Colorectal Cancer Screening

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Group Health Research Institute

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Quality Improvement Specialist
Group Health Cooperative
Overview

• Why this topic was selected
• Colorectal Cancer Screening Guidelines
• Fecal testing comparisons
• HEDIS
• Impact of offering choice
• Patient considerations in choices
• Shared-decision making
“I'd have been here sooner if it hadn’t been for early detection.”
Decreasing the burden of Colorectal Cancer

• Colorectal Cancer (CRC) second leading cause of cancer death

• CRC screening decreases incidence and mortality:
  • find and remove pre-cancerous lesions
  • find cancers early

• Acceleration of these gains most rapidly achieved by increasing screening rates

Source: American Cancer Society
Case Study

Steve is a 62 year-old who had normal colonoscopy 9 years ago.

What screening is recommended now?

- Colonoscopy?
- Fecal test? Which one?
- What about sigmoidoscopy?
# Group Health Screening Guidelines

<table>
<thead>
<tr>
<th>Age</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 - 49</td>
<td><strong>Review family history to identify patients at increased risk for CRC</strong>&lt;br&gt;• For African-American patients with unknown family history, consider beginning routine screening at age 45.</td>
</tr>
<tr>
<td>50 - 75</td>
<td><strong>Routine screening for patients at average risk</strong>&lt;br&gt;• Annual fecal test – high sensitive test – Fecal Immunochemical Tests (FIT) increasingly preferred&lt;br&gt;• Flexible sigmoidoscopy every 5 years. Group Health recommends combining this with annual FIT&lt;br&gt;• Colonoscopy every 10 years</td>
</tr>
<tr>
<td>76 - 84</td>
<td>Due to lack of evidence of benefit versus harm, consider routine screening <em>only</em> for average risk patients who have not been up to date with screening prior to age 75 years and/or who are healthy and have a life expectancy of 10 years or more.</td>
</tr>
<tr>
<td>85+</td>
<td>Screening not recommended.</td>
</tr>
</tbody>
</table>
Influences

Group Health’s guidelines informed by:

- US Preventive Services Task Force (USPSTF)
- National societies/organizations

Coverage based on guidelines and regulatory requirements (ACA, Medicare):

- Commercial – no patient out of pocket costs for USPTF recommended screening tests
- Medicare – Depends on plan. Basic Medicare may pay 20%
High Sensitivity Fecal Testing

What is a high sensitivity fecal test?

- **Guaiac Test (SENSA)** – 3 samples, 2 windows
  - Reacts with peroxidase also present in red meat, cruciferous vegetables and some fruit
  - False negative with vitamin C
- **Fecal Immunochemical Tests (FIT)** - 1 sample, higher completion rates

Mandel – hydrated guaiac test annual fecal test at 13 years

- 33% reduction in CRC mortality (42% at 30 yrs)
- 18% reduction in CRC incidence

Biennial fecal test arm had somewhat smaller benefit (21%)
Fecal Testing Comparison

Group Health Research Institute Study randomized over 2000 patients overdue for screening to receive one of three mailings:

- Stool FIT (OC-MICRO®) FIT
- Stool (InSure®) FIT
- Stool guaiac-SENSA test (Hemoccult)
# Fecal Testing Comparison

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Samples</th>
<th>Where</th>
<th>How processed</th>
<th>Positive</th>
<th>Sensitivity for CRC</th>
<th>Positive Predictive Value for Advanced Adenoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>OC-Micro *</td>
<td>1</td>
<td>LabCorp/Group Health</td>
<td>quantitative</td>
<td>5-8%</td>
<td>86%</td>
<td>25-33%</td>
</tr>
<tr>
<td>OC-Lite**</td>
<td>1</td>
<td>On-site (Polymedco)</td>
<td>visual</td>
<td>12%</td>
<td>87%</td>
<td>27%</td>
</tr>
<tr>
<td>Insure FIT</td>
<td>2</td>
<td>Quest</td>
<td>visual</td>
<td>13%</td>
<td>86%</td>
<td>35%</td>
</tr>
<tr>
<td>Hemoccult ICT+</td>
<td>1-3</td>
<td>On-site (Beckman Coulter)</td>
<td>visual</td>
<td>3%</td>
<td>82%</td>
<td>25%</td>
</tr>
<tr>
<td>SENSA++</td>
<td>3++</td>
<td>On-site (Beckman Coulter)</td>
<td>visual</td>
<td>4-6%</td>
<td>64%</td>
<td>30-41%</td>
</tr>
<tr>
<td>Consult Diagnostics</td>
<td>1</td>
<td>On-site</td>
<td>visual</td>
<td>9%</td>
<td>unknown</td>
<td>unknown</td>
</tr>
<tr>
<td>Hemosure</td>
<td>2</td>
<td>Asante</td>
<td>visual</td>
<td>9%</td>
<td>unknown</td>
<td>unknown</td>
</tr>
</tbody>
</table>

* Can quantitate the amount of blood and set a threshold
** Mostly tested in Taiwan, included young adults and those with symptoms
+ Higher cutoff than other tests (less sensitive/more specific)
++ Only high sensitivity gFOBT Dietary restrictions
Indirect Evidence Of Colonoscopy Benefit

• Observational studies suggest a 40-60% reduction in death and incidence. Controversy as to whether benefit is to entire colon or distal colon only.
• Two US studies in process comparing colonoscopy to annual Fecal Immunochemical Test (FIT)
• Recent trial in Spain compared baseline colonoscopy and FIT:

<table>
<thead>
<tr>
<th></th>
<th>Colonoscopy</th>
<th>FIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed test</td>
<td>25%</td>
<td>34%</td>
</tr>
<tr>
<td>CRC detected</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Advanced adenoma detected</td>
<td>1.9%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Colonoscopies/1 CRC found</td>
<td>191</td>
<td>18</td>
</tr>
<tr>
<td>Colonoscopies/1 AA found</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Major complications</td>
<td>24 (0.5%, 1/200)</td>
<td>10 (0.1%/1/1000)*</td>
</tr>
</tbody>
</table>

Source: Quintero NEJM, 2013
Flexible Sigmoidoscopy Efficacy

Strong evidence of efficacy from 4 very large trials US, UK, Scandinavia, Italy Over 400,000 patients, 11 years follow-up

• Reduced CRC mortality and incidence by about 1/3
• Low risk of serious adverse events

1 Schoen, NEJM, 2012 ; 2 Atkin, Lancet, 2010 ; 3 Holme, JAMA 2014; 4 Segnan. JNCI 2011
<table>
<thead>
<tr>
<th>Community Screening Rates*</th>
</tr>
</thead>
<tbody>
<tr>
<td>GH Network</td>
</tr>
<tr>
<td>63.5%</td>
</tr>
</tbody>
</table>

*Counties shown had over 2,000 eligible patients

Sources: Washington State Health Alliance Community Check-up 2014
Group Health Cooperative July 2015
HEDIS Fax Back

Colorectal Cancer screening measure looks backward up to 10 years. Provider and health plan changes for the patient make complete documentation challenging.

Group Health offers opportunity to fax in evidence:

<table>
<thead>
<tr>
<th>Documentation for HEDIS Compliance</th>
<th>Documentation for HEDIS Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab results of FOBT or FIT performed between 1/1/2015 - 12/31/2015, or Procedure or <strong>office visit</strong> record indicating: - Colonoscopy performed between 1/1/2006 - 12/31/2015, or - Sigmoidoscopy performed between 1/1/2011 - 12/31/2015</td>
<td>Surgical or <strong>office visit</strong> record indicating: - Total colectomy - Complete colectomy - Radical colectomy</td>
</tr>
<tr>
<td></td>
<td>FOBT</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------------------------</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td>G0328</td>
</tr>
<tr>
<td><strong>LOINC</strong></td>
<td>2335-8, 12503-9, 12504-7, 14563-1, 14564-9,</td>
</tr>
<tr>
<td></td>
<td>14565-6, 27396-1, 27401-9, 27925-7, 27926-5,</td>
</tr>
<tr>
<td></td>
<td>29771-3, 56490-6, 56491-4, 57905-2, 58453-2</td>
</tr>
<tr>
<td><strong>ICD-9</strong></td>
<td></td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
</tr>
</tbody>
</table>
HEDIS® Colorectal Cancer Screening

Individuals 50-75 years of age who have had one of the following as of Dec 31:

- Fecal occult blood testing in the past calendar year.
- Colonoscopy in the past 10 calendar years.
- Flexible sigmoidoscopy in the past 5 calendar years.

Effective Jan 1 2015, FOBT tests performed in an office setting or performed on a sample collected via a digital rectal exam (DRE) do not meet criteria.

ICD-10 coding criteria for 2015 not yet released. Will be used to measure 2015 performance in 2016.
Offering Choice

The best colorectal cancer screening test is…

the one the patient will COMPLETE

- Modeling studies show that adherence to any of the recommended tests results in similar outcomes.
- Shared decision making as an approach to getting patients from UN- to SCREENERED
CRC screening rates highest if patients offered fecal testing or choice

Figure 3. Adherence by study arm and race/ethnicity. Among participants offered a choice of screening tests, white participants adhered more often to colonoscopy than nonwhite participants (odds ratio [OR], 3.2; 95% CI, 1.7-6.1), and less often to fecal occult blood testing (FOBT) (OR, 0.3; 95% CI, 0.1-0.6). Among participants offered FOBT, Asians (OR, 2.6; 95% CI, 1.2-5.3) and Latinos (OR, 2.1; 95% CI, 1.0-4.2) adhered more often than whites.

Source: Inadomi et al. 2012
Study of uninsured patients aged 54-64 at a safety net health system.

Randomized patients into 3 groups:
- Free FIT (n = 1593)
- Free colonoscopy (n = 479)
- Usual care (n = 3898)

Source: Gupta et al. JAMA Internal Medicine 2013
Ongoing study. Almost 5000 patients randomized to receive:
- Usual Care
- Mailed Fecal Kits
- Mailed Kits + Brief phone assistance
- Mailed Kits + Brief + Navigation

<table>
<thead>
<tr>
<th>Proportion Current (Years 1 and 2) Adjusted percent</th>
<th>Usual Care n=1166</th>
<th>Automated n=1169</th>
<th>Assisted n=1159</th>
<th>Navigated n=1170</th>
</tr>
</thead>
<tbody>
<tr>
<td>26.3%</td>
<td>50.8%</td>
<td>57.5%</td>
<td>64.7%</td>
<td></td>
</tr>
</tbody>
</table>
SOS Trial – Years 1-2

Test completed:

- UC: 15.7, 0.1
- Acute: 13.3, 27.5, 4.5, 3.7
- Assist: 13.7, 30.5, 6.1, 5.1
- Navigate: 16.1, 35.8, 5.4, 4.4

- Not Current
- FOBT Y1
- FOBT Y1, Y2
- FOBT Y1, CS/FS Y2
- FS Y1
- CS Y1
## Comparison of Screening Benefits

<table>
<thead>
<tr>
<th>Method</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Colonoscopy</strong></td>
<td>• Allows screening of entire colon&lt;br&gt;• More adenomas detected&lt;br&gt;• Interruption of the adenoma→cancer sequence&lt;br&gt;• If normal, no further screening for 10 years</td>
</tr>
<tr>
<td><strong>Sigmoidoscopy</strong></td>
<td>• Interruption of the adenoma→cancer sequence&lt;br&gt;• No sedation or dietary restrictions&lt;br&gt;• If normal, no further screening for 5 years</td>
</tr>
<tr>
<td><strong>Fecal Testing</strong></td>
<td>• Easy to perform at home, privately, independently&lt;br&gt;• Costs likely to be covered when coded correctly&lt;br&gt;• Reduced colonoscopies = reduced patient costs, complications</td>
</tr>
</tbody>
</table>
Comparison of Screening Risks

**Colonoscopy**
- Serious complications in 1:250-300 procedures
  - Perforation (3:10,000)
  - Major bleeding (12:10,000)
  - Death (1:15,000)
- Medication reactions

**Sigmoidoscopy**
- Less risks than colonoscopy
- If adenoma found, follow-up colonoscopy still needed

**Fecal Testing**
- False positives
- False negatives
- If positive, follow-up colonoscopy still needed
## Comparison of Screening Barriers

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colonoscopy</td>
<td>• Polyp removal can result in unexpected costs</td>
</tr>
<tr>
<td></td>
<td>• Transportation and time-off arrangements</td>
</tr>
<tr>
<td></td>
<td>• Discomfort and apprehension</td>
</tr>
<tr>
<td></td>
<td>• Dietary restrictions and laxative</td>
</tr>
<tr>
<td>Sigmoidoscopy</td>
<td>• Polyp removal can result in unexpected costs</td>
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<tr>
<td></td>
<td>• Time-off arrangements</td>
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<tr>
<td></td>
<td>• Discomfort and apprehension</td>
</tr>
<tr>
<td></td>
<td>• Dietary restrictions and laxative</td>
</tr>
<tr>
<td>Fecal Testing</td>
<td>• Completing 3 samples for traditional FOBT</td>
</tr>
<tr>
<td></td>
<td>• FIT adherence 10% greater than FOBT, 1 or 2 samples</td>
</tr>
<tr>
<td></td>
<td>• Repeated annually</td>
</tr>
</tbody>
</table>
Patient Costs

- **Preventive colonoscopy**: No patient charges under ACA
- **Diagnostic colonoscopy** (e.g., polyp removal): Can result in co-pay, co-insurance, deductible, etc.
- **Fecal testing**: No lab fees if preventive dx code is used by provider

### 100 patients with FIT screening
7 patients test positive, undergo and charged for diagnostic colonoscopy (7.2%)

### 100 patients with Colonoscopy screening
32 Patients with polyps, charged for diagnostic colonoscopy (31.7%)

*Source: Quintero NEJM, 2013*
Shared-decision making conversations

Prepare for opportunistic conversations
Review patient screening needs during pre-visit work, daily huddle
Introduce during rooming, discuss during each visit
Have example stool kit in room for demonstrating

Describe screening in general

“You’re due for a test that looks for signs of colon cancer. Colon cancer is a slow growing cancer that starts in your large intestine. You can have cancer or a polyp, a growth that might turn into cancer, and still feel healthy. There aren’t many cancers we can find early and prevent, but this is one that we can.”
Add a personal perspective:

“I’ve had patients diagnosed with colon cancer and most could’ve found the cancer earlier, or even prevented it by finding and removing pre-cancerous polyps, if they had been screened.

I want you to be in the much larger group of my patients who’ve been screened and have lower risk of getting or dying from colon cancer. And personally I never want to have the experience of having to tell another of my patients that they have colon cancer.”
Review options:

- I recommend getting tested using a **kit** we’ll give you today. It has a small plastic stick and a container to collect a stool sample at home and send it to the lab to check for invisible blood. This test is done every year. I recommend this test because it’s easy, can be done at home, takes very little time, and doesn’t interrupt your work or daily activities.

*If you don’t choose the kit, I can explain two other equally effective tests:*

- **Flexible Sigmoidoscopy** is where a short scope is inserted into your rectum while you’re awake and allows the doctor to see your lower bowel where most colon cancers start. To prepare, you follow a special diet for a few days before the test. This test is done every 5 years along with a stool test every 3 years.

- **Colonoscopy** is a test where a small camera, as wide as your little finger, on a long tube, is inserted into your rectum, and lets the doctor see your entire colon. To prepare, you follow a strict diet for a few days and drink a special drink the day before the test. This is to make sure your colon is completely clean for the test. You’ll be put to sleep for this test and someone will need to drive you home from the doctor’s office. This test is done every 10 years.
Shared-decision making conversations (cont.)

Get a commitment

• “Which test would you like to do?” rather than “Would you like to…?”
• If response is vague, obtain commitment

“Let’s start with the kit because it’s the easiest choice. If I send one home with you today, will you take a sample in the next two weeks? I know how busy you are, so we’ll also call to remind you next week.”
# Shared-decision making tools

## What screening tests are there for colon cancer? Which one is best for me?

<table>
<thead>
<tr>
<th>Fecal Occult Blood Test (FOBT)</th>
<th>Flexible Sigmoidoscopy</th>
<th>Colonoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>- A screening test you do at home. It's sometimes called the stool test.</td>
<td>- An exam of the inside of the rectum and lower colon.</td>
<td>- An exam of the inside of the rectum and entire colon.</td>
</tr>
<tr>
<td>- Recommended once per year.</td>
<td>- Recommended once every 5 years. When it is combined with a yearly FOBT, it can be done every 10 years.</td>
<td>- Recommended once every 10 years.</td>
</tr>
<tr>
<td>- Polyps and cancers may bleed slightly into the stool, but you usually can't see the blood. The FOBT looks for hidden blood in the stool. If the FOBT finds blood, more tests are needed to determine the cause.</td>
<td>- This test looks for polyps or cancer in the lower part of the colon.</td>
<td>- This test looks for polyps or cancer throughout the entire colon. It is a longer version of a sigmoidoscopy.</td>
</tr>
</tbody>
</table>

### How to prepare for and take the test

The FOBT uses stool samples taken from 3 bowel movements in a row. You use a test kit to take the samples at home, and then mail the kit to the lab. To prepare for the FOBT, you can't eat red meat starting 3 days before the test.

### Advantages of this test (the pros)

- You can do the FOBT in the privacy of your own home.
- You don't need to clean out your colon before the test.
- There are no complications.
- Having this test once per year lowers your chances of getting or dying from colon cancer by about 30%.

### Disadvantages of this test (the cons)

- If the FOBT is positive (meaning there was blood in your stool), more tests will be needed. A colonoscopy is usually recommended.
- Many people with a positive FOBT don’t have polyps or cancer. (These are called false positives.)
- Some people with a negative FOBT do have polyps or cancer. (These are called false negatives.)

*Not enough studies have been done yet to know for sure.*

### Where can I get more information?

Contact your Group Health doctor.

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## Colon Health — Screening tests save lives!

No screening test can find all colon polyps or cancers or prevent all colon cancer deaths.

Besides screening, here are some other things you can do to help keep your colon healthy:

- Be active — Try to get some exercise every day.
- Eat healthy — Fruits and vegetables are rich in fiber and other nutrients that fight cancer.
- Don’t smoke — If you smoke, your risk of cancer goes down as soon as you stop.

Find more healthy lifestyle tips at [mygrouphealth.org](http://mygrouphealth.org).

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This pamphlet includes information about colon cancer and what you can do to keep your colon healthy.

### What is colon cancer?

Colon cancer is cancer of the colon or rectum. It is sometimes called colorectal cancer. Anyone can get colon cancer, but it occurs more often in people 50 and older. Colon cancer is common and often deadly.

- About 1 in 20 people over age 50 will develop colon cancer. It is the 3rd most common type of cancer.
- In the United States, colon cancer kills 1 person every 19 minutes. It is the 2nd leading cause of cancer death.

### What can I do to prevent colon cancer?

Colon cancer usually has no symptoms in the early stages. The best way to prevent colon cancer is to have a screening test. Screening tests save lives by stopping the cancer before it starts. If you have a screening test, polyps can be found and removed before they turn into cancer.

A screening test can also find cancer early, when the chances for survival are highest. If everyone 50 and older were screened for colon cancer, we could prevent at least one-third of colon cancer deaths.

Here are some terms you will need to know:

- Colon — The hollow tube in your large intestine. Your colon turns the food you eat into waste matter. This waste matter is often called stool or feces.
- Rectum — The last 6 to 10 inches of your large intestine.
- Polyp — A growth (usually benign) in the colon or rectum that is not normal. Some polyps can turn into cancer.
- Screening test — A test that looks for signs of disease before any symptoms show up. If testing finds cancer or polyps early, it can prevent cancer or find it early.

The red area shows where your colon is located.

This illustration shows a growth—or polyp—inside a colon.
FIT kit instructions
### Not Recommended

<table>
<thead>
<tr>
<th><strong>Virtual colonoscopy</strong></th>
<th><strong>Fecal DNA (Cologuard)</strong></th>
<th><strong>Double contrast barium enema</strong></th>
</tr>
</thead>
</table>
| • Requires specially trained radiologist  
• If positive, requires colonoscopy and second prep  
• Radiation exposure  
• Extra-colonic findings require further and often invasive evaluation  
• May be useful in limited settings such as anticoagulated or frail patients, or for other diagnostic reason | • Now covered by Medicare  
• Sensitive for cancer  
• Long term outcomes not known  
• Interval for testing unknown  
• $150 per test  
• USPSTF concluded insufficient evidence | |
Follow up after a positive fecal CRC screening test or colonoscopy

When should you repeat a fecal test?
  • Answer: Never (almost)

What is the recommended interval for a surveillance colonoscopy?
  • 1-2 small adenomas?
    • 5 years
  • Large adenomas (10 mm or more)?
    • Sooner
Case Study

Carlos is a 78 year old who requests colonoscopy. Previous colonoscopy done 10 years prior was normal.

What is the appropriate recommendation?
CME Credit

For presentation materials, including slides, shared decision-making handout, and Fax Back flyer, and information on receiving 1.0 hours of Category 1 CME credit:

Email anderson.bk@ghc.org by Wed. October 14, 2015

Include:
  • Full name
  • Title
  • Organization