include implementation of provider reminders or other practice-based efforts to increase appropriate recommendation or referral of patients for screening or follow-up, whereas system-level interventions focus on addressing aspects of the healthcare system that may discourage or otherwise act as a barrier to screening.

Methods

We used standard systematic review methodology with additional guidance from a Technical Expert Panel and present additional information on the methods in our first abstract (see conference question 1).

Results

This key question (KQ3) focuses on the evidence about the effectiveness of strategies that have attempted to increase appropriate CRC screening and follow-up. We classified interventions into those that targeted the patient, the provider, and/or the health system (there were no studies included that tested community-level interventions). We included 15 studies that targeted the patient,^{3–17} 2 that targeted the provider,^{16,18} and 5 that targeted the healthcare system.^{19–24} The impact of these interventions on CRC screening rates ranged from 0% to 41.9% when the intervention groups were compared with the control groups. Studies that examined the use of educational materials presented via small media^{3–5,15} had no impact on screening rates (high strength of evidence); those that provided means for eliminating structural barriers, such as access to CRC screening tests or addressing language barriers,^{4,8,11,13,17} demonstrated the highest impact on screening rates overall (14.6–41.9 percentage-point change; high strength of evidence). Those that delivered decision aids to patients through small media had mixed results

(low strength of evidence); two studies demonstrated an overall increase in CRC screening (14.2–23.0 percentage-point change),^{6,7} and the other demonstrated only a 3 percentage-point increase in CRC screening.¹⁰ Interventions that provided patient reminders in the mail or over the telephone had a significant impact on screening using any CRC test ranging from 5.4% to 11.7% and 15% (high strength of evidence).^{4,12,13,16} Two studies tested an education intervention in a group setting and found no difference in screening rates between their groups (low strength of evidence).^{14,15}

Only one study measured increases in discussions between the patient and providers as an outcome: a decision aid intervention using small media, which reported a 25.1% increase in discussions among patients in the intervention group compared with those in the control group (low strength of evidence).⁶ While findings from one study favored providing reminders to physicians to increase surveillance colonoscopies, the other found no difference between CRC screening rates of patients whose providers received reminders or not ($p=0.47$; low strength of evidence).¹⁶ The five studies (or 6 articles) on system-level interventions^{19–24} implemented system-based changes to improve referral of patients for screening^{21–23} or identified a person such as a patient navigator¹⁹ or someone in a similar role^{20,24} to help patients navigate the healthcare system. Their findings indicated that this type of intervention may provide promising effects on at least moderately increasing CRC screening (high strength of evidence).

Discussion

Interventions with direct interactions with patients to either eliminate structural or cultural barriers to screening or to better align the healthcare system to meet the needs of patients seemed to result in the greatest increases in CRC screening. To determine if these interventions would be feasible, more research is needed to assess the cost-benefit ratio of interventions to increase CRC screening and to determine which subgroups of the population are more likely to respond. Studies in this review suggest that those least likely to be screened regularly (e.g., low income, uninsured, low English proficiency) would benefit the most from interventions to increase CRC screening and therefore may be the populations to target through additional research.

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Intervention Strategies in Diverse Populations

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Disparities in colorectal cancer (CRC) incidence, stage at diagnosis, survival, and mortality are well documented,^{1,2} as are racial/ethnic and socioeconomic disparities in receipt of CRC screening.^{1,2} It is important to note that CRC screening rates are suboptimal for the U.S. population as a whole, but that low-income, ethnic minority, and other disadvantaged groups are particularly underserved in this regard. Still, the literature is fairly limited with respect to controlled trials that test interventions to increase CRC screening among disadvantaged groups.

Several studies report interventions targeting minorities but do not employ comparison groups, which makes it difficult to assess the true impact of the interventions.³⁻⁷ For example, Nash et al.⁷ conducted a multi-pronged system intervention in an urban public hospital to increase screening colonoscopy among its largely Latino patient population (n=470), which included patient navigators and an endoscopic referral system. The authors report a dramatic pre-post reduction in broken appointments (from 67% to 5%) following implementation of the intervention and an increase (relative risk [RR]=3.0) in colonoscopy rates in the catchment area of the hospital.

Many of the controlled trials to increase CRC screening rates among minority populations have employed system-level interventions such as physician reminders or enhancements in office system procedures.⁸⁻¹⁰ Roetzheim et al.¹⁰ conducted a cluster-randomized trial in eight primary care clinics (n=1,237) and tested a system intervention to increase fecal occult blood test (FOBT) rates. The intervention components included a cancer screening checklist; chart stickers that indicated whether specific tests were due, ordered, or completed; and reorganization of office responsibilities to increase efficiencies. They report an overall 14% relative increase in FOBT utilization in the intervention compared to the control group. Although over half the patient sample was of Latino or African American descent (about 25% each), analyses were not conducted to determine whether the intervention was equally or differentially effective by ethnicity. Potter et al.⁹ conducted a “time-randomized” trial (n=514) in which patients attending a flu clinic were offered a flu shot alone or a flu shot plus FOBT kit, brief education, and reminder calls. In this predominantly minority patient sample (about 50% Asian, 30% Latino), they report that the pre-post change in screening was 25% points greater in the intervention compared to the control group (odds ratio [OR]=11.3). Tu et al.¹¹ and Dietrich et al.⁸ similarly report effectiveness of system interventions delivered in the context of community health centers serving predominantly minority patients.

Another promising intervention strategy targeting minority groups in clinical settings has been the use of patient navigators to assist patients to obtain CRC screening.^{12,13} For example, Percac-Lima et al.¹³ conducted a large randomized trial (n=1,223) in a community health center (40% Latino patients) comparing a usual care control condition to a patient navigator intervention condition. They report a large intervention effect for colonoscopy receipt as well as for any CRC screening. This study was unusual in reporting stratified analyses by ethnicity, which showed significant effects in all of the subgroups examined, including Latinos. The importance of including sufficiently large sample sizes to enable stratified analyses is illustrated by Bastani et al.,¹⁴ who found that their mail plus telephone intervention was effective among Caucasians, Latinos, and Asians but failed to have an effect among African Americans (Table 1).

Table 1. Community-Based Trial: Randomized Trial To Increase Colorectal Cancer Screening Among First-Degree Relatives of Colorectal Cancer Cases

		Total	White	Latino	African American	Asian
	N	1280	351	403	284	242
Treatment vs. Intervention	OR	1.95*	1.69*	3.65*	1.13	2.60*

*p<.05

Source: From Bastani.¹⁴

A few studies in the literature report trials conducted in nonclinical settings and samples.^{15–18} A small-group randomized study targeting African Americans (n=134), conducted through senior centers, reported no significant intervention effect.¹⁸ Another larger study (n=2,098) tested the effect of community-based outreach and clinic-based in-reach strategies delivered by American Cancer Society volunteers.¹⁷ The intervention failed to increase CRC screening in the largely African American target population.

Thus, the majority of interventions targeting increased CRC screening among minority populations have been conducted in clinical settings. This is an important strategy and likely an effective way to reduce CRC screening disparities. However, many minority individuals do not have health insurance or systematic contact with a health provider or health setting. This is particularly true for Latino and Asian immigrant groups who are unlikely to be eligible for Medicare or other public programs that may cover routine CRC screening. To increase CRC screening among immigrant and other indigent groups will require rigorous testing of community-based outreach approaches that can connect individuals to available free or low-cost services.

Also, free or low-cost services that target uninsured minority and immigrant groups are generally not equipped to offer endoscopic procedures, especially colonoscopy, which is rapidly becoming the procedure of choice in the general population of insured individuals. Therefore, until the cost of colonoscopy is substantially reduced, we are likely to continue to see a two-tier system in which minority individuals will be relegated to FOBT as the only realistic option for CRC screening.¹⁹ Newer technologies such as fecal immunochemical tests²⁰ or stool DNA tests^{21,22} may provide more sensitive and specific options for earlier detection, assuming that costs will be modest as they become more widely available.

In response to these realities, a number of ongoing and recently completed trials are testing community-based interventions to increase FOBT receipt in various minority subgroups. For example, Maxwell et al.²³ just completed a randomized trial among Filipino immigrants and found large intervention effects (Table 2). Nguyen et al.²⁴ are testing a lay health worker intervention among low-income Chinese that will capitalize on existing social networks and norm changes to increase FOBT receipt. Nguyen et al.²⁵ are testing a community-wide intervention consisting of a media campaign, CRC education materials, and hotline to increase FOBT receipt among low-income Vietnamese. Early results suggest that community strategies have promise for narrowing the gap in CRC screening between the general population and minority groups.

Table 2. Community-Based Trial: Results of a Community-Based Randomized Trial To Increase Colorectal Cancer Screening Among Filipino Americans

	Screened During Follow-up Period (Self-Report)		Odds Ratio (95% CI)	P
Intervention with FOBT kit	30%	61/202	4.8 (2.6–9.1)	<.001
Intervention without FOBT kit	25%	45/183	3.6 (1.9–6.9)	<.001
Control (reference group)	9%	14/163		

Source: From Maxwell.²³

Lessons learned from breast and cervical cancer screening suggest that another important solution for reducing CRC screening disparities will lie in the wide availability and promotion of free screening made available through Federal and state programs that target low-income and uninsured individuals. Although rigorous evaluation is lacking, there is general consensus that the Centers for Disease Control and Prevention (CDC)-funded National Breast and Cervical Cancer Early Detection Program has greatly increased access to screening and diagnostic follow-up for the most needy segments of our population. The recent introduction by CDC of a program for CRC screening^{26–28} holds promise for similarly addressing access barriers to CRC early detection for low-income and minority groups.

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Primary Care Practice-Based Interventions

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Primary care provides a natural point of entry into the cancer screening process, but screening rates are lower for colon cancer than for breast or cervical cancer screening. A comparison of what is involved in screening for each in primary care is instructive.

Cervical cancer screening has been a routine part of women's primary healthcare since the development of the Pap test with its natural link to contraception and to maternity care. While it is tragic that more than 4,000 women die of this disease each year in the United States,¹ most women are more likely to be screened too often than not often enough. Breast cancer screening is also a well-established part of primary care, in fact, so well established that in some regions the primary care clinician is only engaged at the end of the screening process, getting the results after the test is done. This is because some mammography centers and insurance plans notify women directly when a repeat is due. In addition, the Pap and the mammogram have been stable single targets, although cervical cancer screening and preventive practices are now evolving.²

Colon cancer screening is another story. Over the past decade, the screening target recommended most in primary care has shifted from the fecal occult blood test (FOBT) to colonoscopy.³ Newer tests like computed tomographic (CT) colonography are very much in the news, although the evidence base is still evolving. Colonoscopy is costly, inconvenient, involves seeing another physician, and may not even be available depending on the region and a person's insurance status.⁴ Some primary care clinicians are still confused about the screening alternative of established effectiveness, FOBT, and mistakenly consider a specimen obtained in the office by digital rectal to be adequate.⁵

So what do we know about interventions to increase appropriate screening in primary care? The answer is quite a bit! Almost 20 years ago in the Cancer Prevention in Community Practice project, Patricia Carney and I demonstrated that an office system involving office staff, routines, and tools increased screening rates in the community practices of the Dartmouth Primary Care Cooperative Information Project (COOP) from 45% to 60%.⁶ Here the emphasis was on providing patients with a clear recommendation from the clinician and staff during a visit. Other studies have shown that mailed or telephone outreach increases colon cancer screening rates in a wide range of populations.^{7,8}

So what is to be done? Attention is needed in three areas: screening methods, implementation, and policy. All need an underpinning with research. The evidence base on newer home stool tests needs to be stronger. The fecal immunochemical test (FIT) has a number of advantages over FOBT,⁹⁻¹¹ but it has not been widely adopted and fell short of a clear endorsement in the most recent U.S. Preventive Services Task Force recommendation.¹² These tests can be done in the primary care office, may be better at detection and easier for patients than FOBT, and are less costly than colonoscopy.

We also need to know more about the strengths and limitations of colonoscopy and CT colonography. Why was no survival benefit from colonoscopy found from right-sided cancers in a recent study,¹³ and what is the role of biology, colonoscopist technique, pathologist interpretation, and patient prep?

Studies have shown that uptake of colon cancer screening can increase with office systems and patient outreach, but we do not know the most efficient ways to do this and have not explored the impact of the increasing time pressures in primary care. We also do not know enough about patient barriers for underserved groups and how to overcome them.

Policy matters as well. Quality indicators that evaluate health plans and may be tied to financial incentives often include rates of breast and cervical cancer screening but may not include incentives for rates of colon cancer screening. The rationale I have heard for this is the challenge of the 10-year time frame for most patients getting screening by colonoscopy. The issues are getting the data and who gets credit if the patient is up to date. Do these incentives matter and, if so, how can plans and physicians be rewarded?

There is work to be done in primary care to achieve the potential of colon cancer screening. Our challenge is to refine what we know now, apply it, and continue to seek new knowledge about the tests, the outcomes that they achieve, how to get them done, and how to follow up.

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Quality Improvement Initiatives and Programs

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Background

Despite the availability of effective screening tests and widespread recognition of the importance of early detection through screening, colorectal cancer (CRC) screening rates remain low.¹ In 2000, only 34% of the eligible U.S. population was screened for CRC within recommended time frames, while commercial health plan enrollees achieved 47% and Medicare beneficiaries 50% screening rates.^{2,3} In sharp contrast, the Veterans Health Administration (VA) achieved 80% CRC screening rates.⁴ Rates of follow-up of positive fecal occult blood tests (FOBTs) with complete diagnostic evaluation are much lower, with even VA rates ranging from 31% to 41%.

Design of effective quality improvement (QI) interventions and programs requires information on the determinants of variations in CRC screening and follow-up. To date, most assessments of screening deficiencies have focused on patient factors (e.g., payment sources, knowledge deficits, beliefs, preferences, income, patient compliance).⁵⁻⁷ However, efforts to improve screening rates through patient education programs have met with less than optimal effect.⁸ Primary care (PC) physicians play a critical role in promoting and ordering screening,⁹ although patients report lack of physician recommendation as the main reason they are not up to date.¹⁰ Nearly one-third of PC physicians rely on single-sample in-office FOBT, the least accurate CRC screening method, despite guidelines to the contrary.¹¹ Another third recommend repeat FOBT only after a positive test, again in contrast to most recommended guidelines. While inadequate provider training and knowledge of CRC screening guidelines for average-risk and high-risk patients are blamed for some of the variation,¹² interventions to improve provider knowledge run the risk of being “necessary but not sufficient,” given the general inadequacy of continuing medical education alone in invoking change.^{13,14} Provider-reported barriers and facilitators in their practice environments (e.g., office reminder systems) have shown particular promise in determining CRC screening variation.⁴ Practice characteristics also are consistently associated with delivery of preventive care,¹⁵ more so than physician characteristics (e.g., practice size, availability of information technology for guidelines, reminders) but not for CRC.¹⁶ PC practice “office processes” account for half of all comments among patients and providers regarding what fosters or hinders CRC screening.¹⁷ Interventions that focus on changing organizational care processes demonstrate the largest effects on prevention performance, including colon cancer screening.¹⁸ However, less is known about provider or practice characteristics associated with complete diagnostic evaluation (i.e., follow-up on positive FOBTs).

Quality Improvement Initiatives and Programs

Efforts to improve the quality of CRC screening span patient, provider, and organizational interventions. This talk will focus on QI initiatives and programs chiefly advanced by integrated health systems, such as the VA healthcare system and Kaiser Permanente, as well as smaller systems. Particular emphasis will be on the VA, which has undergone substantial restructuring toward primary care delivery, implementation of an electronic health record with decision support and practice management utilities, and incentivized audit and feedback of externally collected performance measures, including a continuous focus on CRC screening and follow-up for nearly 15 years.¹⁹⁻²² As a relatively unique public-sector turnaround, the VA's performance

accomplishments raise vital questions about how to translate lessons from their successes into opportunities for QI outside the VA.²³ The VA and other initiatives that will be presented reflect effective research-clinical partnerships designed to enhance CRC screening and follow-up, with the focus being on recently completed studies and work in progress that is as yet unpublished.^{24,25} These QI initiatives include efforts to address patient-level barriers to CRC screening, estimate prevalence and costs of duplicative CRC screening and CRC surveillance, implement QI toolkits to promote screening, establish collaborative care processes to promote screening and follow-up, and redesign systems to improve conduct and timeliness.

In addition to specific single- and multisite trials and QI implementation studies, findings from the national VA Clinical Practice Organizational Survey will be presented. Spanning the census of VA medical centers and large community-based outpatient clinics (90% response rate), these data describe variations in the conduct of best practices identified by the VA Office of Quality and Performance even among the highest-performing facilities. For example, VA PC practices use computerized reminders (93.8%), specialized (CRC-specific) computerized templates (40.0%), performance profiling and feedback for individual providers (55.1%), financial and nonfinancial incentives (20.4%), designated local clinical champions (20.4%), designated registered nurses for disease-specific management (8.4%), and/or provider education (40.4%). Colonoscopies are chiefly provided outside of primary care (i.e., in a gastroenterology clinic) (52.4%), with 28.0% of VA practices sending their patients to another VA facility and 13.8% obtaining colonoscopies through community providers. The remainder obtain colonoscopies within PC (4.4%) or do not provide them (0.4%). Gastroenterology services are not available onsite in 36.0% of VA practices. Most (83.6%) VA facilities train their PC practitioners in the use of CRC screening guidelines, chiefly through periodic lectures (75.1%), bulletins/notices (56.0%), new PC provider orientations (23.8%), Web sites/Continuing Medical Education (19.2%), or provider retreats (9.8%). More than two-thirds (69.3%) of VA PC practices have fully implemented service agreements between PC and gastroenterology clinics for coordinating CRC screening and follow-up. Only 29.8% of VA primary care practices had designated clinic support staff (other than the PC provider) to identify abnormal test results and order necessary follow-up for positive FOBT tests. Variations in best practices for QI will be described by urban/rural location, academic affiliation, and practice size and complexity.

Traditionally, cancer screening programs have been evaluated solely on the basis of screening rates, yet this not uncommonly represents an incomplete diagnostic assessment. For example, while VA CRC screening rates are higher than the national average, 41% of patients with positive FOBTs failed to receive follow-up testing.²⁶ Colonoscopies were performed an average of 9 months after the positive FOBTs. As a result, the VA launched a national effort to increase timely colonoscopy among patients with positive FOBT results, including institution of a national performance measure (with audit and feedback to managers and providers of colonoscopy) to follow up positive FOBTs within 60 days. Within 1 year, only one in four veterans received follow-up colonoscopies within 60 days of a positive FOBT. Activities designed to develop QI infrastructure (e.g., creating measurement tools and assembling QI teams) were positively associated with 60-day follow-up, although this relationship was mediated by implementation of specific process changes.²⁷ Constrained capacity (e.g., insufficient gastroenterology staffing) was associated with lower rates of timely follow-up. By 2009, the national 60-day monitor rate was 55%, the national target on VA's path to QI achieved by nearly 70% of VA facilities; however, one-third (34%) of patients with positive FOBTs eligible for follow-up colonoscopy did not undergo it even within 90 days. Newer monitors exclude patient refusals (14%), non-VA-referred follow-up (8%), and cases deemed "inappropriate" for follow-up (16%) to enhance credibility and use of monitors among providers. A majority of VA facilities use an Excel FOBT tracking tool, which provides them with patient-level information and tables, and runs charts to

track monthly follow-up timeliness measures (87% of 111 facilities with complete data). Screening and diagnosis tracking is now part of a more complete CRC treatment and surveillance monitor (e.g., time from diagnosis to treatment initiation). New studies focused on QI interventions to improve timely follow-up also will be discussed. For example, introduction of an electronic reminder for timely follow-up was associated with significant improvements in both timeliness and gastroenterology consultation rates for evaluation among veterans with positive FOBTs.²⁸ QI initiatives to improve complete diagnostic evaluations, timeliness of follow-up, and quality of bowel prep will be included.

Gaps in Knowledge That Require Further Research

Much work to date has focused on screening; however, follow-up rates for positive FOBTs remain low with completion rates for colonoscopy being far from optimal. To achieve the full benefits of CRC screening, we need to better understand the primary barriers to colonoscopy completion. We lack adequate research on the relative contribution of patient, provider, system, and environmental barriers to completion (e.g., notification problems, referral delays/inefficiencies, capacity constraints, patient no-shows/cancellations, poor prep, lack of transportation, or other factors). There also is very little evidence on how to address these barriers (e.g., whether group or individual instruction is most cost-effective for educating patients about bowel prep, how to minimize appointment no-shows, whether directly notifying the gastroenterologist is preferable to requiring a PC referral). Lessons from non-CRC-related QI initiatives also require consideration. For example, evidence suggests that QI interventions (e.g., educational resources, decision support) must be adapted to address local context.²⁹ They need to be tailored and/or have explicit intervention components added that address local needs, gaps, and capacities.³⁰ Translation of the VA's successes into QI strategies outside the VA also would be useful. This would include greater focus on the importance of implementation science, capitalizing on provider behavior and organizational change theories that will help inform design of more effective multifaceted QI initiatives. Other important issues include strategies for maximizing effective use of the United States' limited colonoscopy resources, reducing overuse or overzealous surveillance in favor of optimal allocation, more study of emerging technologies, and informed decision-making about the choice of screening mode.

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CT Colonography Capacity in U.S. Hospitals

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Computed tomographic (CT) colonography (or virtual colonoscopy) is a relatively new procedure used to detect colorectal polyps and cancers by taking a CT scan of the inside of the colon. Preliminary results from a large, community-based trial in 2007 indicate that CT colonography may be as effective as optical colonoscopy for colorectal cancer screening.¹ In 2008, the American Cancer Society (ACS) issued a new set of colorectal cancer screening guidelines that, for the first time, included CT colonography as a recommended option.²

Anecdotally, it is clear that many hospitals have adopted CT colonography services, yet there are many unanswered questions about the prevalence of the service and the implementation of the service into practice. The purpose of our study was to address two questions:

- What is the current capacity of U.S. hospitals to conduct CT colonography?
- What are the factors that influence a hospital's decision to adopt CT colonography?

Percent of U.S. Hospitals Offering CT Colonography Services

Using data from the 2005–2008 American Hospital Association (AHA) Annual Surveys, we compiled information on the percentage of hospitals offering CT colonography services. In 2008, 17% of all general, non-Federal hospitals in the United States offered the service, up from 13% in 2005. Members of the Council of Teaching Hospitals (COH), large hospitals, urban hospitals, private nonprofit hospitals, and hospitals located in the Northeast were more likely to offer the service than other hospitals (Table 1). Among hospitals offering CT colonography services in 2008, 69% also offered optical colonoscopy.

Table 1. Percent of Hospitals Offering CT Colonography Services, 2005–2008

	2005	2006	2007	2008
All Hospitals	13.0%	14.7%	15.9%	16.8%
Small (<100 beds)	8.1	8.6	9.1	8.8
Medium (100–299 beds)	13.1	15.1	16.2	17.7
Large (300+ beds)	26.1	30.2	34.0	36.5

Table 1. Percent of Hospitals Offering CT Colonography Services, 2005–2008 (continued)

	2005	2006	2007	2008
Private not-for-profit	14.6	16.7	19	20.5
Private for-profit	10.6	12.1	10.4	9.8
Public	10.3	11.1	11.5	11.6
Midwest	13.1	14.3	16.1	17.4
Northeast	18.8	20.7	25.4	27.1
South	11.5	13.0	13.0	13.8
West	12.1	14.9	15.4	15.0
Territories	16.0	11.1	13.0	17.7
Nonurban	8.6	9.6	10.5	10.8
Urban	17.0	19.5	20.1	22.2
COTH Member	39.3	45.7	48.3	51.3
Non-COTH Member	11.3	12.6	13.7	14.4
Network Hospital (i.e., part of a hospital system)	16.2	16.6	19.6	20.4
Independent Hospital	11.6	13.6	14.3	15.4

Source: Authors' calculations based on data from the 2005–2008 AHA Annual Surveys.

Factors Influencing the Adoption of CT Colonography

We conducted exploratory interviews with individuals from radiology departments at six hospitals that offer CT colonography services and three hospitals that do not offer the service to

explore the factors that influence the decision to adopt the service. Among those offering the service, the most frequently cited reason for adoption was to provide an alternative for patients with a failed colonoscopy or those unable to undergo optical colonoscopy. Other motivating factors included long waits for optical colonoscopy, a desire to address low screening rates in the community, and promising evidence on CT colonography in the peer-review literature. Most respondents reported that gastroenterologists were proponents of the service because it provided an alternative for patients who could not undergo optical colonoscopy. Only two respondents reported an initial hesitation or lack of support for the service among gastroenterologists.

All respondents from hospitals offering CT colonography noted that reimbursement was an important issue as they considered adoption of the service. CT colonography is currently not covered by Medicare³ or many other private payers except for patients with contraindications for optical colonoscopy or after a failed optical colonoscopy. Perhaps due to the lack of reimbursement, all but one of the hospitals perform less than 50 CT colonographies each year, typically for patients with failed optical colonoscopies.

Respondents indicated that staffing, physical space, and the availability of CT colonography services at neighboring hospitals were generally not important considerations in the decision to offer the service. Public awareness of CT colonography was low, so patient demand for the service also was not a motivating factor. All respondents had adopted the service prior to 2008, so the ACS screening guidelines were not a consideration.

Respondents from hospitals that offer CT colonography reported that the planning and implementation of CT colonography took less than 6 months. All of the hospitals had CT scanners with the capability to perform CT colonography. Half reported that they had to purchase a CO2 insufflator and/or software but considered these costs minor.

Respondents from the three hospitals that do not currently offer CT colonography said that they had at least considered offering the service. All indicated that a lack of reimbursement and the cost of implementing the service were major barriers that prevented the hospitals from proceeding with implementation. The estimated costs, as reported by respondents, ranged from \$5,000 to \$20,000. Factors such as the availability of onsite gastroenterological service, staffing needs, physical space, and local competition from hospitals offering the service were generally not major impediments to adopting the service. One hospital, however, did mention that the physical layout of its current facility limited its ability to provide patients with the necessary space to prepare for the screening test.

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CT Colonography: Training Issues, Quality Control, and Potential Certification

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Computed tomography (CT) colonography (CTC) is a specialized CT examination of the abdomen and pelvis where image data, combined with advanced imaging software, provide a full structural evaluation of the colorectum using multiple types of image displays. The radiology scientific literature is rich in reports of its advancement and effectiveness. The publication of the National CT Colonography Trial (ACRIN 6664) completed the clinical validation of CTC as a screening application.¹ This trial, the largest to date evaluating the effectiveness of CTC, evaluated 2,600 asymptomatic adults who were prescheduled for colonoscopy screening at 15 centers across the United States (including both academic and private practices). All patients were at least 50 years of age and had a full bowel preparation before undergoing both state-of-the-art CTC and colonoscopy (which served as the reference standard). The mean±SE sensitivity, specificity, positive and negative predictive values, and area under the receiver operating characteristic curve for patients with adenomas 1 cm or larger was 0.90±0.03, 0.86±0.02, 0.23±0.02, 0.99±<0.01, and 0.89±0.02, respectively.¹ The sensitivity for adenomas greater than 0.6 cm was 0.78 and greater than 0.8 cm was 0.87, with specificities of 0.88 and 0.87, respectively. These performance estimates are similar to those reported by Pickhardt et al.² and indicate that CTC can be performed at a high level at many institutions, including community hospitals. These estimates of performance are also similar to those reported for colonoscopy.² Overall, 12% of CTC screening patients would have been referred for colonoscopy if a polyp threshold of 6 mm or larger was selected, including CT false positives. Estimates of performance for polyps smaller than 5 mm were not possible because readers were instructed not to report lesions smaller than this threshold.

To achieve these results, a protocol for the conduct of the CT examination, patient preparation, and patient insufflation were standardized. In addition, all interpreting radiologists were required to meet training or experience minimums and pass a qualifying examination.

All patients were required to ingest oral contrast material to tag residual stool and residual fluid in the colon. The same colon preparation used for colonoscopy was required for this trial as CTC is dependent upon a fully cleansed colon, and nearly all patients had same-day colonoscopy (the trial reference standard). Colon distention was standardized using a mechanical insufflator. The CT examination protocol specified the type of CT scanner (16 slice or higher), slice thickness, and reconstruction intervals as well as tube current settings (mA and kVp settings). These parameters are important for visualizing small polyps and controlling radiation dose (currently half the dose of a standard body CT).

Radiologist training was required unless the radiologist had previously interpreted 500 CTC examinations. Training consisted of a 1½-day review of the appearance of common colorectal lesions and full case examples to detect unknown lesions. All radiologists were required to take a qualifying examination by detecting 90% of the polyps ≥1 cm that were deemed easy and moderately difficult to detect. For approximately half of the readers (8 of 15), this training or their prior experience was not adequate to pass the qualification test. These readers returned for more training specific for difficult-to-detect lesions, additional full case review, and successful retesting with passing scores.³ This experience underscores the need for CTC-specific training, even if radiologists are accomplished cross-sectional imagers. Multiple training opportunities

exist nationally, and both the American Gastroenterological Association and American College of Radiology (ACR) include training requirements in their practice recommendations and guidelines.^{4,5}

It is interesting to note that the requirement to detect 90% of polyps 1 cm or larger is the same sensitivity as determined in the ACRIN trial. Whether trial results can be engineered by careful training cannot be determined by this study—but it is encouraging that with adequate training, testing, and radiologist selection that high test performance could be achieved.

I believe that maintaining these high standards within the community also will require a concerted effort, similar to the mammography quality improvement program required by the Mammography Quality Standards Act. A quality database has been developed by the ACR for CTC within the National Radiologic Data Registry.⁶ Data elements collected include both process and outcome metrics. Process metrics include CT technique, the amount of residual stool in the colon, and the amount of colon distention. Outcome metrics include the true positive rate and false positive rate for patients with a detected 1 cm polyp using colonoscopy as the reference standard. CTC complications (perforation) and the rate of detecting significant extracolonic findings that can increase the overall patient costs also are measured. These findings are available for individual institutions to review their missed cases for learning and to compare their results with other reporting centers. Unfortunately, this database has been underutilized since its inception—with only six centers routinely using it. Without a requirement to participate, I believe that its full potential for learning, improving, and maintaining high-quality CTC will not be realized.

CTC has come of age as a viable colorectal cancer screening tool. Education and testing can result in high levels of examination performance. To ensure continued high performance, a quality improvement program will likely be required.

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Endoscopy Capacity

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Screening rates for colorectal cancer remain low compared to rates for other cancer screening tests,¹ and estimates of the capacity to screen the U.S. population are limited. In 2000, the Centers for Disease Control and Prevention (CDC) estimated the number of average-risk persons age ≥ 50 years not screened for colorectal cancer, the number of procedures required to screen this population, and the available endoscopic capacity to satisfy this unmet need. A national study was conducted in 2002 among U.S. physician practices, ambulatory surgery centers, and hospitals, and a similar methodology was subsequently used to conduct 15 U.S. state-specific capacity assessments from 2003 to 2005 (in Colorado, Georgia, Iowa, Maine, Maryland, Massachusetts, Minnesota, Michigan, North Carolina, New Mexico, New York, Ohio, South Carolina, Texas, and Washington State). These findings have been published in two peer-reviewed journal articles^{2,3} and in 15 unpublished state-specific reports, and presented at multiple meetings.⁴

The estimated available capacity of flexible sigmoidoscopies and colonoscopies, nationally and in 15 U.S. states, was obtained through the administration of a standardized survey instrument, the national Survey of Endoscopic Capacity (SECAP) (cdc.gov/cancer/colorectal/pdf/secap-national.pdf) and modified slightly for the state capacity assessments (cdc.gov/cancer/colorectal/pdf/secap-state.pdf). The estimate of the number of endoscopic procedures needed to screen the U.S. population for colorectal cancer was obtained through the development of national and state-specific models.

At the national level, approximately 1,800 medical practices were surveyed in 2002 using the SECAP survey. Questions were asked at the facility level regarding the endoscopist and practice specialty type, the current number of lower endoscopic procedures performed, and the potential maximum number that could be performed. The difference between the current and potential number of procedures was considered to be the available capacity. At the state level, between 2005 and 2006, a census was conducted of all practices in each participating state that used lower endoscopy for colorectal cancer screening.

The sampling frame for the national study included all U.S. medical facilities known to have purchased or leased sigmoidoscopes and/or colonoscopes between 1996 and 2003. The four leading U.S. endoscopic equipment manufacturers in 1999—Fujinon, Olympus America, Pentax Precision Instruments, Inc., and Welch-Allyn—as well as AmSurg, a practice management company that in 1999 owned and managed the majority of U.S. single- and multi-specialty ambulatory endoscopy/surgery centers, provided CDC with lists of these customers, from which the sampling frame was created. Nondisclosure agreements were signed for the transfer of these lists. The survey response rate was 74.4% for the national survey and ranged from 69.9–94%, with an average response rate of 80.5% for the state surveys.

The sampling frame for the national study included all U.S. medical facilities known to have purchased or leased lower endoscopic (sigmoidoscopy and colonoscopy) equipment between January 1, 1996, and December 31, 2000. The four leading U.S. endoscopic equipment manufacturers in 1999—Fujinon, Olympus America, Pentax Precision Instruments, Inc., and Welch-Allyn—as well as AmSurg, a practice management company that in 1999 owned and managed the majority of U.S. single- and multi-specialty ambulatory endoscopy/surgery centers (AECs), provided CDC with lists of these customers, from which the sampling frame was created. The sales lists and AEC lists are protected by legal agreements between CDC, the individual companies, and Battelle, the research company contracted by CDC to assist with these studies, as proprietary and sensitive business information. This list was updated with sales/leasing data through 2003 for the state assessments. The survey response rate was 74.4% for the national survey and ranged from 69.9–94%, with an average response rate of 80.5% for the state surveys.

Using data from the U.S. Bureau of the Census and CDC's National Health Interview Survey (NHIS), a national forecasting model was designed to estimate the number of U.S. adults not screened for colorectal cancer nationally and regionally, and the number of examinations needed to screen these persons. Similar models were designed for each participating state, using Behavioral Risk Factor Surveillance Survey data instead of NHIS data to estimate state-based screening rates.

In 2002, a total of 8,207 U.S. practices reported performing flexible sigmoidoscopy or colonoscopy for colorectal cancer screening in the United States. Gastroenterologists performed 82.5% of the colonoscopies and 43.7% of the sigmoidoscopies; surgeons performed 10.8% of the colonoscopies and 20.5% of the sigmoidoscopies; and primary care physicians performed 2% of the colonoscopies and 24.9% of the sigmoidoscopies. All practices combined in the United States performed approximately 2.8 million (95% confidence interval [CI], 2.4–3.1) flexible sigmoidoscopies and 14.2 million (95% CI, 12.1–16.4) colonoscopies but reported that they could increase to approximately 9.5 million flexible sigmoidoscopies (95% CI, 8.4–10.5) and 22.4 million colonoscopies (95% CI, 20.1–24.8) in a year. This represented an available capacity of 6.7 million additional sigmoidoscopies and 8.2 million colonoscopies, respectively, which could be used to screen the unscreened U.S. population.

This available capacity was compared to the number of tests needed to screen the unscreened population in a variety of hypothetical screening programs, including a fecal occult blood testing program, a sigmoidoscopy program, a colonoscopy program, and a program that represented current screening patterns. In 2000, approximately 41.8 million average-risk people age ≥ 50 had not been screened for colorectal cancer according to national guidelines. Sufficient endoscopic capacity existed to screen the unscreened ~42 million persons within 1 year using fecal occult blood testing, followed by diagnostic colonoscopy for positive tests. Depending on the proportion of available capacity used for colorectal cancer screening, it could take up to 10 years to screen the unscreened population using flexible sigmoidoscopy or colonoscopy as primary screening tests.

At the state level, capacity varied widely, with several states having sufficient capacity to provide state-wide endoscopic colorectal cancer screening within 2 years (Maine, North Carolina, South Carolina). At the substate level, when capacity was compared to need, some regions had an excess capacity of colonoscopies available for screening (Manhattan and Long Island, New York). The proportion of nonphysician endoscopists, surgeons, gastroenterologists, and primary care physicians performing either type of endoscopy differed by state and from the national

patterns, as did the type of specialty practice where the procedures were performed (single-specialty practices versus mixed-specialty practices).

The volume of sigmoidoscopy and colonoscopy, and the provider type varied by state and over time. This change in endoscopist practice is consistent with other reports.⁵ Despite reports suggesting potential provider shortages, the mix of providers performing endoscopy may offset variable availability of specific provider types.⁶ In the context of increased attention to colorectal cancer screening, with evolving screening technologies and provider patterns, the variability in capacity suggests the need for periodic endoscopic reassessment. Capacity estimates and needs assessments are currently being updated by CDC, in collaboration with Battelle and CISNET modelers, at the national level and simultaneously in 14 additional states, tribal organizations, and U.S. territories (Alabama, Alaska Native Tribal Health Consortium, Arkansas, Florida, Guam, Hawaii, Kentucky, Nebraska, Nevada, New Jersey, North Dakota, Pennsylvania, Utah, West Virginia). At the national level, the endoscopic resource requirements for colorectal cancer screening are being re-estimated in collaboration with CDC, Battelle, and CISNET modelers and, at the state level, resource requirements will be estimated with state/tribal/territorial specific models designed by CDC and Battelle.

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National Estimates of Resource Requirements for Delivering Colorectal Cancer Screening

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Introduction

The need for colorectal cancer (CRC) screening is real and immediate. CRC is the number two cause of cancer deaths in the United States, and yet it can be prevented with screening. Because colonoscopy is used for primary screening and diagnostic follow-up of other CRC screening tests, the availability of endoscopic capacity for screening and diagnostic colonoscopies is critical in planning for widespread CRC screening in the United States. The national endoscopic capacity in the United States for CRC screening has been estimated previously and is currently being updated by Seeff.^{1,2} The question we address is how many CRC screening tests and colonoscopies are needed to conduct CRC screening and surveillance for the U.S. population. We compare these numbers in a variety of screening scenarios and will match these numbers to the potential availability of colonoscopy for CRC screening and surveillance.

Methods

MISCAN Microsimulation Model

We used the well-validated population-based MISCAN microsimulation model to simulate the U.S. population for the years 1995–2030. Based on these simulations, we assess the resources required for population-based screening for different scenarios, starting currently and accounting for past screening. The MISCAN model represents the adenoma-carcinoma sequence as a series of potential changes from normal colon, to one or more adenomas, to the potential growth of an adenoma by size, to transformation to preclinical or clinical CRC, and sometimes to death. We simulate the population with the natural history of the adenoma-carcinoma sequence and overlay screening interventions, which can interrupt this sequence by detecting and removing adenomas or detecting early-stage disease. A detailed description of the model is given at cisnet.cancer.gov³ for the Cancer Intervention and Surveillance Modeling Network (CISNET).

Screening Population

We assumed that 5% of the population had colonoscopy screening starting as early as age 40 because of known higher risk due to family history of CRC.⁴ The other 95% of the population would follow screening recommendations directed to the general population.⁵ In this population group, screening interventions were initiated at age 50. We did not account for the other high-risk categories of inflammatory bowel disease, hereditary nonpolyposis CRC, and familial adenomatous polyposis because of limitations in measurement of these populations.

Screening Program

We considered several hypothetical single-test screening programs initiated in 2008, using colonoscopy, flexible sigmoidoscopy, guaiac-based fecal occult blood test (FOBT), immunochemical fecal occult blood test (FIT), or computer tomographic (CT) colonography. The test characteristics of these CRC screening tests are reviewed by Zauber.^{6,7} In all simulated programs, persons with familial risk received colonoscopy only.

Resource needs were assessed for each of these screening programs, including screening and diagnostic colonoscopy of newly screened individuals and surveillance for those with an adenoma or CRC detected at screening. In the simulated population, we assumed previous screening rates using FOBT, sigmoidoscopy, and colonoscopy as estimated from the National Health Interview Survey.⁴ Follow-up surveillance colonoscopies were performed at appropriate intervals based on findings at index colonoscopy for any of the past or new screening colonoscopies. For some, surveillance continues after negative colonoscopy findings, consistent with the U.S. Multi-Society Task Force on Colorectal Cancer recommendations.⁸

Adherence to screening program. We assumed 100% adherence rates for screening in each simulated program but assumed 75% adherence rates as a sensitivity analysis. Although the assumption of 100% adherence is not realistic, it provides a maximum estimate for colonoscopy resources required.

Population implementation of nationwide screening. In practical terms, nationwide CRC screening cannot easily be delivered within 1 year. We used the microsimulation modeling to derive CRC screening programs that would be delivered within 1 year or phased in over 5 and 10 years.

Results

We present the screening resource requirement results for a colonoscopy screening program initiated in 2008 for the total population without phasing (Figure 1) and phased in over 10 years (Figure 2), with prior screening history displayed and accounted for when scheduling current screening. Resource requirements for a FIT program are presented without phasing (Figure 3) and with 10-year phasing (Figure 4).

Prior Screening Impact on Current Screening Resources

In 1995, FOBT and flexible sigmoidoscopy were the most commonly used screening tests, respectively, with a decline in these tests and an increase in colonoscopy screening increasing by 2005 (Figure 1). Total colonoscopies performed from 2008 forward (solid line) include diagnostic colonoscopies performed for prior positive screening tests, and screening and surveillance colonoscopies started in 2008.

Figure 1. Number of Tests or Procedures Before and After Implementing Colonoscopy Screening Program—Delivered Over 1 Year

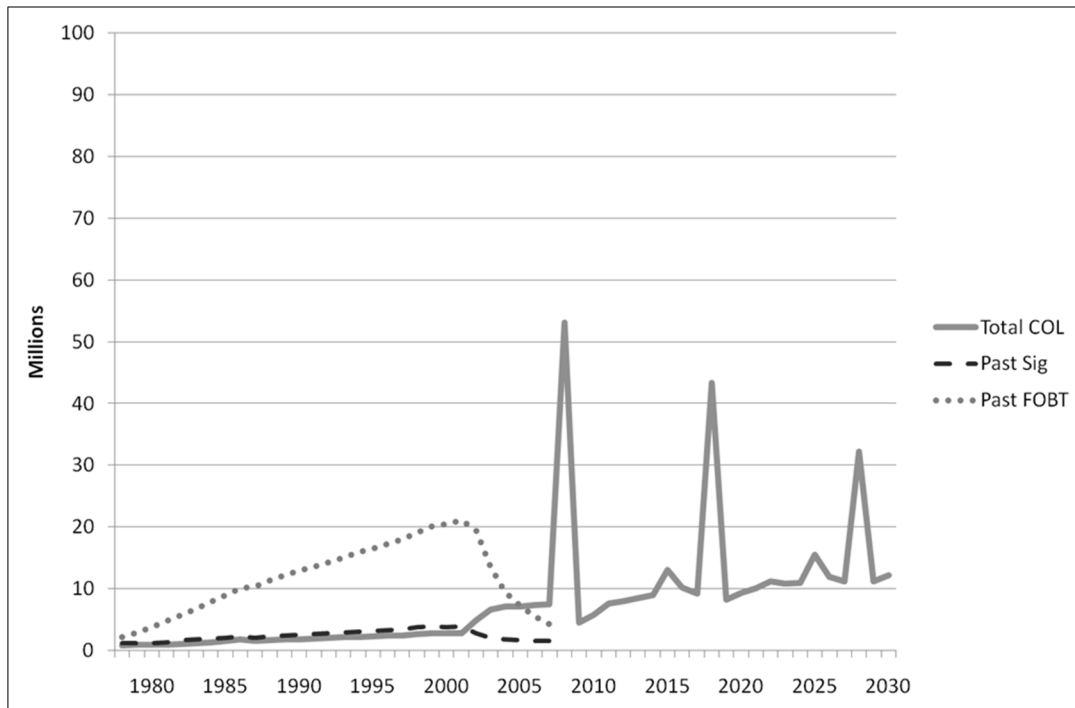


Figure 2. Number of Tests or Procedures Before and After Implementing Colonoscopy Screening Program—Delivered Over 10 Years

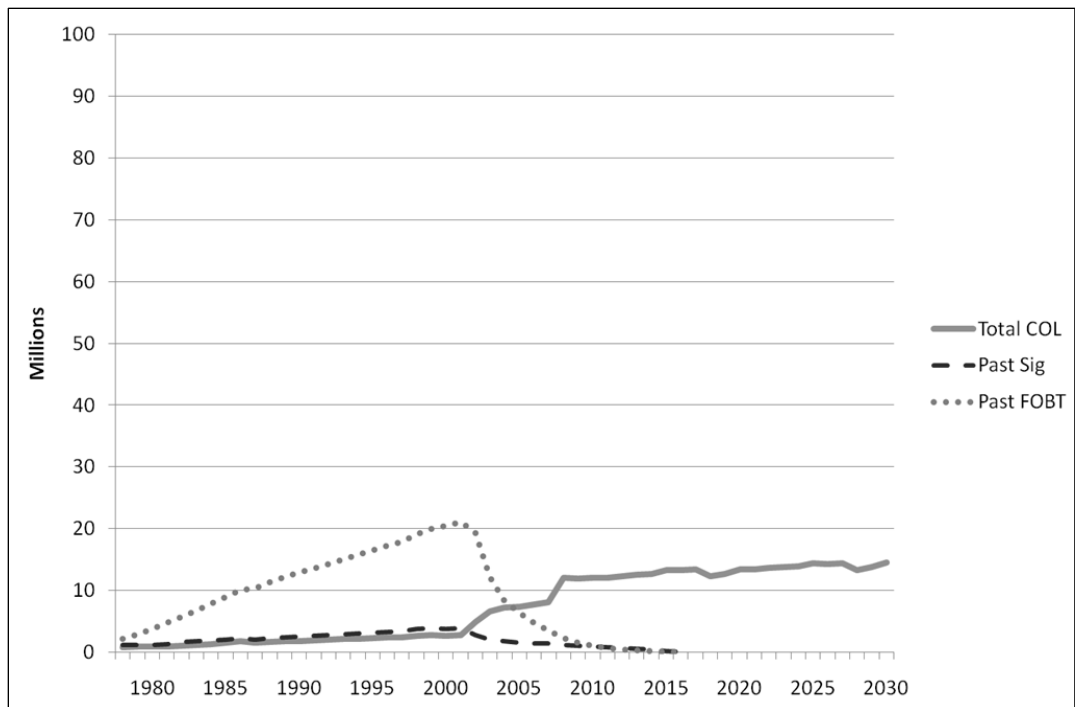


Figure 3. Number of Tests or Procedures Before and After Implementing FIT Screening Program—Delivered Over 1 Year

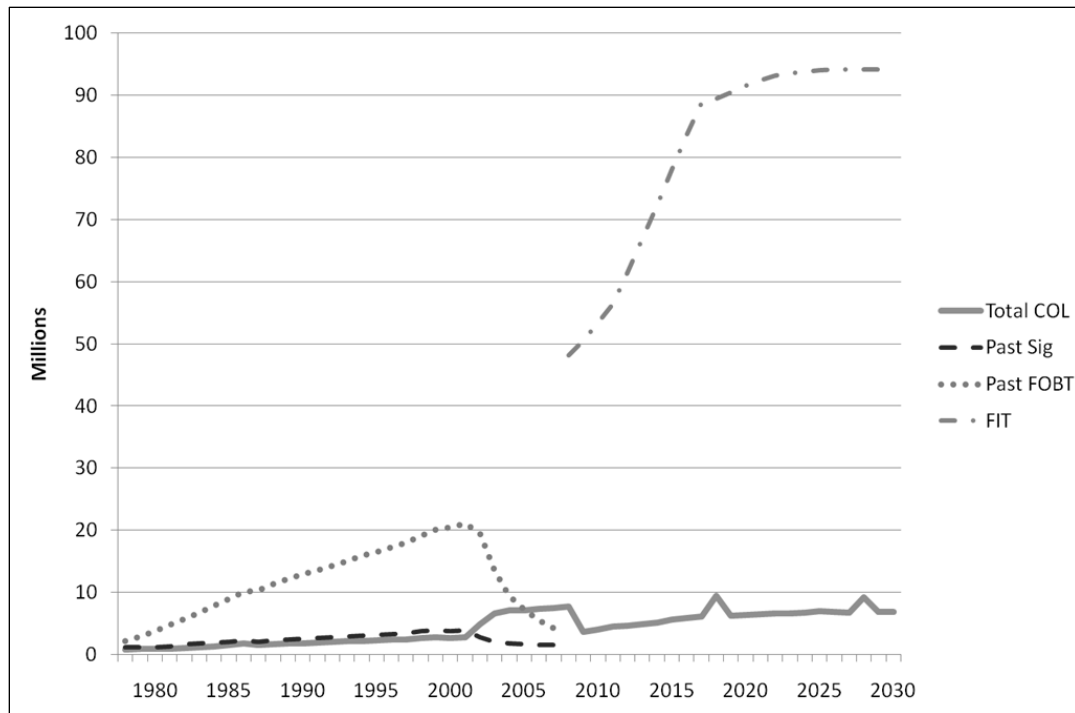
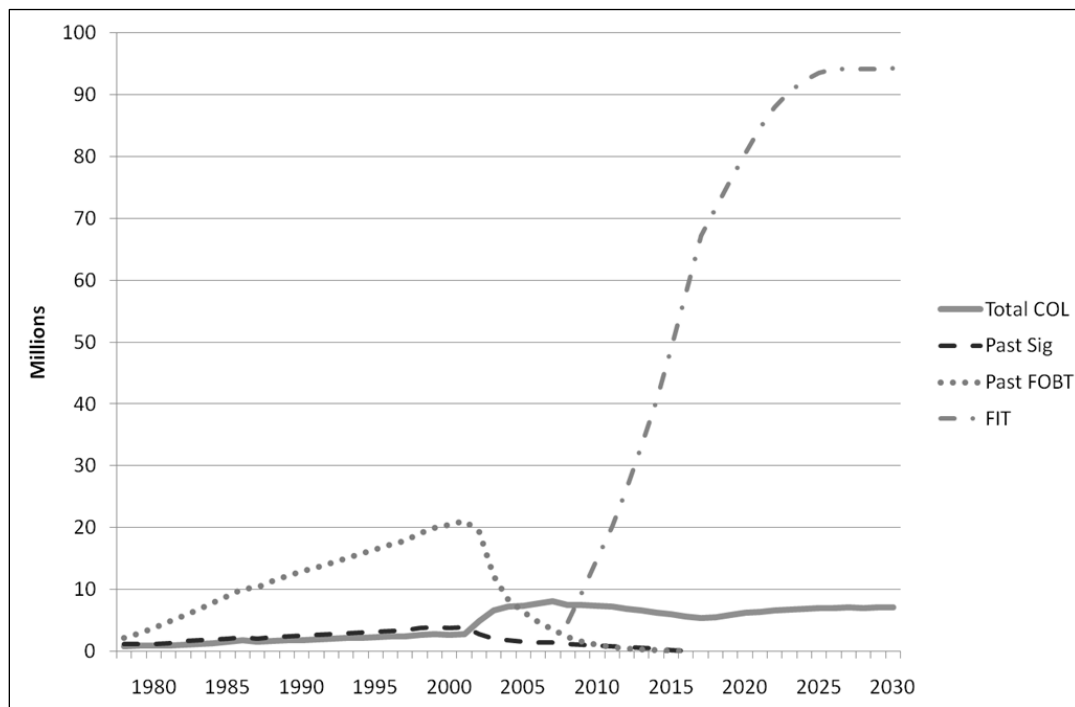
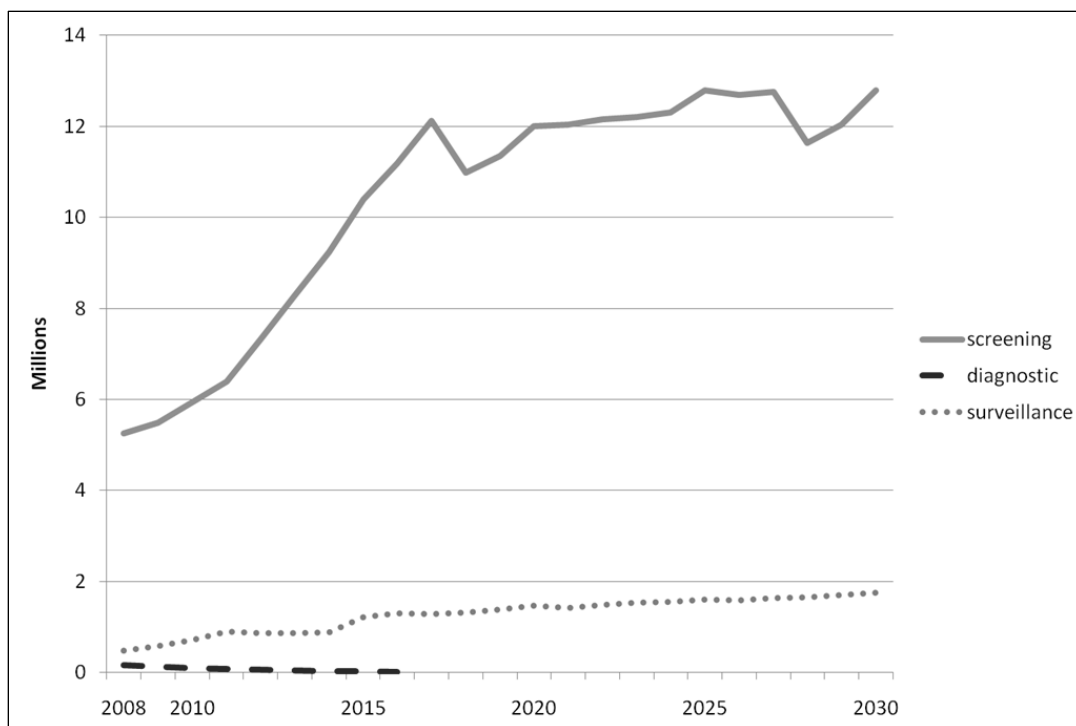


Figure 4. Number of Tests or Procedures Before and After Implementing FIT Screening Program—Delivered Over 10 Years



If population-based colonoscopy screening was introduced without phasing (Figure 1), 53 million colonoscopies would be required for initial screening and surveillance in 2008, with 5 to 13 million colonoscopies required per year in each of the next 9 years for surveillance, and 43 million colonoscopies required again in year 10 of the program. However, with phasing in over 10 years (Figure 2), colonoscopies would be required in a more uniform, predictable delivery; 12 million to 15 million colonoscopies per year would be required for screening and surveillance. If annual FIT was used with no phasing (Figure 3), 5 to 9 million colonoscopies would be required (with a range of 48 to 94 million FITs annually). With 10-year phasing for FIT (Figure 4), 5 to 9 million colonoscopies would be required (with a range of 5 to 94 million FITs in a given year). Most of the required colonoscopies for a 10-year phase-in for screening colonoscopy are for screening rather than for surveillance (Figure 5).

Figure 5. Number of Colonoscopies by Indication After Implementing Colonoscopy Screening Program Over 10 Years



For a colonoscopy screening program phased in over 10 years, the majority of colonoscopies will be provided for screening, with a much smaller proportion for diagnosis and surveillance (Figure 5).

Conclusion

Resource utilization varies based on the primary screening test used. We conclude from these model estimates that in order to provide screening tests at a steady state, a population-based CRC screening would need to be phased in over time. Two-stage screening tests such as FIT, where an initial screening test would be followed by colonoscopy if positive, will require fewer overall colonoscopy resources. Required tests will be compared to updated available capacity assessments to estimate if the test requirements match test availability. Currently, the present available colonoscopy capacity for screening is a gap in our knowledge.

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Evidence-based Practice Center Presentation IV: Current and Projected Capacity To Deliver Colorectal Cancer Screening and Surveillance and Effective Approaches for Monitoring Use and Quality of Colorectal Cancer Screening

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Background

The final session to be presented by the RTI-UNC Evidence-based Practice Center will address two key questions (KQs)—KQ4, KQ5—from the systematic review. The first KQ involves two issues: (1) what is the current capacity for conducting the various recommended screening and surveillance tests, and (2) what is the projected capacity for these tests, given the recommended screening and surveillance strategies of the two national guideline groups? If the projected demand is greater than the current capacity for certain tests, then either capacity must be increased or another strategy must be prioritized. While it is possible to gather data on the first question with research methods, the second question requires assumptions and modeling. The second KQ in this session addresses effective approaches to monitoring the use and quality of testing. It is impossible to optimize screening, and to avoid the problems of underuse, overuse, and misuse, without having effective monitoring systems in place. An effective system is one that conducts routine assessment of use and quality on a scale wide enough to provide accurate estimates of underuse, overuse, and misuse, and that is acceptable, timely, useful, and not unreasonably expensive.

Methods

We used standard systematic review methodology with additional guidance from a Technical Expert Panel and present additional information on the methods in our first abstract (see conference question 1).

Results

For KQ4 (**What are the current and projected capacities to deliver colorectal cancer [CRC] screening and surveillance at the population level?**), we found six studies (seven articles) of good or fair quality that report national estimates of current capacity (current volume and/or additional available capacity), projected demand, and ability of current capacity to meet projected demand.¹⁻⁷ We found varying estimates of current volume of flexible sigmoidoscopy (FS) (2.8–4.9 million) and screening colonoscopy (1.6–6.6 million).¹⁻⁵ Overall, evidence suggests that FS current volume is not sufficient to meet projected demand if a significant proportion of the population is screened by FS or by a combination of fecal occult blood test (FOBT) and FS (FOBT/FS).^{1,3,6} Current volume of colonoscopy is likely to be sufficient to meet projected demand if a significant proportion of the U.S. population is screened by FOBT or FS but not by colonoscopy.¹⁻⁶ One study did attempt to estimate additional available capacity,

finding that current capacity for FS (alone or with FOBT) and colonoscopy alone could be increased sufficiently to meet projected demand from FOBT, FOBT/FS, or colonoscopy screening programs.³ All of these estimates represent steady-state scenarios in terms of demand. If the United States were to adopt a colonoscopy-only approach to CRC screening, colonoscopy capacity would need to be substantially increased to do the “catch-up” screening required to screen people who have not been screened.⁴

Specific to KQ5 (**What are the effective approaches for monitoring the use and quality of CRC screening?**), we began by identifying frameworks for ideal public health surveillance systems from both the United States and Canada that provided complementary lists of characteristics or attributes of surveillance systems.^{8,9} These characteristics (data quality, timeliness, acceptability, simplicity, complexity, compliance, stability, cost) are applicable to the design of an ideal approach to monitoring CRC use and quality. In our review, we identified studies that addressed only data quality. We found seven studies of good or fair quality that reported on the quality of data for monitoring CRC screening use.^{10–16} Although none of the three data sources for monitoring CRC screening use (self-report, medical record review, administrative data) can be considered a gold standard, the evidence suggests that all three are generally appropriate for monitoring CRC screening status. However, self-reported rates of CRC screening are consistently higher than rates obtained from either medical records or administrative data.^{10,12,13–15} The studies reported a wide range of measures of concordance (agreement and/or kappa statistic, which accounts for agreement expected by chance) comparing CRC screening measures from the three data sources. In most studies that report accuracy of self-report for FOBT, any endoscopy, or any testing, concordance between self-report and medical record or administrative data was at least moderate (agreement greater than 70% or kappa greater than 0.40).^{10,13–15} Concordance appears to be higher for endoscopy than for FOBT.^{10,13,14}

Discussion

If the United States decided to use a strategy of preferring colonoscopy only (over other strategies), then our review indicates a considerable degree of uncertainty about whether there is existing—or even latent—capacity to first conduct “catch-up” screening of people who have not been screened, and then to sustain current screening and the resulting surveillance for the longer term. There also is substantial uncertainty regarding the ability of the current capacity of FS to meet projected demand if a strategy of FS alone or FOBT/FS were adopted. In addition, the capacity for FS has been declining in the United States. Using primary care providers and other potential sources, we assume that capacity is adequate for screening strategies that include many FOBT tests.

Whatever strategy is chosen for CRC screening and surveillance, our review found no existing monitoring system that provides adequate information about the entire spectrum of underuse, overuse, and misuse. Our review found that some national surveys (e.g., National Health Interview Survey, Behavioral Risk Factor Surveillance System) provide adequate information of self-reported use (which is especially useful in considering underuse, less helpful with overuse, and not helpful at all with misuse). The Veterans Administration and Healthcare Effectiveness Data and Information Set systems also collect data that can be used for assessing underuse, and some cases of overuse and misuse. Some administrative data also are available for the Medicare program. However, without more information that is systematically collected through provider practices, hospitals, clinics, and other primary care organizations, our understanding of CRC screening will continue to be less than satisfactory, especially for overuse and misuse.

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Achieving Population-Based Performance Measurement for Colorectal Cancer Screening in the United States

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Background

Over the past decade, performance measurement and reporting have become established tools for improving the quality of healthcare in the United States.^{1,2} Increasingly, performance measures serve as a basis for public reporting and payment incentives.³⁻⁵ In 2003, the National Committee for Quality Assurance (NCQA) introduced a measure for monitoring colorectal cancer screening that is now widely used by health plans and physician groups to compare rates of screening and assess progress over time in assuring that the eligible population receives screening.^{6,7} Some evidence suggests that health plans and physician groups have responded to measurement and reporting by introducing quality improvement initiatives.⁸⁻¹¹ Despite the introduction of these measures, colorectal cancer screening is not optimal, prompting the question: are current performance measures sufficient to increase and improve population-based screening?

Method

This abstract summarizes a targeted review of published literature since 2003, the year the NCQA measure was released. Search terms included colorectal cancer screening *and* each of the following topics: guidelines, performance measurement, and quality improvement.

Results

Two general types of performance measures have emerged. "Population-centered measures," exemplified by the NCQA measure, assess the proportion of a sampled population that is being screened appropriately. "Procedure-centered measures" assess the quality of the performance of screening tests among individuals who are receiving screening. Procedure-centered performance measures have been developed by the Society of American Gastrointestinal and Endoscopic Surgeons and the American Society of Gastrointestinal Endoscopists.^{12,13} These include rates of cecal intubation, withdrawal times, polyp detection, adenoma detection, cancer detection, and patient complications.

Population-centered colorectal cancer screening measures continue to be used to assess the performance of health plans and physician groups. They reveal that population screening is persistently low.¹⁴⁻¹⁶ Procedure-centered measures are increasingly used to assess the quality of colonoscopy performed by gastroenterologists, primary care physicians, and surgeons both in the United States and abroad.¹⁷⁻²⁰ On average, different types of providers achieve comparable levels of technical performance of colonoscopy, but these studies also reveal substantial variability among individual providers on these measures.

Studies have questioned the validity of colorectal cancer screening measures on the basis of the difficulty in accounting for age and comorbidity when determining whether screening is appropriate, the challenge of distinguishing screening and diagnostic procedures, and inconsistency of results across health plans and data sources.²¹⁻²³

Recent literature on colorectal cancer screening suggests additional opportunities for new measure development within the population-centered and procedure-centered areas. Population-centered opportunities for measure development include the following:

- The communication process used to promote screening^{24,25}
- The level of connectedness and trust achieved between health plans and members and between primary care clinicians and patients^{26,27}
- Successful communication of test results and follow-up of abnormal results^{28–30}
- Effective surveillance.³¹

Procedure-centered opportunities for measure development include the following:

- Enhancing patient comfort during preparation and procedure^{32–34}
- Additional technical dimensions of CT colonography and colonoscopy^{35–37}
- Novel approaches to image processing of colonographic videos³⁸
- Assessment of training and certification.^{39–41}

To date, there has been limited use of electronic health records and health information exchange to improve the validity of colorectal cancer screening performance measures.

Discussion

Efforts to develop measures of the quality of colorectal cancer screening have revealed the complexity of the screening process. Current metrics may not address aspects of the colorectal screening process that may affect individual willingness to undergo screening and may strongly influence the success of testing. Unmeasured processes may be amenable to intervention, so measurement of these processes could increase the success of population screening over the long term.^{42–44}

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Implementing and Monitoring Colorectal Cancer Screening Performance Improvement in an Integrated Healthcare System

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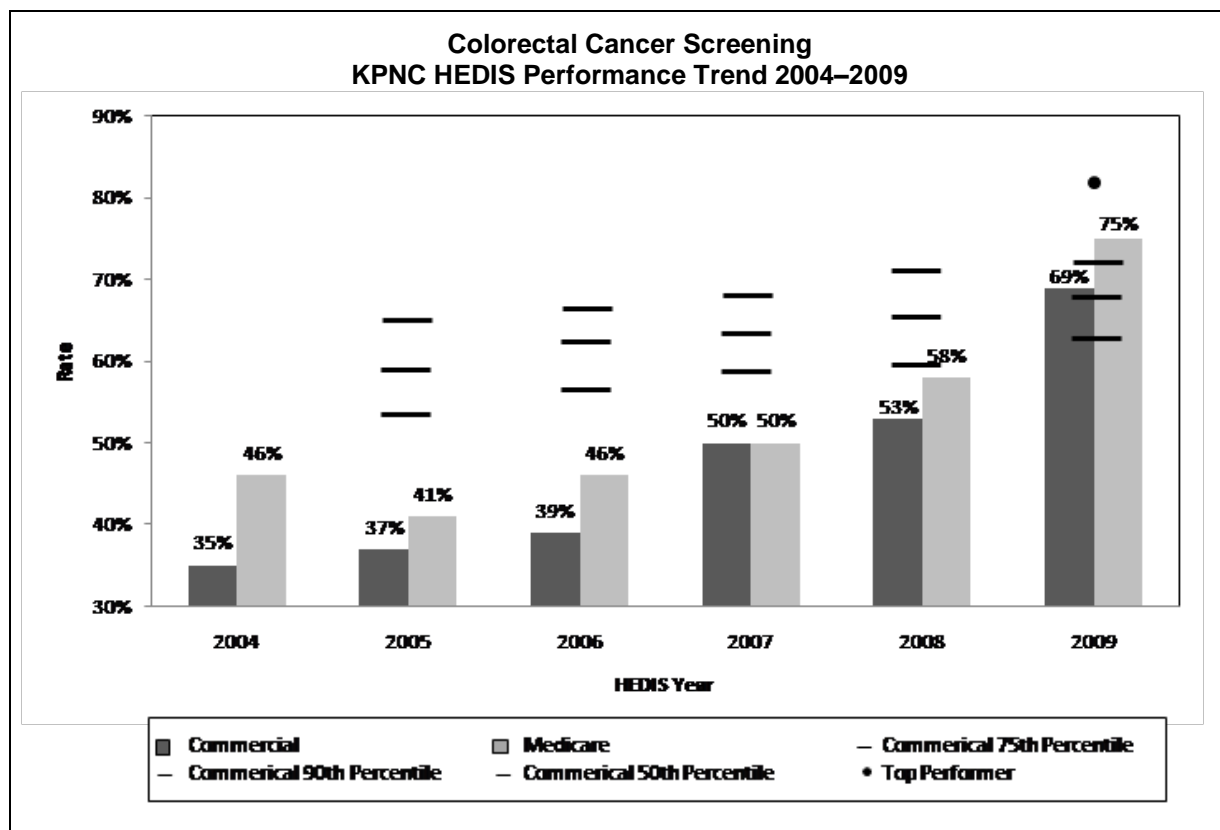
Kaiser Permanente of Northern California (KPNC) is an integrated healthcare delivery system with 3.2 million members, approximately 900,000 of whom are between the ages of 50 and 80. Nearly all outpatient care is delivered by the 7,000 physicians of The Permanente Medical Group (TPMG), Inc., through a network of 19 medical centers located between Fresno, Santa Rosa, and Sacramento. TPMG began an active clinical program in colorectal cancer (CRC) screening using flexible sigmoidoscopy, starting in 1994.¹ This program was built upon the evidence of effectiveness of sigmoidoscopy screening,² and the predictors of proximal colorectal cancer and advanced adenomas based on findings in the distal colon.^{3,4} The initial approach was opportunistic, rather than organized, relying on physician referrals for flexible sigmoidoscopy.⁵ There was no direct outreach to members or active monitoring of population screening rates.

In 2004, the National Committee for Quality Assurance (NCQA) introduced a clinical performance measure of CRC screening prevalence into the Health Effectiveness Data and Information Set (HEDIS), a nationally standardized, widely used set of clinical performance measures.⁶ The CRC measure is a hybrid measure, relying on administrative data and chart review to detect evidence of CRC screening, either with fecal blood testing within 1 year, flexible sigmoidoscopy within 5 years, colonoscopy within 10 years, or double contrast barium enema within 5 years. With this new measure, TPMG had an agreed-upon method for tracking our performance. The denominator of our population consisted of men and women between the ages of 50 and 80, who had been continuously enrolled in the health plan for 2 years, without evidence of CRC or a total colectomy. The HEDIS measure provided a “report card” to monitor CRC screening performance.

Figure 1 demonstrates the utility of an organized population approach to improving CRC screening rates. There are six key features to this program: Leadership alignment, financial alignment, organized outreach with the fecal immunochemical test (FIT), facilitated inreach, increasing capacity, and quality assurance.

- 1. Leadership Alignment.** The important stakeholders include the executive director of TPMG; the physicians in chief at each of 19 medical centers; the medical center-based chiefs of gastroenterology, adult medicine, and family practice; the regional medical director of quality and safety; and the director of the regional laboratory.
- 2. Financial Alignment.** Each Kaiser Permanente medical center receives an operating budget through a regional allocation of resources based on health plan membership. A portion of each medical center’s financial allocation is held back and released monthly, depending on performance on selected quality measures. Therefore, medical center budgets are aligned to support allocating sufficient resources toward quality targets set at the beginning of each fiscal year. TPMG physicians are salaried, and individual physician compensation is not affected by this process.

Figure 1. CRC Screening HEDIS-Reported Rates



- 3. Organized Outreach.** The fecal immunochemical test (FIT) was selected as the outreach screening test of choice. Fecal occult blood testing is the most common method of organized CRC screening throughout the world.⁵ KPNC has had long experience doing research using the FIT.^{7,8} A small pilot study was conducted to compare the use of the Quest InSure test (a two-sample, brush collection, qualitative, manual FIT) and the Polymedco OC Auto Micro 80 (a one-sample, automated machine-read, quantitative FIT).⁹ The Polymedco test was selected for use in the population screening program. KPNC members due for screening are identified using automated data. Each week a random sample of members is uploaded to a Health Insurance Portability and Accountability Act-compliant third-party vendor, and FIT outreach packets are assembled and mailed. Each packet contains a standardized letter and preprinted lab requisition order form. A reminder letter is mailed 6 weeks following the initial outreach. Improvements currently being evaluated include the use of interactive voice recognition software to make reminder phone calls to members who have not responded to the initial mailing or the reminder letter, personalized reminder phone calls by staff members at local medical centers, and personalized secure electronic messages to members who are overdue for screening. In some centers, the annual influenza vaccine clinics provide an additional opportunity to remind members about the need for CRC screening.
- 4. Facilitated Inreach.** A preventive health prompt uses automated data to identify members who are overdue for preventive health services. A CRC screening prompt can be reviewed by support staff and physicians, regardless of the clinical department where the patient is seen. In this way, the entire organization is accountable for CRC screening.

5. **Increasing Capacity.** Improved performance on CRC screening measures has placed substantial demand on existing colonoscopy resources, through the need to follow up positive FITs, and increased demand for screening colonoscopy. Improvements in colonoscopy capacity have depended on maximizing existing space through full scheduling and minimizing room turnover time, and the exploration of alternative venues for high-throughput colonoscopy centers. It is essential to account completely for all procedure demands (including surveillance and symptomatic evaluation) to ensure an adequate match of supply and demand.
6. **Quality Assurance.** The HEDIS CRC screening quality measure focuses on the proportion of the population that is screened. The quality of CRC screening depends on much more: adequate training in the performance of FIT processing by laboratory personnel and monitoring patients with positive FITs for timely access to colonoscopy follow-up. If colonoscopies are not done due to patient refusal or medical contraindication, the reasons are recorded in the electronic medical record. Finally, colonoscopy adenoma detection rates may provide an important indicator of the overall quality of the colonoscopies being performed.^{10,11} The electronic medical records available in KPNC provide a basis for calculating quality measures at each step.

Future Directions

Future evaluations will focus on alternative approaches to delivering CRC screening test kits and screening messages to KPNC members. Currently identified opportunities include the use of a premailing letter or other communication, alerting members to the pending arrival of a test kit, and some preliminary instructions on how to complete the collection. We also anticipate further tailoring and segmenting our messages based on demographic factors (age, gender, race/ethnicity) and prior screening test use.

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Implementing and Monitoring Colorectal Cancer Screening Performance in the National Health Service

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Monitoring Performance

The English Bowel Cancer Screening Programme began operations in July 2006. In the program, men and women, age 60–69 initially, are offered a guaiac fecal occult blood test (FOBT) every 2 years. If positive, they are referred for colonoscopy within the program; if they are deemed to be at increased risk following adenoma detection, their surveillance also is managed within the Bowel Cancer Screening Programme.¹ Thus the program includes the initial invitation to be screened, the testing of individuals, and the diagnostic process for those for whom it is necessary. Patients with cancer are then referred on for treatment.

The need for quality to be built into a cancer screening program from the outset is well recognized in the National Health Service (NHS) based on the experience of operating the breast and cervical screening programs over the last 20 years. Experience in the breast screening program in particular demonstrates that a full program of quality assurance can lead to improved performance.² Therefore, this model was followed for the new NHS Bowel Cancer Screening Programme.

Following the decision of the National Screening Committee that the evidence for the benefits of bowel cancer screening had reached the point where a national program should be considered, a pilot was undertaken in a small controlled area in the Midlands of England. There was close partnership with a similar pilot in the northeast of Scotland. This enabled various practicalities to be worked through and also enabled debate on the issue of whether surveillance should be included in the service. In addition, at this stage, there was a technical evaluation of the kits to be used as part of the pilot process. In parallel to this, the Department of Health in England embarked on a program of modernization of endoscopy services. This included the institution of a national training initiative through the Joint Advisory Group on Gastrointestinal Endoscopy (JAG),³ a major effort to reduce the waiting times in endoscopy, and the introduction of the Global Rating Scale.⁴ The scale is a quality improvement and assessment tool for the gastrointestinal endoscopy service, which enables endoscopy units to assess how well they provide a patient-centered service and compare their situation with others across the country. The waiting-time initiative was part of a major drive in the NHS to reduce waiting times, which had to be at an acceptable level before a screening program could be introduced.

In designing the program, again lessons were learned from the other screening programs. In particular, there was a concentration of the call and recall process and of the biochemical testing process in five centers for the entire population of England (53 million people). This not only enabled consistency in the testing but also avoided problems with variations in practice that have occurred from time to time elsewhere. It was recognized that the quality of endoscopy services around the country was very varied and that there was variation in the phase of modernization that various units had achieved. Therefore, a program of accreditation of screening centers ready for bowel cancer screening was embarked upon. This was undertaken jointly with the JAG, which wished to visit units to accredit them for endoscopy training. Thus the two organizations working together minimized the load on local services. Key points of the accreditation process included audited results and inspection of the decontamination facilities.

Most controversial of all was the decision to accredit individuals. There was evidence of poor quality in endoscopic practice,⁵ and a program to accredit individuals who could achieve a 90% completion rate or better was embarked upon. This involved multiple-choice questions and direct observation of practice.

Now that the implementation phase is over, monitoring is becoming increasingly important. The quality assurance initiative of the NHS Bowel Cancer Screening Programme aims to maintain minimum standards and a constant striving for excellence. Each component of the program has a separate quality assurance stream to develop and review standards and to monitor performance against those standards.

Within each local bowel cancer screening program, there is a lead for each function within the service—for example, nurse lead, endoscopy lead, pathology lead. These are then mirrored at a regional level where each lead meets with his or her peers from the rest of the region. There are 10 regions in England. One of the local leads is appointed as the regional lead, and the regional leads for all the different disciplines together make up the regional quality assurance team. Its role includes local oversight of screening centers and hubs, liaison between different parts of the screening program and the different parts of the NHS, validation of local data, investigation of suspected incidence, and the undertaking of regional initiatives and research projects to move the program forward. It is led by a quality assurance director and funded nationally via the regional health authority, and the quality assurance team is accountable to the regional health authority. The regional leads then meet together at a national level to form national groups; for example, the 10 regional endoscopy leads come together to form the national endoscopy group.

There are four levels of statistical reporting within the program: overall population reports, profession-specific quality reports, operational reports, and ad hoc reports. These each can be deployed in different circumstances to monitor the activity of the program and to assist in the evaluation of the quality of the service delivered. Different things are monitored at different levels; for example, the hub monitors the number of days from positive result to the first offered nurse appointment. The local health authority is very interested in the acceptance rate of its local population, perhaps broken down by ethnicity or deprivation index. The screening center looks at the number of patients attending its clinics and the adenoma and cancer detection rates.

The program overall has linked in with the cancer registries in England and the relatively new National Cancer Intelligence Network to look at the impact that the screening program is having on colorectal cancer. This includes identification of interval cancers and cancers in nonparticipants, survival rates, cancer incidence in patients diagnosed with adenomas through the screening program, and variations in characteristics, management and pathological features across England, and between screen-detected and non-screen-detected tumors. At the moment, at the start of the screening program, there is a great deal of interest in quality of pathology and completeness of pathological reporting. A full evaluation of the program's effectiveness is independently commissioned by the Department of Health from the University of London. It also should be noted that in due course the NHS Information Center will validate and publish the official returns.

The program is compliant with the European Union Quality Assurance Guidelines and has been a major contributor to the development of those guidelines through the European Network. It also is actively involved in the International Colorectal Cancer Screening Network to develop international comparators. It is linked with the European Network on Colorectal Cancer Research. The next step for the NHS Bowel Cancer Screening Programme is to extend its

service to men and women up to age 75. This is just the beginning. All our quality standards will need to be changed to reflect not only the older age group but the fact that the vast majority of people having their first screening are now age 60 and the vast majority of those age 61 and older are repeat screens. To do this, we will examine epidemiological evidence principally from the trials.

Quality assurance is a constant process. Data are routinely collected and analyzed and compared with the original standards. As each standard is reached universally, the best units will move forward and then the bar will be raised so that even the lowest-achieving unit is always striving to improve.

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