Guidance on Implementing FIT-based Screening Programs

June 29th, 2016
12:00pm ET
Presenters:

Emily Bell, MPH (Moderator)
NCCRT Associate Director

Durado Brooks, MD, MPH
Managing Director,
Cancer Control Intervention
American Cancer Society

Gloria D. Coronado, PhD
Mitch Greenlick Endowed
Senior Investigator in Health
Disparities Research
Kaiser Permanente Center for
Health Research
Purpose of Today’s Webinar

• Review the rationale for screening with FIT
• Understand strategies for implementing quality FIT-based programs
• Learn possible solutions to common barriers
• Q&A
Stool Tests for Colorectal Cancer Screening: A Brief Overview

NCCRT Webinar
June 29, 2016

Durado Brooks, MD, MPH

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## Table. Characteristics of Colorectal Cancer Screening Strategies

<table>
<thead>
<tr>
<th>Screening Method</th>
<th>Frequency</th>
<th>Evidence of Efficacy</th>
<th>Other Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stool-Based Tests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>gFOBT</td>
<td>Every year</td>
<td>RCTs with mortality end points: High-sensitivity versions (e.g., Hemoccult SENSA) have superior test performance characteristics than older tests (e.g., Hemoccult II)</td>
<td>Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)</td>
</tr>
<tr>
<td>FIT</td>
<td>Every year</td>
<td>Test characteristic studies: Improved accuracy compared with gFOBT. Can be done with a single specimen</td>
<td>Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)</td>
</tr>
<tr>
<td>FIT-DNA</td>
<td>Every 1 or 3 y</td>
<td>Test characteristic studies: Specificity is lower than for FIT, resulting in more false-positive results, more diagnostic colonoscopies, and more associated adverse events per screening test. Improved sensitivity compared with FIT per single screening test.</td>
<td>There is insufficient evidence about appropriate longitudinal follow-up of abnormal findings after a negative diagnostic colonoscopy, may potentially lead to overly intensive surveillance due to provider and patient concerns over the genetic component of the test.</td>
</tr>
<tr>
<td>Direct Visualization Tests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>Every 10 y</td>
<td>Prospective cohort study with mortality end point</td>
<td>Requires less frequent screening. Screening and diagnostic followup of positive results can be performed during the same examination.</td>
</tr>
<tr>
<td>CT colonography</td>
<td>Every 5 y</td>
<td>Test characteristic studies</td>
<td>There is insufficient evidence about the potential harms of associated extracolonic findings, which are common</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy</td>
<td>Every 5 y</td>
<td>RCTs with mortality end point: Modeling suggests it provides less benefit than when combined with FIT or compared with other strategies.</td>
<td>Test availability has declined in the United States</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy with FIT</td>
<td>Flexible sigmoidoscopy every 10 y plus FIT every year</td>
<td>RCT with mortality end point (subgroup analysis)</td>
<td>Test availability has declined in the United States. Potentially attractive option for patients who want endoscopic screening but want to limit exposure to colonoscopy.</td>
</tr>
</tbody>
</table>
### CRC Screening Strategies (USPSTF June 2016)

#### Stool-Based Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Frequency</th>
<th>Additional Characteristics</th>
<th>Advantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>gFOBT</td>
<td>Every year</td>
<td>RCTs with mortality end points: High-sensitivity versions (e.g., Hemoccult SENSA) have superior test performance characteristics than older tests (e.g., Hemoccult II)</td>
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<td>There is insufficient evidence about appropriate longitudinal follow-up of abnormal findings after a negative diagnostic colonoscopy; may potentially lead to overly intensive surveillance due to provider and patient concerns over the genetic component of the test</td>
</tr>
</tbody>
</table>

*Stool tests recommended only for **average risk** screening*
Guaiac Tests

- Most common type in U.S.
- Solid evidence (3 RCT’s)
- 30 year f/u (NEJM Oct 2013)
- Need specimens from 3 bowel movements
- Non-specific
- Results influenced by foods and medications
- Better sensitivity with newer versions (Hemoccult Sensa)
- Older forms (Hemoccult II) **not recommended**!
- ACS and USPSTF recommend high sensitivity guaiac; only brand with data is Hemoccult Sensa
Fecal Immunochemical Tests (FIT)

- Specific for **human blood** and for **lower GI bleeding**
- Results not influenced by foods or medications
- Some types require only 1 or 2 stool specimens
- Higher sensitivity than older forms of guaiac-based FOBT
- Costs more than guaiac tests (but higher reimbursement)
PCP Perceptions of Screening Tests

- FOBT/FIT used, but:
  - Effectiveness questioned by many clinicians
  - Lack of knowledge re: performance of new vs. older forms of stool tests, other quality issues

- Colonoscopy viewed as the best screening test, but recognize that many patients face barriers or not willing to undergo
  - Often recommended despite access or other challenges
  - Focus on colonoscopy associated with low screening rates in a number of studies
  - Patient preferences rarely solicited
Patient Preferences

- FOBT completed: 67%
- Colonoscopy completed: 38%
- Choice Arm: 38%

P = .64

P < .001

P < .001

Inadomi, Arch Intern Med 2012
Many Patients Prefer FOBT/FIT

- Diverse sample of 323 adults given detailed side-by-side description of FOBT and colonoscopy (DeBourcy et al. 2007)
  - 53% preferred FOBT
  - Almost half felt very strongly about their preference

- 212 patients at 4 health centers rated different screening options with different attributes (Hawley et al. 2008)
  - 37% preferred colonoscopy
  - 31% preferred FOBT

- Nationally representative sample of 2068 VA patients given brief descriptions of each screening mode (Powell et al. 2009)
  - 37% preferred colonoscopy
  - 29% preferred FOBT
Accuracy of Fecal Immunochemical Tests for Colorectal Cancer
Systematic Review and Meta-analysis

Jeffrey K. Lee, MD, MAS; Elizabeth G. Liles, MD, MCR; Stephen Bent, MD; Theodore R. Levin, MD; and Douglas A. Corley, MD, PhD

Background: Performance characteristics of fecal immunochemical tests (FITs) to screen for colorectal cancer (CRC) have been inconsistent.

Purpose: To synthesize data about the diagnostic accuracy of FITs for CRC and identify factors affecting its performance characteristics.

Data Sources: Online databases, including MEDLINE and EMBASE, and bibliographies of included studies from 1996 to 2013.

Study Selection: All studies evaluating the diagnostic accuracy of FITs for CRC in asymptomatic, average-risk adults.

Data Extraction: Two reviewers independently extracted data and critiqued study quality.

Data Synthesis: Nineteen eligible studies were included and meta-analyzed. The pooled sensitivity, specificity, positive likelihood ratio, and negative likelihood ratio of FITs for CRC were 0.79 (95% CI, 0.69 to 0.86), 0.94 (CI, 0.92 to 0.95), 13.10 (CI, 10.49 to 16.35), 0.23 (CI, 0.15 to 0.33), respectively, with an overall diagnostic accuracy of 95% (CI, 93% to 97%). There was substantial heterogeneity between studies in both the pooled sensitivity and specificity estimates. Stratifying by cutoff value for a positive test result or removal of discontinued FIT brands resulted in homogeneous sensitivity estimates. Sensitivity for CRC improved with lower assay cutoff values for a positive test result (for example, 0.89 [CI, 0.80 to 0.95] at a cutoff value less than 20 µg/g vs. 0.70 [CI, 0.55 to 0.81] at cutoff values of 20 to 50 µg/g) but with a corresponding decrease in specificity. A single-sample FIT had similar sensitivity and specificity as several samples, independent of FIT brand.

Limitations: Only English-language articles were included. Lack of data prevented complete subgroup analyses by FIT brand.

Conclusion: Fecal immunochemical tests are moderately sensitive, are highly specific, and have high overall diagnostic accuracy for detecting CRC. Diagnostic performance of FITs depends on the cutoff value for a positive test result.

Primary Funding Source: National Institute of Diabetes and Digestive and Kidney Diseases and National Cancer Institute.

For author affiliations, see end of text.
Figure 2. Pooled sensitivity and specificity for fecal immunochemical tests for the detection of colorectal cancer for all included studies.

<table>
<thead>
<tr>
<th>Author, Year (Reference)</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sohn et al, 2005 (14)</td>
<td>0.25 (0.05–0.57)</td>
<td>0.99 (0.98–0.99)</td>
</tr>
<tr>
<td>Levi et al, 2011 (15)</td>
<td>1.00 (0.54–1.00)</td>
<td>0.88 (0.86–0.90)</td>
</tr>
<tr>
<td>Allison et al, 1996 (31)</td>
<td>0.69 (0.50–0.84)</td>
<td>0.94 (0.94–0.95)</td>
</tr>
<tr>
<td>Allison et al, 2007 (32)</td>
<td>0.86 (0.57–0.98)</td>
<td>0.97 (0.96–0.97)</td>
</tr>
<tr>
<td>Levi et al, 2007 (33)</td>
<td>0.67 (0.09–0.99)</td>
<td>0.83 (0.73–0.91)</td>
</tr>
<tr>
<td>Cheng et al, 2002 (34)</td>
<td>0.88 (0.62–0.98)</td>
<td>0.91 (0.90–0.92)</td>
</tr>
<tr>
<td>Morikawa et al, 2005 (35)</td>
<td>0.66 (0.54–0.76)</td>
<td>0.95 (0.94–0.95)</td>
</tr>
<tr>
<td>Nakama et al, 1999 (36)</td>
<td>0.56 (0.31–0.78)</td>
<td>0.97 (0.96–0.97)</td>
</tr>
<tr>
<td>Nakama et al, 1996 (37)</td>
<td>0.83 (0.52–0.98)</td>
<td>0.96 (0.95–0.96)</td>
</tr>
<tr>
<td>Launoy et al, 2005 (38)</td>
<td>0.86 (0.67–0.96)</td>
<td>0.94 (0.94–0.95)</td>
</tr>
<tr>
<td>Itoh et al, 1996 (39)</td>
<td>0.87 (0.78–0.93)</td>
<td>0.95 (0.95–0.95)</td>
</tr>
<tr>
<td>Nakazato et al, 2006 (40)</td>
<td>0.53 (0.29–0.76)</td>
<td>0.87 (0.86–0.88)</td>
</tr>
<tr>
<td>Park et al, 2010 (41)</td>
<td>0.77 (0.46–0.95)</td>
<td>0.94 (0.92–0.95)</td>
</tr>
<tr>
<td>de Wijkerslooth et al, 2012 (42)</td>
<td>0.75 (0.35–0.97)</td>
<td>0.95 (0.93–0.96)</td>
</tr>
<tr>
<td>Parra-Blanco et al, 2010 (43)</td>
<td>1.00 (0.77–1.00)</td>
<td>0.93 (0.91–0.94)</td>
</tr>
<tr>
<td>Chiu et al, 2013 (44)</td>
<td>0.85 (0.55–0.98)</td>
<td>0.92 (0.91–0.92)</td>
</tr>
<tr>
<td>Chiang et al, 2011 (45)</td>
<td>0.96 (0.82–1.00)</td>
<td>0.87 (0.85–0.88)</td>
</tr>
<tr>
<td>Brenner and Tao, 2013 (46)</td>
<td>0.73 (0.45–0.92)</td>
<td>0.96 (0.95–0.96)</td>
</tr>
<tr>
<td>Brenner and Tao, 2013 (46)</td>
<td>0.60 (0.32–0.84)</td>
<td>0.95 (0.94–0.96)</td>
</tr>
</tbody>
</table>

Combined

- Sensitivity: 0.79 (0.69–0.86)
- Specificity: 0.94 (0.92–0.95)

- Q = 57.05; P = 0.00
- $I^2 = 68.45\%$ (95% CI, 53.48%–83.42%)

- Q = 1200.46; P = 0.00
- $I^2 = 98.50\%$ (95% CI, 98.21%–98.79%)
FOBT/FIT: Efficacy (USPSTF 2015)

Advantages of Stool Tests

- Less expensive
- No bowel preparation
- Done in privacy at home
- No need for time off work or assistance getting home after the procedure
- Non-invasive – no risk of pain, bleeding, perforation
- Limits need for colonoscopies – required only if stool blood testing is abnormal
Making the Best Use of Scarce Resources: Screening colonoscopy vs. FIT

- Represents 20 patients

Screening colonoscopy (refer 1,000 patients)

Eligible population, referred

Patient refusal, no shows

1 cancer in 400-1000 colonoscopies

FIT testing (2,000 patients)

Eligible population

Patients with a positive FIT

1 cancer in 20 colonoscopies

Slide courtesy of Dr. G. Coronado
Stool Test Quality Issues

- Use only high sensitivity guaiac or FIT
  - Hemoccult II and other less sensitive guaiac tests should not be used for screening
- Must be repeated annually
- All positive tests must be followed up with colonoscopy
- “Throw in the toilet bowl” tests **not recommended**
  - Very little data, and existing studies show poor sensitivity for cancer
- DRE samples **not recommended**
  - Missed 19 of 21 cancers in one large study of guaiac
FIT Quality Issues

All FIT are not created equal

- FDA clears guaiac FOBTs and FITs only for “detection of blood” – no assessment of cancer detection capability is required
- Recent study found 56 FITs cleared for use in US, and 23 currently marketed
- Only ~1/4 of FDA-cleared FITs have published data on their performance for detection of CRC or adenoma
- Some tests are currently marketed as “single sample” tests with no performance data on this use
- FDA is updating clearance criteria
FITs With Published Data*
Available in the US

<table>
<thead>
<tr>
<th>Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoccult-ICT/Flexsure OBT</td>
<td>Beckman-Coulter</td>
</tr>
<tr>
<td>Hemosure One Step</td>
<td>WHPM, Inc.</td>
</tr>
<tr>
<td>InSure / ColoVantage</td>
<td>Clinical Genomics</td>
</tr>
<tr>
<td>OC-Sensor / OC FIT-CHEK</td>
<td>Polymedco</td>
</tr>
<tr>
<td>OC-Auto Micro</td>
<td>Polymedco</td>
</tr>
<tr>
<td>OC-Light</td>
<td>Polymedco</td>
</tr>
</tbody>
</table>

*This list may not be comprehensive
High Quality Stool Testing

Clinicians Reference: FOBT
One page document designed to educate clinicians about important elements of colorectal cancer screening using fecal occult blood tests (FOBT).

Provides state-of-the-science information about guaiac and immunochemical FOBT, test performance and characteristics of high quality screening programs.

Available at www.cancer.org/colonmd
Stool DNA Test (sDNA)

- Fecal occult blood tests detect blood in the stool – which is intermittent and non-specific
- Colon cells are shed continuously
- Polyps and cancer cells contain abnormal DNA
- Stool DNA tests look for abnormal DNA from cells that are passed in the stool
- One test currently available (Cologuard); combines tests for stool DNA markers associated with cancers and adenomas plus FIT
Multitarget Stool DNA Testing for Colorectal-Cancer Screening

Thomas F. Imperiale, M.D., David F. Ransohoff, M.D., Steven H. Itzkowitz, M.D., Theodore R. Levin, M.D., Philip Lavin, Ph.D., Graham P. Lidgard, Ph.D., David A. Ahlquist, M.D., and Barry M. Berger, M.D.

ABSTRACT

BACKGROUND
An accurate, noninvasive test could improve the effectiveness of colorectal-cancer screening.

METHODS
We compared a noninvasive, multitarget stool DNA test with a fecal immunochemical test (FIT) in persons at average risk for colorectal cancer. The DNA test includes quantitative molecular assays for KRAS mutations, aberrant NDRG4 and BMP3 methylation, and β-actin, plus a hemoglobin immunoassay. Results were generated with
### Table 1. Sensitivity and Specificity of the Multitarget Stool DNA Test and the Fecal Immunochemical Test (FIT) for the Most Advanced Findings on Colonoscopy.

<table>
<thead>
<tr>
<th>Most Advanced Finding</th>
<th>Colonoscopy (N=9989)</th>
<th>Multitarget DNA Test (N=9989)</th>
<th>FIT (N=9989)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no.</td>
<td>Positive Results</td>
<td>Sensitivity (95% CI)</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>65</td>
<td>60</td>
<td>92.3 (83.0–97.5)</td>
</tr>
<tr>
<td>Stage I to III*</td>
<td>60</td>
<td>56</td>
<td>93.3 (83.8–98.2)</td>
</tr>
<tr>
<td>Colorectal cancer and high-grade dysplasia</td>
<td>104</td>
<td>87</td>
<td>83.7 (75.1–90.2)</td>
</tr>
<tr>
<td>Advanced precancerous lesions†</td>
<td>757</td>
<td>321</td>
<td>42.4 (38.9–46.0)</td>
</tr>
<tr>
<td>Nonadvanced adenoma</td>
<td>2893</td>
<td>498</td>
<td>17.2 (15.9–18.6)</td>
</tr>
<tr>
<td>All nonadvanced adenomas, non-neoplastic findings, and negative results on colonoscopy</td>
<td>9167</td>
<td>1231</td>
<td>86.6 (85.9–87.2)</td>
</tr>
<tr>
<td>Negative results on colonoscopy</td>
<td>4457</td>
<td>455</td>
<td>89.8 (88.9–90.7)</td>
</tr>
</tbody>
</table>

* These stages of colorectal cancer, as defined by the system recommended by the American Joint Committee on Cancer, are associated with an increased rate of cure.
† Advanced precancerous lesions include advanced adenomas and sessile serrated polyps measuring 1 cm or more.
Cologuard

- Every 3 year testing interval approved by FDA (but limited supporting evidence)
- Medicare covers for average risk age 50 – 85 yrs
  - Medicare reimbursement ~ $500 q 3 yrs (price includes “navigation” component)
  - Private insurance coverage has been limited; may increase with USPSTF endorsement
- All positive tests must be evaluated by colonoscopy
- Management of patients with positive Cologuard test and normal colonoscopy is uncertain
- Eligible for Medicare “no cost-sharing” screening benefit – but if test is positive patient is subject to cost-sharing for follow up colonoscopy
American Cancer Society FluFOBT Program
Implementation Guide and Materials

American Cancer Society FluFOBT Program

The American Cancer Society FluFOBT program is intended to assist medical practices in increasing colorectal cancer (CRC) screening. It has been demonstrated in the medical literature that offering and providing take-home fecal occult blood tests (FOBTs) or fecal immunochemical tests (FITs) to patients at the time of their annual flu shot increases CRC screening rates. Successful Flu-FIT and Flu-FOBT Programs have been implemented in community health centers, in a public hospital, and in a large health maintenance organization. They have also been pilot tested in commercial pharmacies.

In this section, you will find information to develop and deliver a successful FluFOBT Program. For additional information and resources visit flufbt.org.

ACS FluFOBT Implementation Guide

This guide includes background information about the FluFOBT Program and its benefits, as well as patient eligibility criteria and education materials. It lists the steps required to set up a FluFOBT training program in your health center, including staff training and tracking tools.

www.cancer.org/flufobt


Strategies for improving colon cancer screening in primary care practices

A Focus on STOP CRC

Gloria D. Coronado, PhD
Kaiser Permanente Center for Health Research

June 29, 2016
Key talking points

- Direct-mail programs improve CRC screening;
- Design and preliminary findings from STOP CRC
  - STOP CRC is a high-impact study
  - Promising pilot findings, however must consider cancer continuum
- STOP CRC program adaptations: high quality FIT programs
<table>
<thead>
<tr>
<th>Intervention Classification</th>
<th>N studies</th>
<th>Does Intervention Improve FOBT/FIT Screening?</th>
<th>Strength of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Mail</td>
<td>9</td>
<td>Yes</td>
<td>High</td>
</tr>
<tr>
<td>Flu-FOBT/FIT</td>
<td>2</td>
<td>Yes</td>
<td>High</td>
</tr>
<tr>
<td>Clinic processes</td>
<td>2</td>
<td>Mixed</td>
<td>Moderate</td>
</tr>
<tr>
<td>Patient Navigator</td>
<td>2</td>
<td>Yes (overall screening) Mixed (FOBT only)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Education at clinic visit</td>
<td>5</td>
<td>Mixed</td>
<td>Low</td>
</tr>
<tr>
<td>Education with lay health advisors</td>
<td>4</td>
<td>Unclear</td>
<td>Low</td>
</tr>
<tr>
<td>Education with media (community)</td>
<td>1</td>
<td>Unclear</td>
<td>Insufficient</td>
</tr>
<tr>
<td>Education with media (clinic + community)</td>
<td>2</td>
<td>Mixed</td>
<td>Low</td>
</tr>
</tbody>
</table>

Davis et al. 2015 Systematic Review
STOP CRC is a high-impact study
STOP CRC Activities

What?

Create learning collaborative

Develop EMR tools

Deliver Intervention

Refine the intervention: PDSA

Refine EMR tools

Spread & Sustain

Who is involved?

Advisory Board (clinicians, policymakers, payers)

EMR Specialists

CHR, Virginia Garcia, MCHD, OCHIN, EMR specialists, and clinicians.

Clinics, OCHIN, payers

CHR, Clinics, OCHIN

Clinics, OCHIN, policymakers, payers

Phase 1

Phase 2
STOP CRC intervention

EMR tools in Reporting Workbench, driven by Health Maintenance;
Step-wise exclusions for:
• Invalid address
• Self-reported prior screening
• Completion of CRC screening
Improvement cycle (e.g. Plan-Do-Study-Act)
Participating clinics*

Open Door Community Health Centers (4)
Multnomah County Health Department (6)
La Clinica del Valle (3)
Mosaic Medical (4)
Virginia Garcia Memorial Health Center (2)
Community Health Center Medford (3)
Benton County Health Department (2)
Oregon Health & Science University (OHSU) (2)
Sea Mar Community Health Centers (4; secondary analysis)

*Overall: colonoscopy screening in past 10 years: 5%;
fecal testing in past year: 7.5%
Promising STOP CRC pilot findings
STOP CRC Pilot showed 38% improvement

**STOP CRC Pilot results**

<table>
<thead>
<tr>
<th></th>
<th>Auto Intervention</th>
<th>Auto Plus Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letters mailed</td>
<td>112</td>
<td>101</td>
</tr>
<tr>
<td>FIT kits mailed</td>
<td>109</td>
<td>97</td>
</tr>
<tr>
<td>Reminder postcards mailed</td>
<td>95</td>
<td>84</td>
</tr>
<tr>
<td>Reminder calls delivered</td>
<td>NA</td>
<td>30*</td>
</tr>
<tr>
<td><strong>FIT kits complete</strong></td>
<td><strong>44 (39.3%)</strong>**</td>
<td><strong>37 (36.6%)</strong>**</td>
</tr>
<tr>
<td><strong>Positive FIT result</strong></td>
<td><strong>5 (12.5%)</strong></td>
<td><strong>2 (5.7%)</strong></td>
</tr>
</tbody>
</table>
Direct-mailing reduces health disparity

Response to direct-mail program (n = 1034)

![Chart showing response rates for mailed FIT return in English and Spanish.]
Health disparities persist in f/u colonoscopy receipt

- Based on 56 patients with positive FIT test results (27 non-Hispanic and 29 Hispanic) who received care at Virginia Garcia.
Plan-Do-Study-Act Cycles were important
FIT performance review

<table>
<thead>
<tr>
<th>FIT test</th>
<th>% positive ⁹</th>
<th>Sensitivity ¹</th>
<th>Evaluated in large numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>OC-Micro</td>
<td>3.3 – 6.0%</td>
<td>88%</td>
<td>√</td>
</tr>
<tr>
<td>OC-Light</td>
<td>8.4 – 14.2%</td>
<td>88 – 96%</td>
<td>√</td>
</tr>
<tr>
<td>Insure</td>
<td>4.6 – 5.6%</td>
<td>87.5%</td>
<td>√</td>
</tr>
<tr>
<td>Hemoccult ICT</td>
<td>3.2 – 9.0%</td>
<td>82 – 98%</td>
<td>√</td>
</tr>
<tr>
<td>Hemosure</td>
<td>7.2%</td>
<td>55%</td>
<td>√</td>
</tr>
<tr>
<td>Consult Diagnostics</td>
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<td>QuickVue</td>
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<tr>
<td>One-Step +</td>
<td>Not available</td>
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</tbody>
</table>

⁹ Positivity rate is the proportion of test that have a positive result.

¹ Sensitivity is the proportion of actual positives correctly identified (e.g. % of patients with colorectal cancer who are correctly identified as having the condition).
High variation in FIT positivity rates*

% positive FIT results

FIT A: 6.0%
FIT B: 22.6%
FIT C: 17.9%
FIT D: 11.8%
FIT C: 25.8%
FIT D: 8.2%
FIT D: 9.8%
FIT D: 6.3%

*data from STOP CRC 2016 (unpublished)
FIT samples can be improperly collected

Improperly collected FIT tests: Plan-Do-Study-Act Cycle

Data source: Multnomah County Health Department
Dear Client,

there is an easy test that can find signs of colon cancer before you have symptoms. This test can be done at home and can save your life. You will get the test if you are between the ages of 50 and 74 and have not had a colonoscopy in the past 9 years.

Here is your InSure Fit test. Do the test at home and send it back to us. The test will look at the health of your colon to see if there is any blood in your poop. Finding these warning signs early gives you the best chance for successful treatment.

For the test:
- Start with a clean, empty toilet. Flush it once before you start. Make sure there are no cleaning products in the toilet water.
- Use 2 different poop samples. 1 for slot A, and a different 1 for slot B.
- Write the date on the sticker at the time you do each test.
- Send back the test in the prepaid yellow envelope in 3 days of finishing the test.

If you have any questions, please call your care team at 503-988-5558.

Thank you,

Marty Grasmader, MD
Medical Director

---

Estimado(a) Cliente,

Existen análisis fáciles para encontrar señales de cáncer de colon antes de que tenga síntomas. Estos análisis pueden hacerse en casa y pueden salvar su vida. Usted recibirá este análisis si tiene entre 50 y 74 años de edad y no ha tomado una colonoscopia en los últimos 9 años.

Aqui está su InSure FIT. Haga la en casa y devuélvalo. El examen verá la salud de su colon para ver si hay sangre en su comapedo. Encontrar estas señales de advertencia temprano le da la mejor posibilidad de un tratamiento exitoso.

Para el análisis:
- Empiece con un inodoro limpio y vacío sin productos de limpieza en el agua. Lave la plancha de agua una vez antes de empezar.
- Use 2 muestras de popó diferentes, 1 para el lado A y 1 diferente para el lado B.
- Escriba la fecha en la etiqueta en el momento de hacer cada lado.
- Devuélvalo en el sobre amarillo dentro de 3 días de haber completado el análisis.

Si tiene cualquier pregunta, llame a su equipo de salud al 503-988-5558.

Gracias,

Marty Grasmader, MD
Directora Médica

---

Уважаемый/уважаемая Клиент!

Существует очень простой тест, который может распознавать признаки рака кишечника еще до появления каких-либо симптомов. Он может быть проведен в домашних условиях и может спасти вам жизнь. Вы можете получить данный тест, если вам 50 до 74 лет, и за последние 9 лет вы не прошли его_SUCCESSfully.

Ваш тест следует присылать в домой конверте. Проведя тест дома и вынув пробу из конверта, ваш анализ отправится к нам. По результатам теста будет определено ваше состояние и вы сможете принять решение о дальнейших шагах медицинского лечения.

Для проведения теста:
- Начните с чистого ванны, он должен быть пустой и чистой. Смойте его один раз, чтобы из воды не оставалось никаких частиц.
- Используйте 2 разных образца из 3 для анализа, а не для чистки.
- Отправьте ваши образцы в конверте в нашем конверте в течение 3 дней после выполнения анализа.

Если у вас есть какие-либо вопросы, пожалуйста, свяжитесь с нами по телефону 503-988-5558.

Спасибо!
Action taken: Added Reminder with Instruction

- Don’t forget to put the date you collected your poop sample
- No olvide poner la fecha en la que recolectó la muestra de popó.
- 別忘了填寫您採集大便樣本的日期。
- Не забудьте указать дату, когда вы собрали анализ кала
What is **right** set of reminders?

- Identify patients due for CRC screening
- Mail FIT kit
- Assess CRC screening rates in each group

**Reminders are delivered in English, Spanish and Russian**
Text Messages

- Your colon health test is easy to do at home. Please mail us your completed test today! Your Sea Mar Care Team

- ¡Las pruebas salvan vidas! ¡Por favor envíenos su prueba de colon completa hoy sin costo alguno! Su equipo de salud de Sea Mar

- Анализы спасают жизнь! Пожалуйста, отправьте свой анализ кала сегодня. Это бесплатно! Ваша команда медиков из клиники Sea Mar
Theory-based phone script

“Would it be okay if I asked you some questions about your willingness to complete the FIT kit?”
- “What are your thoughts?”
- “Why do you think it’s a good idea to do this test?”
- “What concerns do you have about doing the test?”

Summarize
- Ask “Did I get it all?”
- “Now that we have spent a few minutes talking about the FIT kit, I wonder what you’re thinking about completing the test at this point.”
- “What’s the next step you feel comfortable taking?”

Show your appreciation by thanking the patient for their willingness to talk with you today.
- “I’m confident that if and when you make a decision and commitment to complete the test you’ll find a way to do it.”

“May I answer any questions you have about the test?” [ANSWER QUESTIONS ONLY IF ASKED]

Open-ended questions: Assess facilitators/barriers
Reflection
Open-ended questions: Assess readiness
Reinforce self-efficacy
Preliminary results

Source: Sea mar data (unpublished)
Reminder response differed by language

Source: Sea mar data (unpublished)
Higher FIT return rate higher in direct-mail program than in-clinic distribution.

Based on 5154 FIT distributed in clinic and 5109 FIT mailed.
Visit www.kpchr.org/stopcrc
Click Materials at the top of the page
Conclusion

• Direct-mail programs improve CRC screening;
• STOP CRC is a high-impact study, with promising pilot findings;
• STOP CRC was adapted using Plan-Do-Study-Act cycles;
• Future efforts might consider reminders to direct-mail program.
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Group Health Research: Beverly Green
OCHIN: Scott Fields, Joy Woodall, Thuy Le, Jon Puro
Questions
Thank You!

- Durado Brooks, MD, MPH
- Gloria D. Coronado, PhD

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Join us for the following upcoming webinar:

Thursday, July 28th, 3:00pm ET – Colorectal Cancer Screening and the Patient-Centered Medical Home
Registration: nccrt.org/webinar-crc-pcmh
For more information contact:
Emily Bell, MPH
Emily.Butler@cancer.org

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