IDAHO

COLORECTAL CANCER ROUNDTABLE

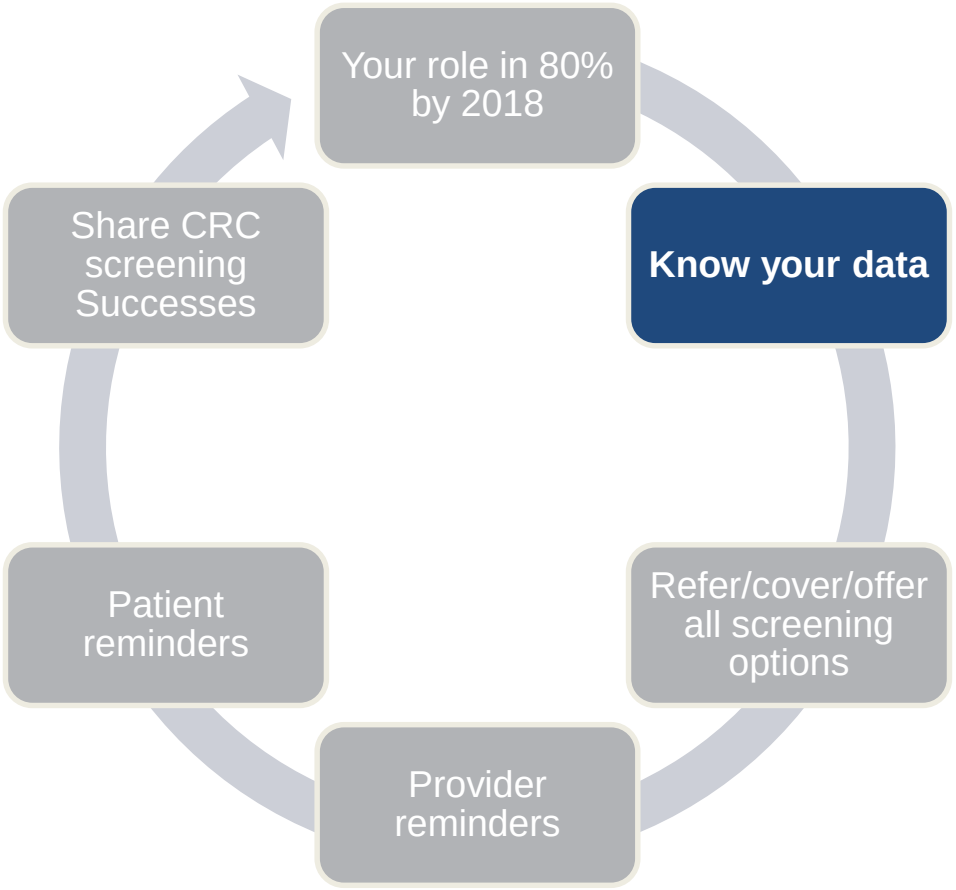
Screening Options: More Than Just a Scope

June 28, 2017

EIGHTYBY2018

April Webinar

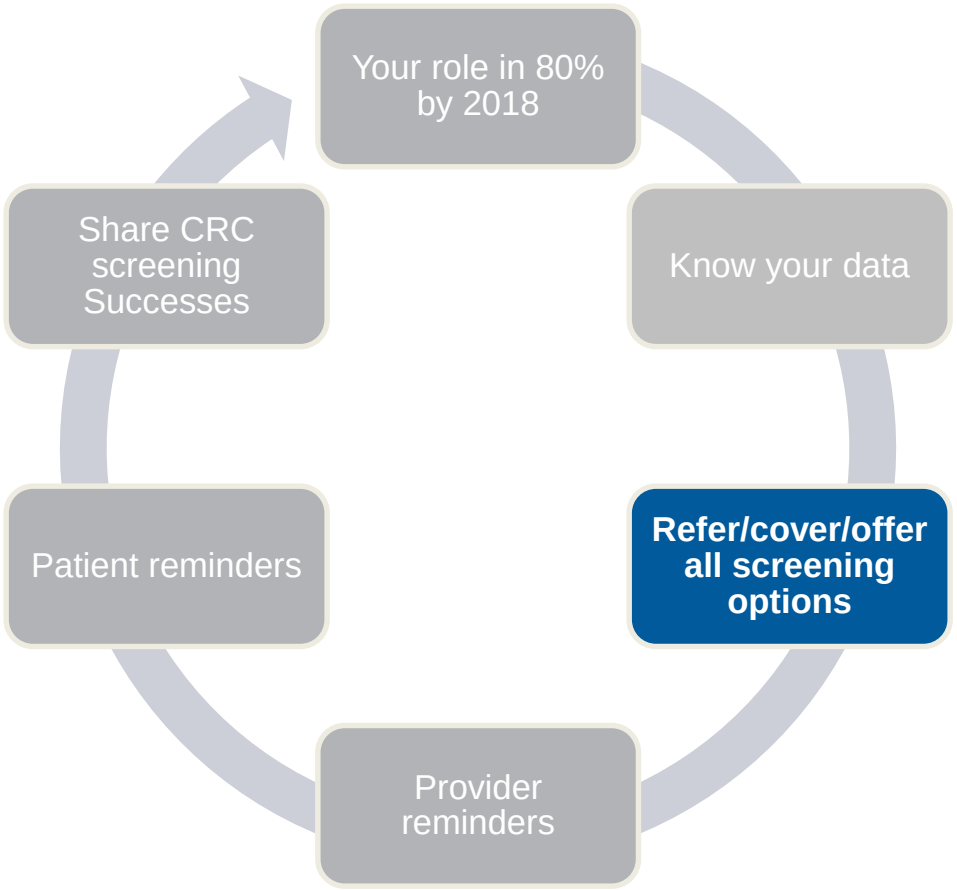
- Increase understanding of national quality measures
- Increase understanding of organizational data that may be available or could be collected
- Describe how to utilize data for quality improvement
- Identify ways to communicate data effectively



EIGHTYBY2018

Webinar Objectives

- Increase understanding of USPSTF recommended CRC screening options
- List benefits and barriers of each screening modality
- Know how to analyze cost and capacity for colonoscopy services



Colorectal Cancer Screening: State of the Science

Idaho Colorectal Cancer Roundtable

June 28, 2017

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Senior Director, Community Initiatives

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American Cancer Society®

Objectives

- Understand the evidence and rationale supporting current recommendations for colorectal cancer screening.
- Identify common barriers to CRC screening and utilize appropriate strategies to identify and address those barriers.
- Discuss key practice-change elements proven to increase CRC screening rates.

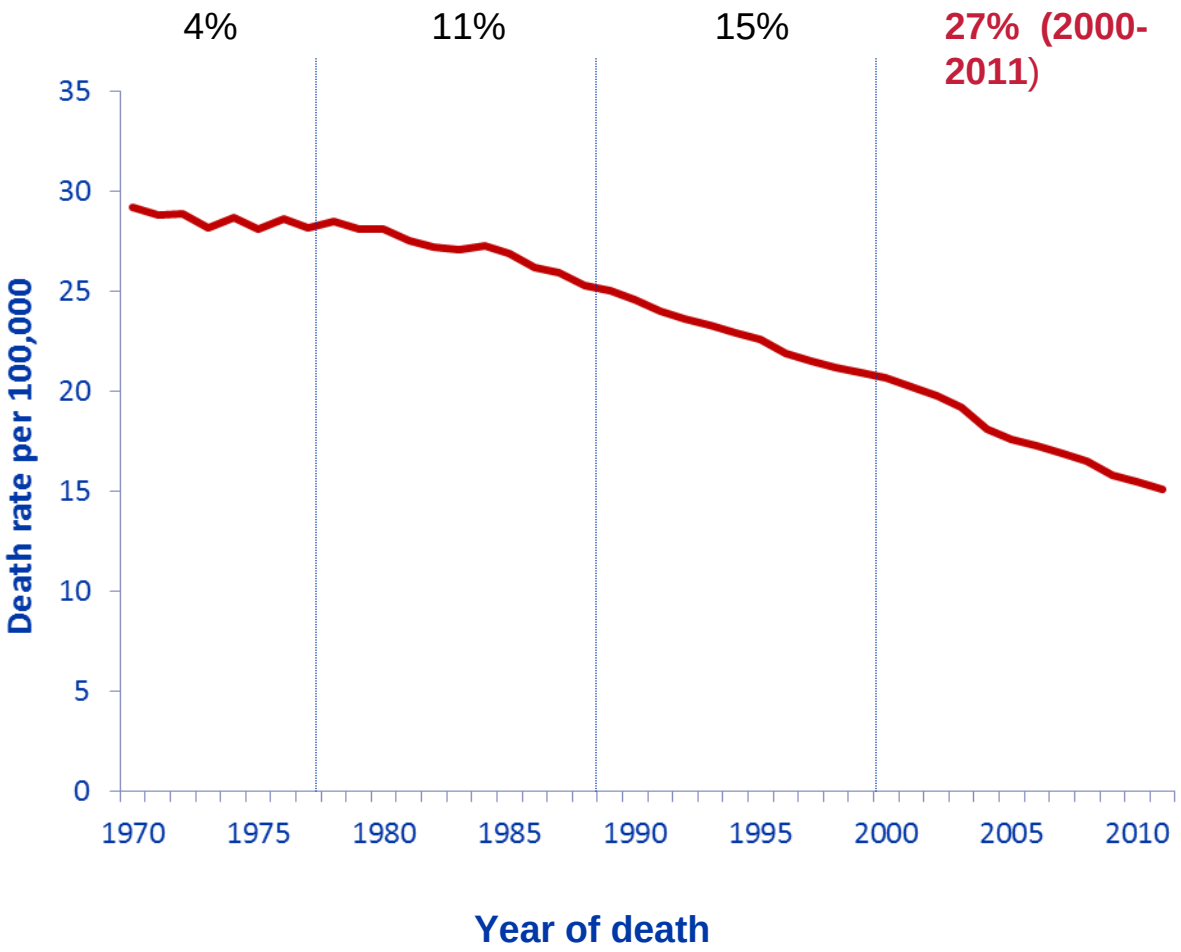
Colorectal Cancer (CRC)

- **2nd** most common cause of cancer death in US
  - 135,430 new cases expected in US in 2017
    - Idaho – 610
  - 50,260 US deaths
    - Idaho – 250
- 1.2 million Americans living with CRC
- Incidence and death rates have fallen steadily past 30 years

Cancer Facts and Figures 2017

Overall CRC death rate decline in the US

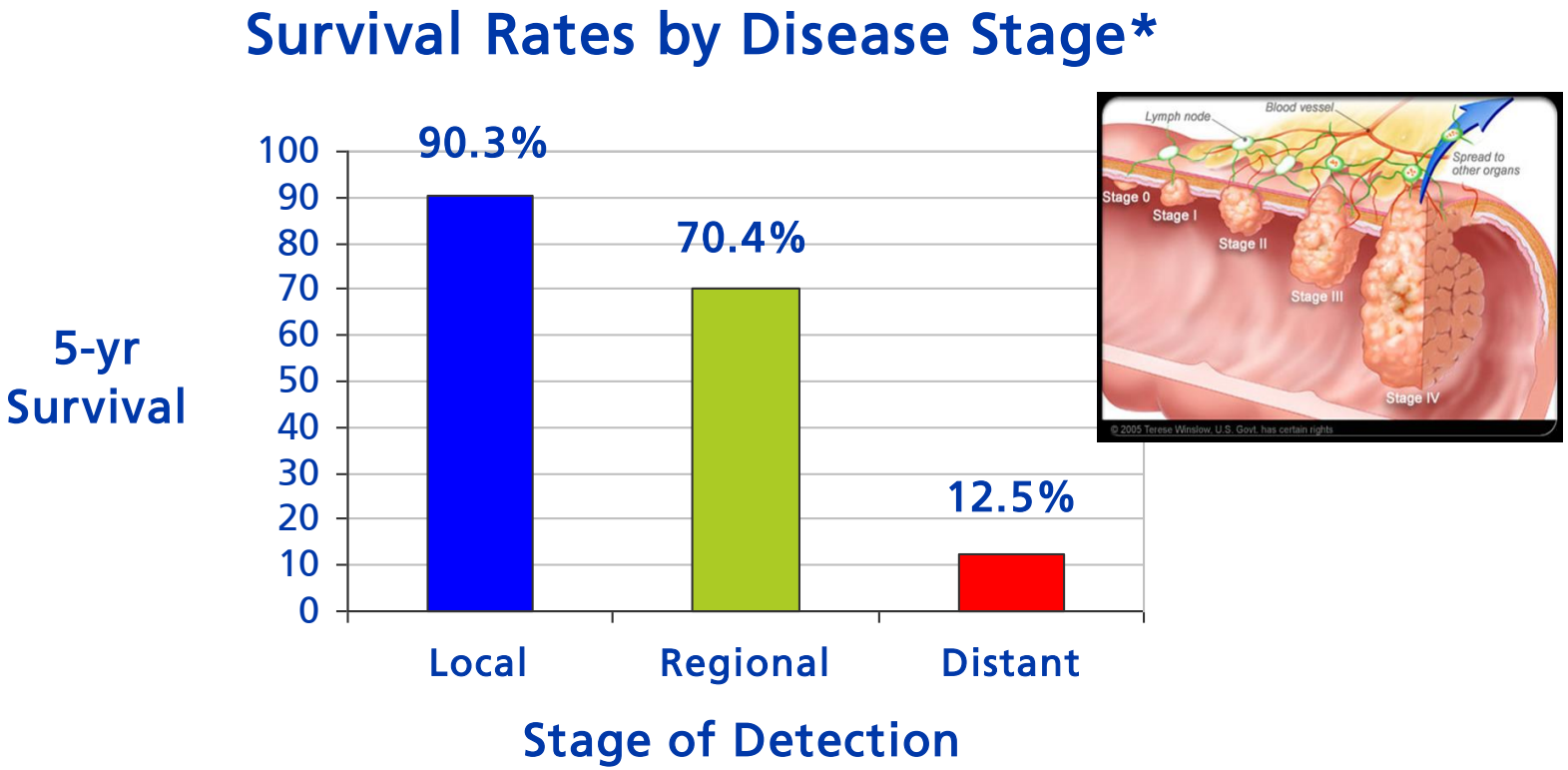
CRC mortality decline per decade:



Siegel et al, CEBP 2015

Decline in CRC Incidence and Mortality

- Decline due to:
  - Improvements in treatment
  - **Screening** → earlier cancer detection → improved survival



Risk factors – polyps

A polyp is a growth of tissue in the lining of an organ.

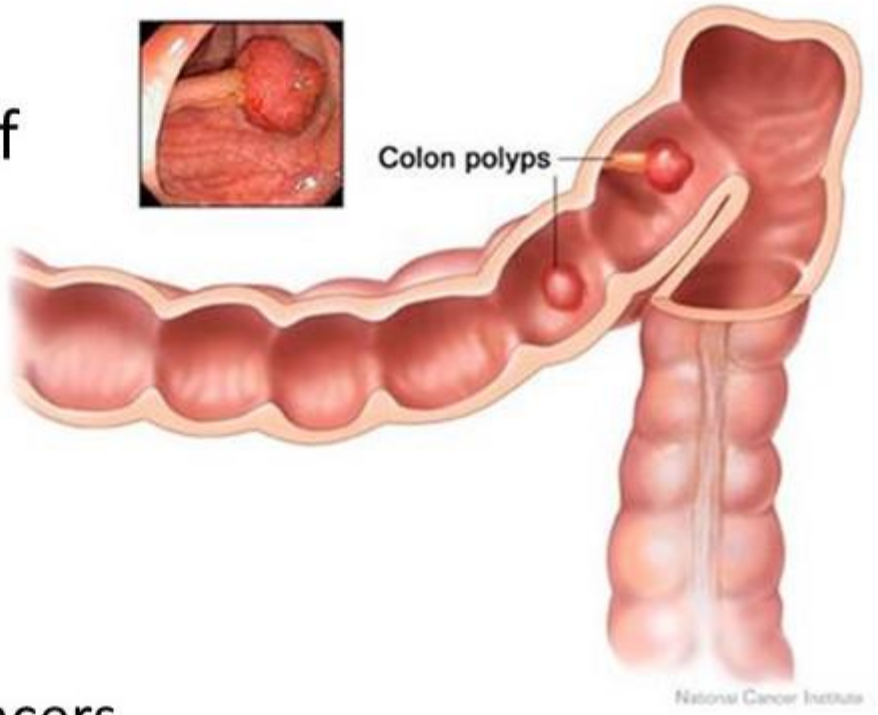
There are 2 main types of colorectal polyps:

- Hyperplastic

  Very small chance they'll grow into cancer

- Adenomatous

  Most colon and rectal cancers start as adenomatous polyps ("adenomas")



Yang, Cancer 2014

Decline in CRC Incidence

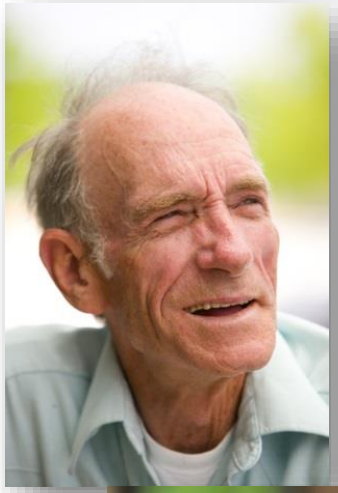
- Decline due to:
  - **Screening** → polyp removal → <u>prevention</u>
- Estimated that screening may have prevented **550,000** cases of colorectal cancer in the US over the past three decades

Yang, Cancer 2014

CRC Screening: Idaho

In 2014, **62.5%** of Idaho adults were up to date with screening (US – 66.3%)

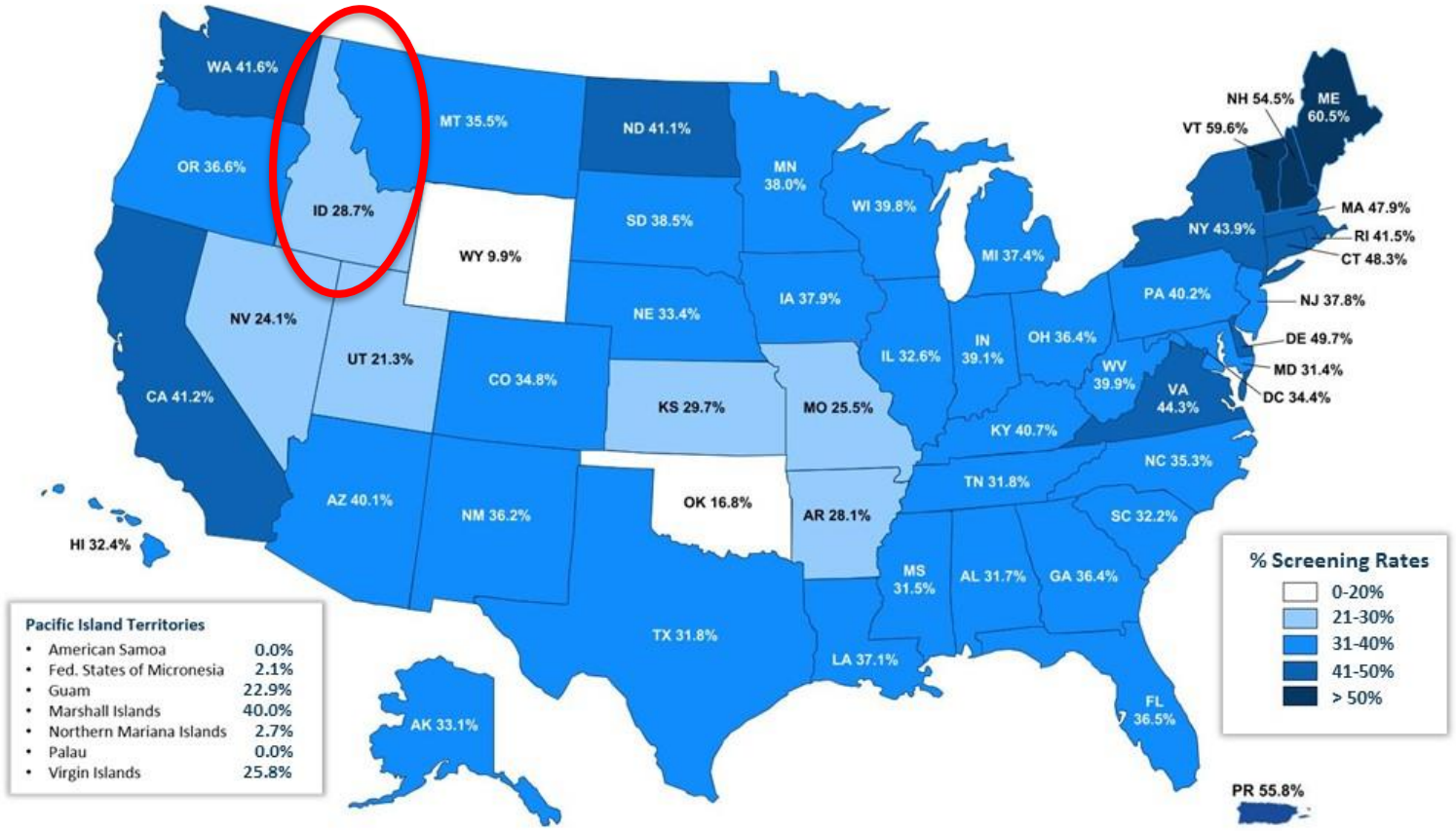
- 1 of 3 eligible adults in Idaho is not up to date
- Idaho ranks 44 out of 51



Source: BRFSS, 2014

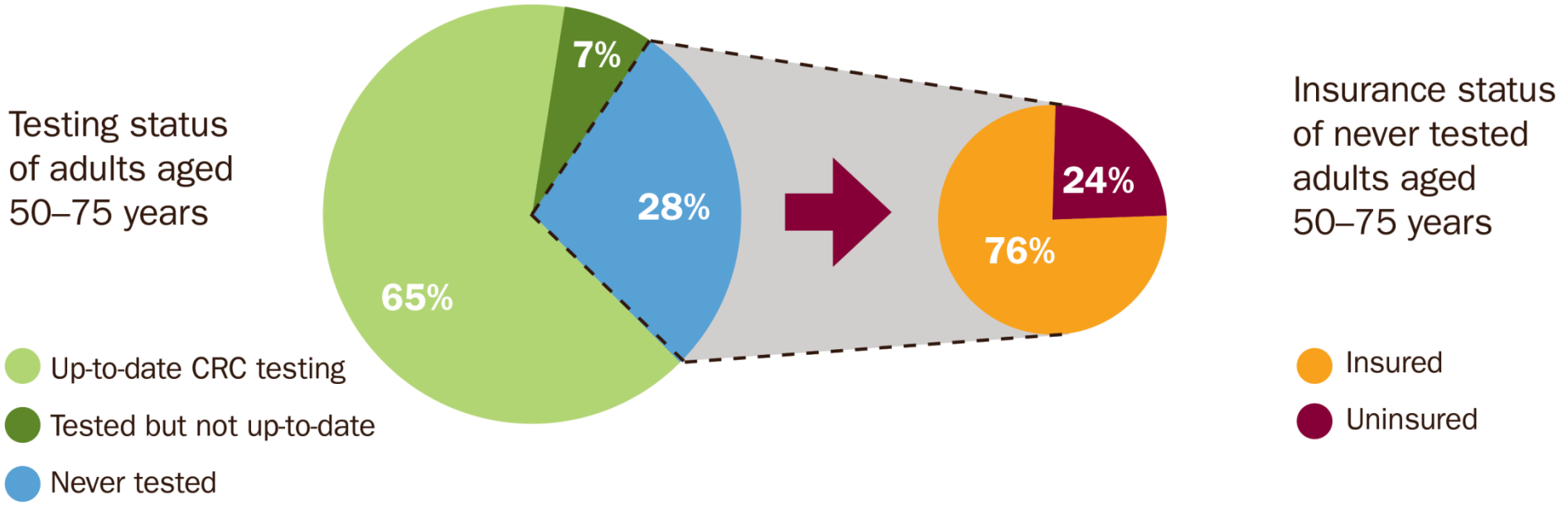
National Colorectal Cancer (CRC) Screening Rates in Health Centers – CY 2015

(38.3% as of December 31, 2015)



HRSA
Health Resources & Services Administration

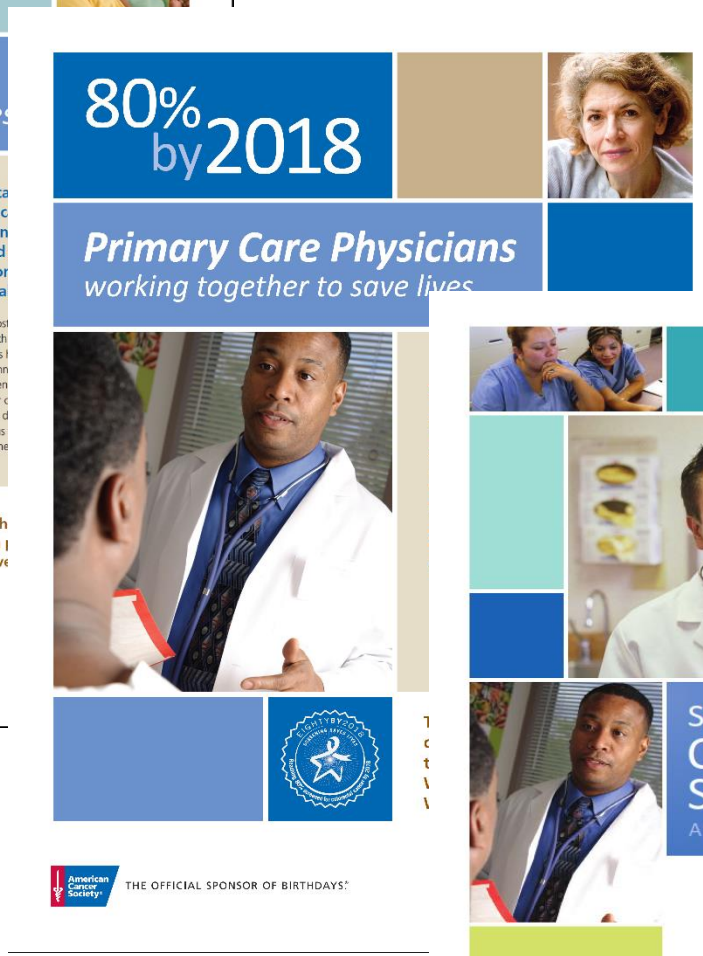
Who's Not Screened?

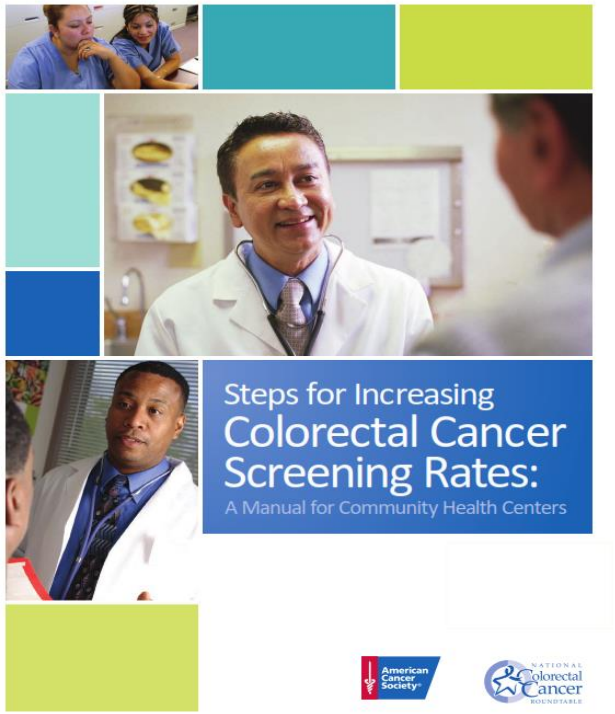


SOURCE: Behavioral Risk Factor Surveillance System, 2012

Barriers to Effective Screening

- Medical practice is demand (patient) driven
- Practice demands are numerous and diverse
- Few practices currently have mechanisms to assure that every eligible patient gets an appropriate recommendation for screening.
- Opportunistic vs organized screening



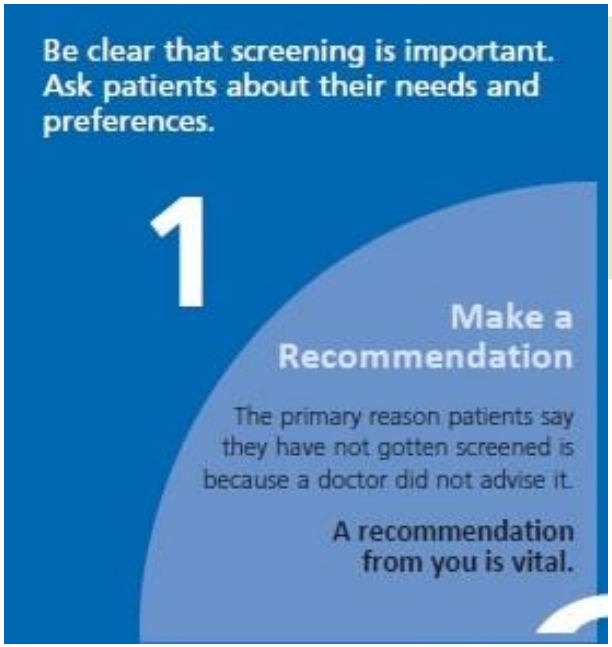


http://nccrt.org/tools/80-percent-by-2018/

Improve Cancer Screening Rates

Using the Four Essential Strategies

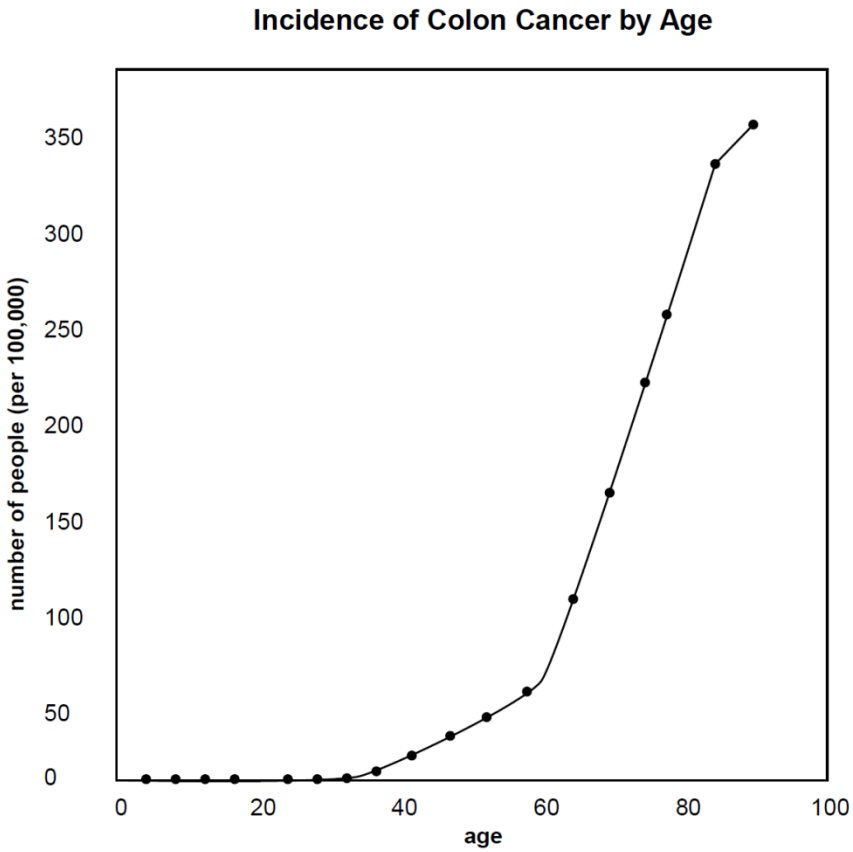
#1: Make a Recommendation



Assess a patient's risk status and receptivity to screening.

Who Should Be Screened

- CRC usually develops after age 50.
- Incidence continues to rise in later years.
- Near-unanimous recommendation across guidelines to begin screening at age 50 – for individuals at average risk.



http://science.education.nih.gov/supplements/nih1/cancer/guide/pdfs/ACT3M.PDF.

Increased and High Risk

- Personal history of
  - Adenomatous Polyps
  - Colorectal cancer
  - Inflammatory bowel disease
    - Ulcerative colitis
    - Crohn's disease
- Family history
  - Colorectal cancer or adenomas
  - Hereditary syndrome (FAP, Lynch Syndrome,…)

For people with these conditions

- *Begin screening earlier (10 yr before age at dx of index case)*
- *Colonoscopy is the only recommended screening test*

CRC Under Age 50 years

- While CRC rates are falling steadily in most over age 50, diagnosis before age 50 is increasing
  - Majority of the increase is in those age 40-49, but some rise among those in their 30s and even 20s
- Rise is predominantly rectal cancer (as opposed to colon)
- Numbers remain too small to justify starting screening at earlier age (i.e. 40) for the entire US population

Siegel, 2017

CRC Under Age 50 years

- Recognize those needing screening before age 50 (family history or other risk factors)
- Need increased awareness among clinicians and young adults of symptoms and the need to take action to facilitate earlier detection

1. Rectal bleeding
2. Abdominal pain
3. Change in bowel habits
4. Weight loss

Remember: Guidelines are for screening only!
***Not** relevant for symptomatic patients – regardless of age*

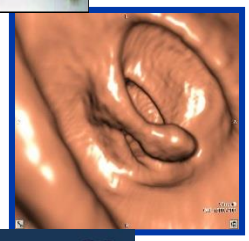
#2: Develop a Screening Policy

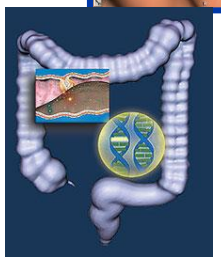
Create a standard course of action for screenings, document it, and share it.

Ensure patient education & follow-up

ACS CRC Screening Guidelines

Options for Average risk adults age 50 and older:





Tests That Detect Adenomatous Polyps and Cancer

Colonoscopy every 10 years, or

Flexible sigmoidoscopy (FSIG) every 5 years, or

Double contrast barium enema (DCBE) every 5 years, or

CT colonography (CTC) every 5 years

Tests That Primarily Detect Cancer

Annual Guaiac-based fecal occult blood test (gFOBT) with high test sensitivity for cancer, or

Annual Fecal immunochemical test (FIT) with high test sensitivity for cancer, or

Stool DNA test (sDNA) with high sensitivity for cancer every 3 years

CRC Screening Strategies (USPSTF June 2016)

Table. Characteristics of Colorectal Cancer Screening Strategies[a]

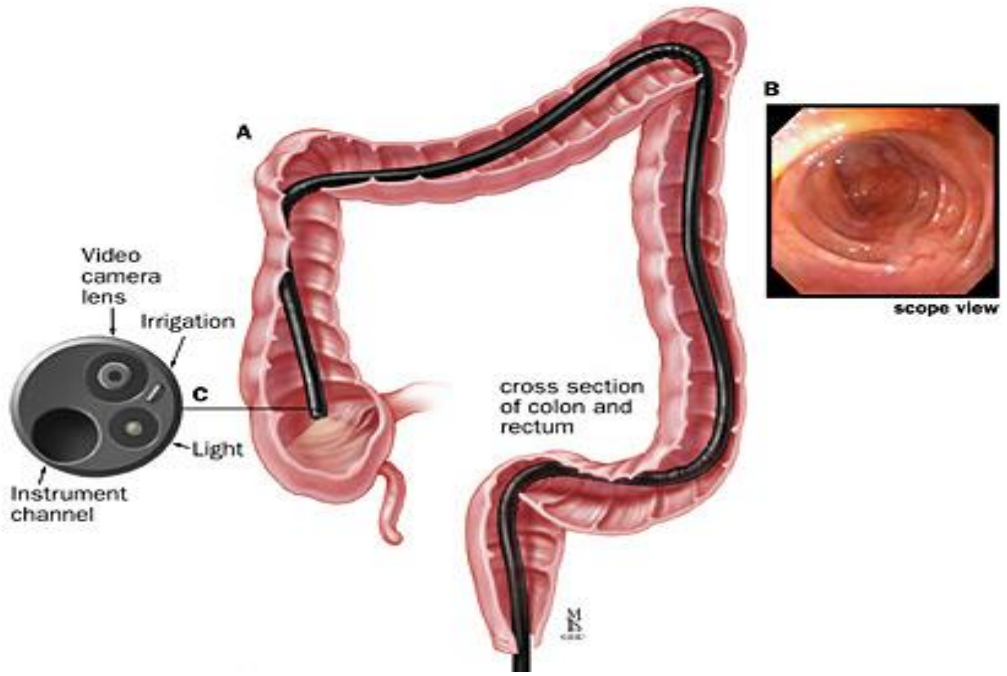
Screening Method	Frequency[b]	Evidence of Efficacy	Other Considerations
Stool-Based Tests			
gFOBT	Every year	RCTs with mortality end points: High-sensitivity versions (eg, Hemoccult SENSA) have superior test performance characteristics than older tests (eg, Hemoccult II)	Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)
FIT[c]	Every year	Test characteristic studies: Improved accuracy compared with gFOBT Can be done with a single specimen	Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)
FIT-DNA	Every 1 or 3 y[d]	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	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
Direct Visualization Tests			
Colonoscopy[c]	Every 10 y	Prospective cohort study with mortality end point	Requires less frequent screening. Screening and diagnostic followup of positive results can be performed during the same examination.
CT colonography[e]	Every 5 y	Test characteristic studies	There is insufficient evidence about the potential harms of associated extracolonic findings, which are common
Flexible sigmoidoscopy	Every 5 y	RCTs with mortality end points: Modeling suggests it provides less benefit than when combined with FIT or compared with other strategies	Test availability has declined in the United States
Flexible sigmoidoscopy with FIT[c]	Flexible sigmoidoscopy every 10 y plus FIT every year	RCT with mortality end point (subgroup analysis)	Test availability has declined in the United States Potentially attractive option for patients who want endoscopic screening but want to limit exposure to colonoscopy

Most Commonly Used Screening Tests

- Colonoscopy
- High Sensitivity Fecal Occult Blood Testing
  - High Sensitivity Guaiac-based Tests
  - Fecal Immunochemical Tests

Colonoscopy

- Allows direct visualization of entire colon lumen
- Screening, diagnostic and therapeutic
- 10 yr interval
- The most common screening test in US (nearly 90%)



Colonoscopy Limitations

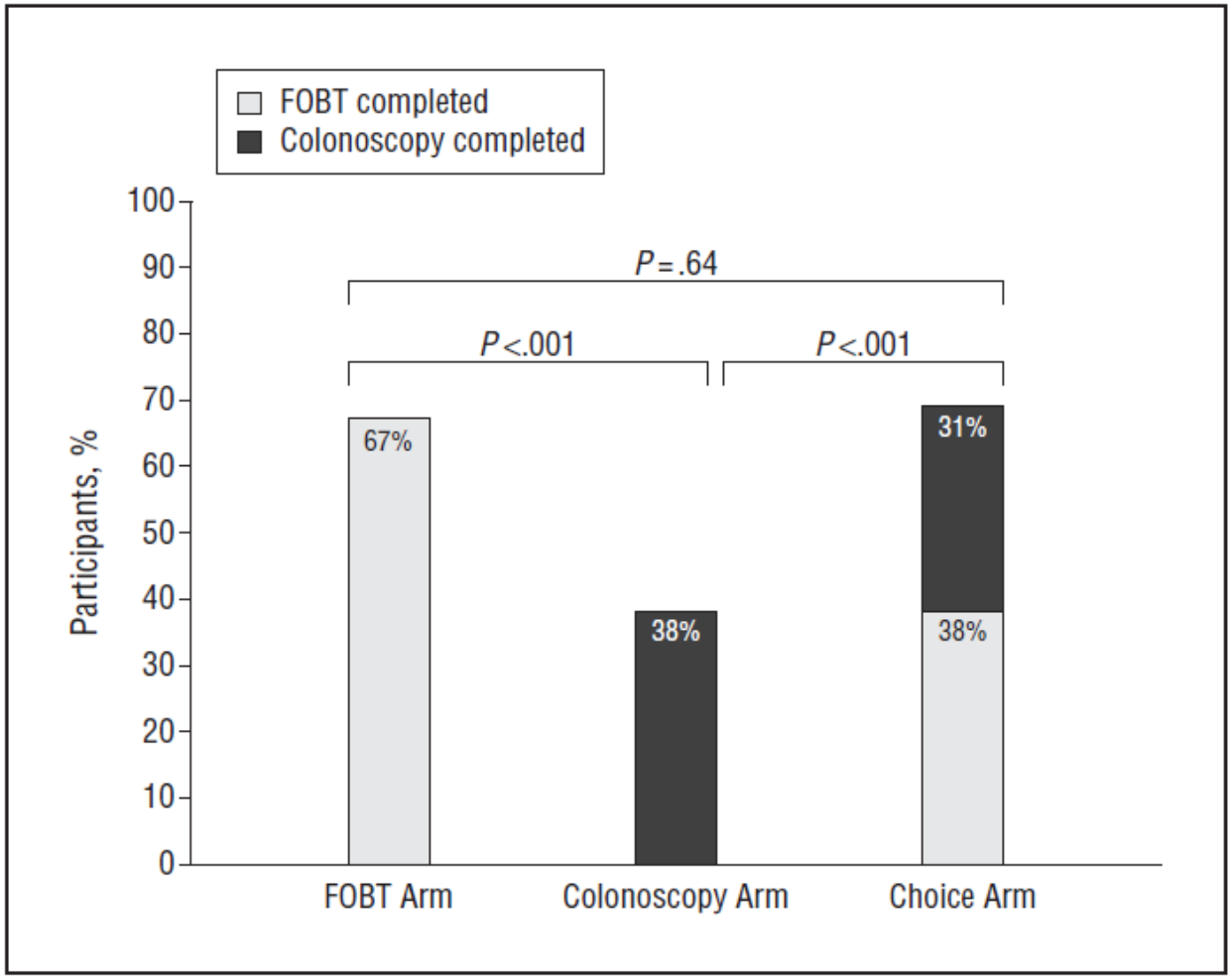
Frequently referred to as “best test” or “gold standard”, but evidence shows:

- Colonoscopy misses ~ 10% of significant lesions in expert settings
- More costly on a one-time basis
- Higher potential for patient injury than other tests
- Wide variation in quality (when data are captured and available)

Colonoscopy Limitations

- Greater patient requirements for successful completion
  - Requires a bowel prep and facility visit, and often a pre-procedure specialty office visit
- Access
  - Limited by insurance status, local resources
- Patient preference
  - Many individuals don’t want an invasive test or a test that requires a bowel prep

Patient Preferences



Inadomi, Arch Intern Med 2012

Patient Preferences

- 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)
  - **31% preferred FOBT**
  - 37% preferred colonoscopy
- Nationally representative sample of 2068 VA patients given brief descriptions of each screening mode (Powell et al. 2009)
  - **29% preferred FOBT**
  - 37% preferred colonoscopy

PCP Beliefs and Preferences

- **Colonoscopy viewed as the best screening test, but:**
  - Many patients face barriers or not willing
  - Colonoscopy often recommended despite access or other challenges
  - Patient preferences rarely solicited
  - Focus on colonoscopy associated with low screening rates in a number of studies
- **FOBT/FIT widely used, but:**
  - Lack of knowledge re: performance of new vs. older forms of stool tests, other quality issues
  - Effectiveness questioned or underestimated

Types of Stool Tests*

A) Tests that detect blood (Fecal Occult Blood Tests)

- Two types (but multiple brands, variable performance)
  - Guaiac-based FOBT
  - Immunochemical (FIT)

B) Tests that detect aberrant DNA

- One test (Cologuard) available in U.S.
  - Combines DNA mutation test with FIT
  - Recently added to USPSTF screening guideline (June 2016)

Stool tests are only appropriate for **average risk patients*

Guaiac-based Stool Tests

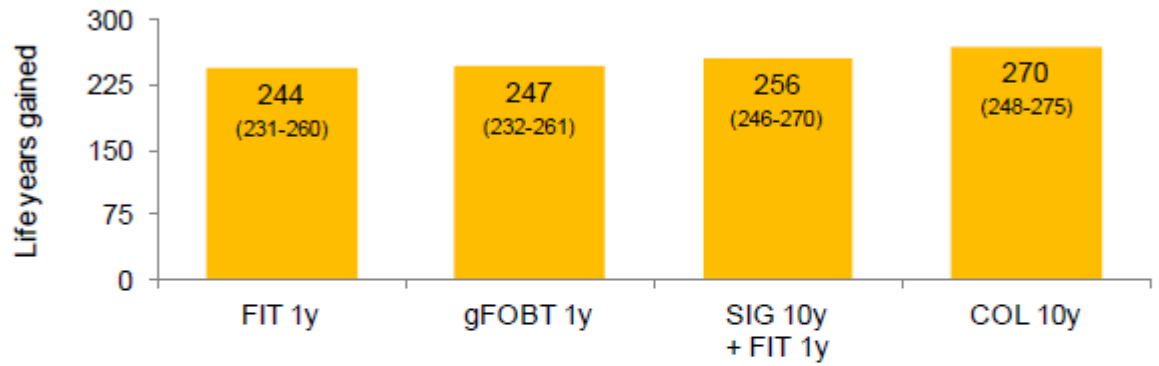
- Most common type in U.S.
- Solid evidence (3 RCT's)
- 30 year f/u (NEJM Oct 2013)
- Need specimens from 3 bowel movements
- Non-specific
- Results influenced by foods and medications
- *Better sensitivity with newer versions (Hemoccult Sensa)*
- *Older forms (Hemoccult II)* ***not recommended!***

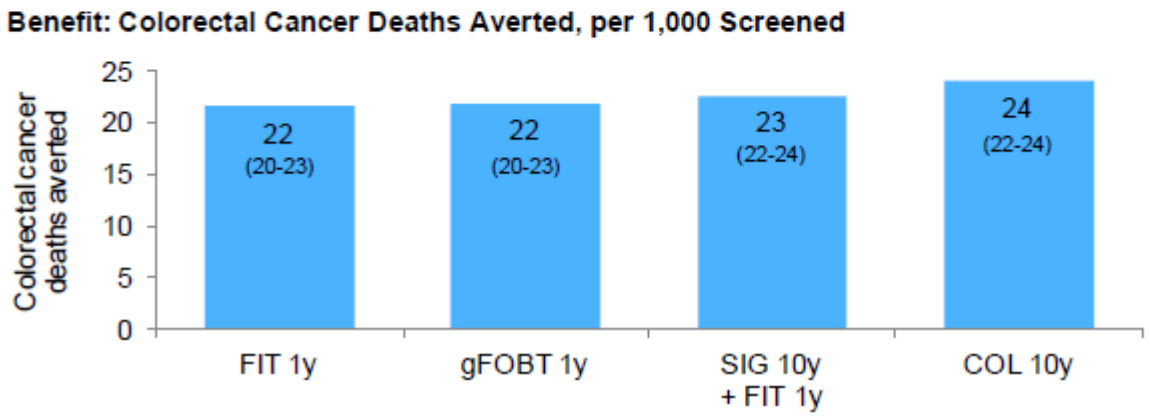
Fecal Immunochemical Tests (FIT)

- 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 guaiac-based FOBT
- Costs more than guaiac tests – but higher reimbursement

FOBT/FIT: Efficacy (USPSTF 2015)

Draft: Figure. Benefits, Harms, and Burdens of Recommended Screening Strategies Over a Lifetime*†





http://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement38/colorectal-cancer-screening2

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.

Stool Test Quality Issues

- Stool tests are appropriate only for *average risk* (no family history, no history of adenomas,…)
- Use only high sensitivity guaiac or FIT
  - Hemoccult II and other less sensitive guaiac tests should *not* be used for screening
- All positive tests must be followed up with colonoscopy
  - Follow up often lacking (<75% adherence in many settings)
  - In-office FOBT from DRE is not an effective screening test for CRC and should NEVER be used. Missed 19 of 21 cancers in largest study

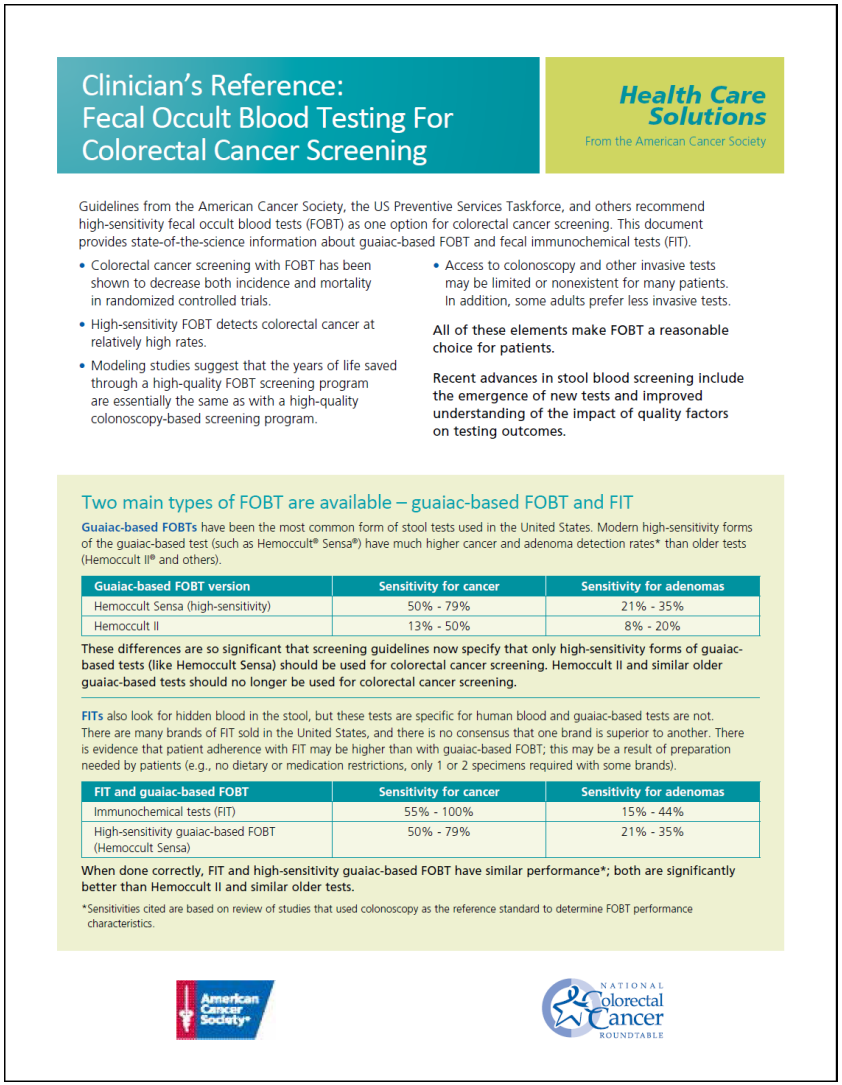
Meta-Analysis of FIT vs Hemoccult Sensa

	FIT	Hemoccult Sensa
Sensitivity:	73-89%	64-80%
Specificity:	92-95%	87-90%

Conclusion: **FIT is a superior option** for annual stool testing.

Lee, JK et. al. Ann Intern Med. 2014 160 (3): 171

High Quality Stool Testing



Clinician's Reference: Fecal Occult Blood Testing For Colorectal Cancer Screening

Health Care Solutions
From the American Cancer Society

Guidelines from the American Cancer Society, the US Preventive Services Taskforce, and others recommend high-sensitivity fecal occult blood tests (FOBT) as one option for colorectal cancer screening. This document provides state-of-the-science information about guaiac-based FOBT and fecal immunochemical tests (FIT).

- Colorectal cancer screening with FOBT has been shown to decrease both incidence and mortality in randomized controlled trials.
- High-sensitivity FOBT detects colorectal cancer at relatively high rates.
- Modeling studies suggest that the years of life saved through a high-quality FOBT screening program are essentially the same as with a high-quality colonoscopy-based screening program.
- Access to colonoscopy and other invasive tests may be limited or nonexistent for many patients. In addition, some adults prefer less invasive tests.

All of these elements make FOBT a reasonable choice for patients.

Recent advances in stool blood screening include the emergence of new tests and improved understanding of the impact of quality factors on testing outcomes.

Two main types of FOBT are available – guaiac-based FOBT and FIT

Guaiac-based FOBTs have been the most common form of stool tests used in the United States. Modern high-sensitivity forms of the guaiac-based test (such as Hemoccult® Sensa®) have much higher cancer and adenoma detection rates* than older tests (Hemoccult II® and others).

Guaiac-based FOBT version	Sensitivity for cancer	Sensitivity for adenomas
Hemoccult Sensa (high-sensitivity)	50% - 79%	21% - 35%
Hemoccult II	13% - 50%	8% - 20%

These differences are so significant that screening guidelines now specify that only high-sensitivity forms of guaiac-based tests (like Hemoccult Sensa) should be used for colorectal cancer screening. Hemoccult II and similar older guaiac-based tests should no longer be used for colorectal cancer screening.

FITs also look for hidden blood in the stool, but these tests are specific for human blood and guaiac-based tests are not. There are many brands of FIT sold in the United States, and there is no consensus that one brand is superior to another. There is evidence that patient adherence with FIT may be higher than with guaiac-based FOBT; this may be a result of preparation needed by patients (e.g., no dietary or medication restrictions, only 1 or 2 specimens required with some brands).

FIT and guaiac-based FOBT	Sensitivity for cancer	Sensitivity for adenomas
Immunochemical tests (FIT)	55% - 100%	15% - 44%
High-sensitivity guaiac-based FOBT (Hemoccult Sensa)	50% - 79%	21% - 35%

When done correctly, FIT and high-sensitivity guaiac-based FOBT have similar performance*; both are significantly better than Hemoccult II and similar older tests.

*Sensitivities cited are based on review of studies that used colonoscopy as the reference standard to determine FOBT performance characteristics.

American Cancer Society

National Colorectal Cancer Roundtable

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

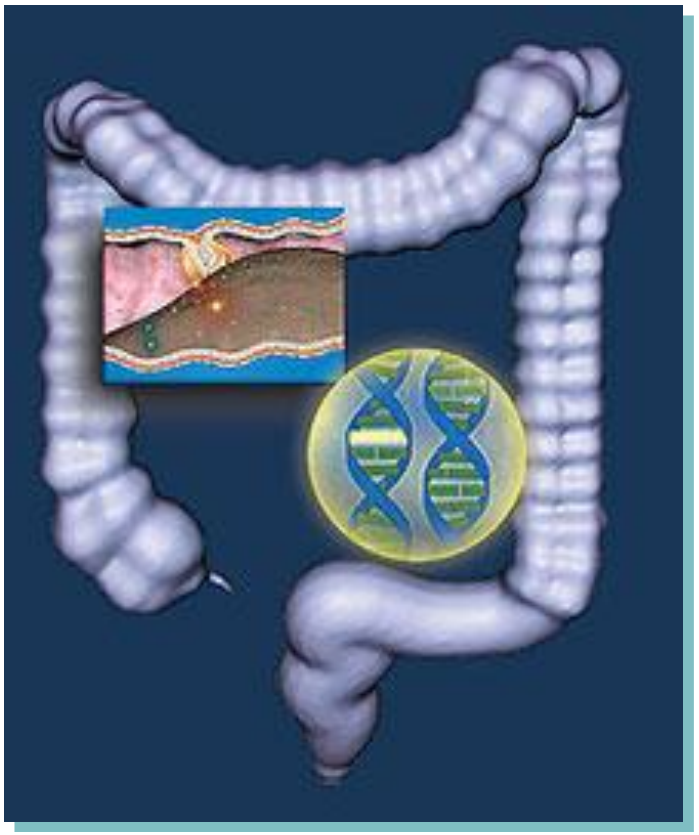
Provides state-of-the-science information about guaiac and immunochemical FOBT, test performance and characteristics of high quality screening programs.

Available at
www.cancer.org/colonmd

Other CRC Screening Tests

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*



*All positive tests must be followed with colonoscopy

Cologuard

- FDA cleared for marketing as CRC screening test
- Every 3 year testing interval recommended by manufacturer
- Included in ACS guideline since 2008, and added to USPSTF guideline (June 2016)
- CMS has agreed to cover Cologuard for Medicare beneficiaries age 50 – 85 yrs
  - Medicare reimbursement ~ $500 q 3 yrs
  - Private insurance coverage – limited (but may increase with USPSTF inclusion)
- All positive tests must be evaluated by colonoscopy (may be subject to cost sharing)

CT colonography

- Air is pumped into the colon through a flexible tube
- CT scans are then done
- Special computer programs create both 2-dimensional x-ray pictures and a 3-dimensional "fly-through" view of the inside of the colon and rectum, which lets the doctor look for polyps and cancer.

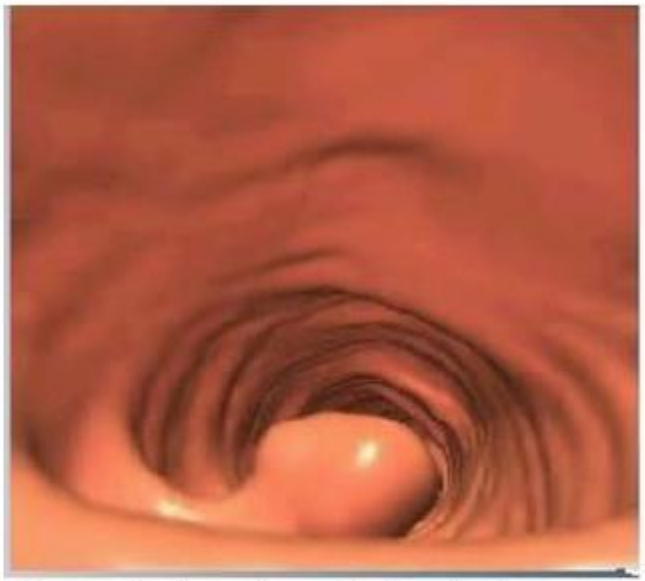


Image of polyp taken with virtual colonoscopy

CT Colonography

- Recommended by ACS since 2008; added to USPSTF guidelines in 2016
- Requires full bowel prep
- Colonoscopy required if abnormalities detected (necessitating second bowel prep if system not coordinated)
- Steep learning curve for radiologists

CT Colonography Limitations

- Extra-colonic findings can lead to additional testing (positive and negative connotations)
- Questions regarding:
  - Management of small polyps
  - Detection of sessile serrated adenomas (”flat polyps”)
  - Radiation risks
- Medicare and many private insurers do not currently cover CTC as a screening modality; may change with addition to USPSTF recommendations

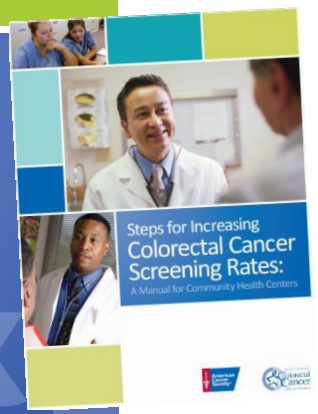
There is no evidence from randomized controlled trials that one screening method is the "best"

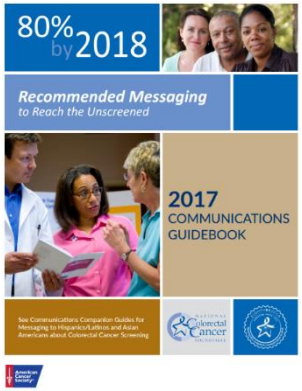
Years of life saved through an **annual high-quality stool blood screening program are COMPARABLE to a high-quality colonoscopy-based screening program** when positive stool tests are followed by colonoscopy

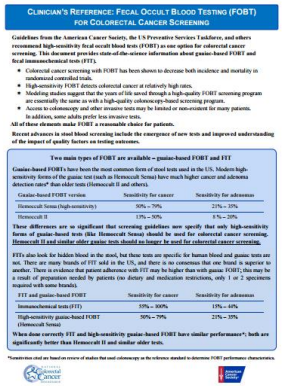
Summary

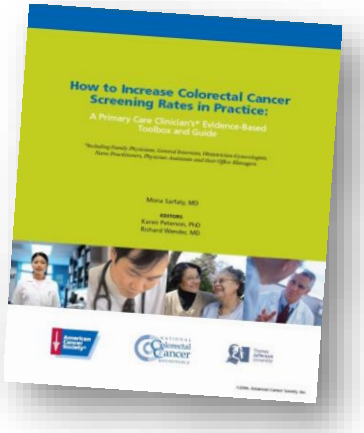
- CRC screening is an important part of preventing cancer, early detection and treatment, and saving lives
- The best screening test is the one that gets done.
- Patient engagement and shared decision-making are important to overcoming barriers to CRC screening.
- Work together, use available resources, and keep making a difference!

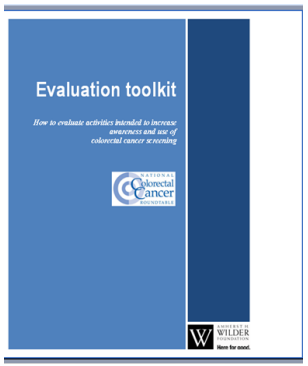
NCCRT Tools, Resources & Publications











Available at:
nccrt.org

www.cancer.org/colonmd
www.cancer.org/professionals

References

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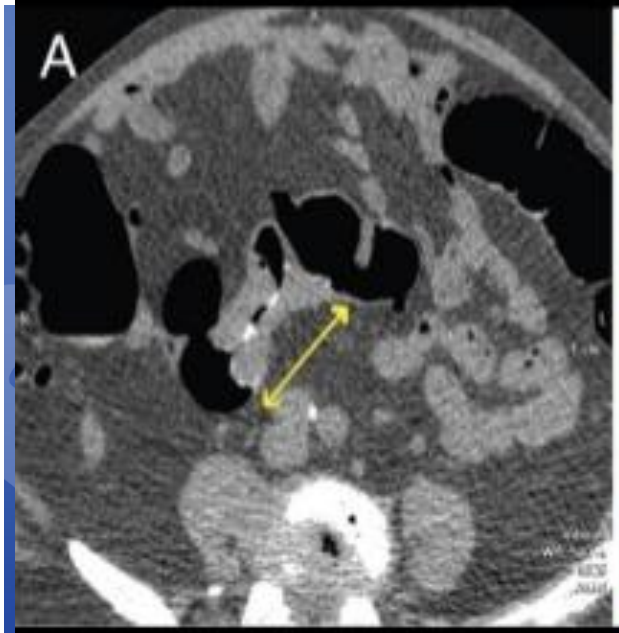
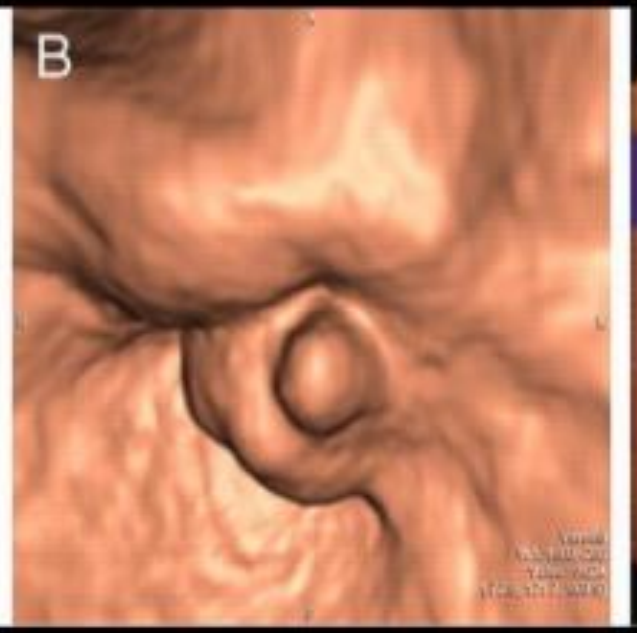
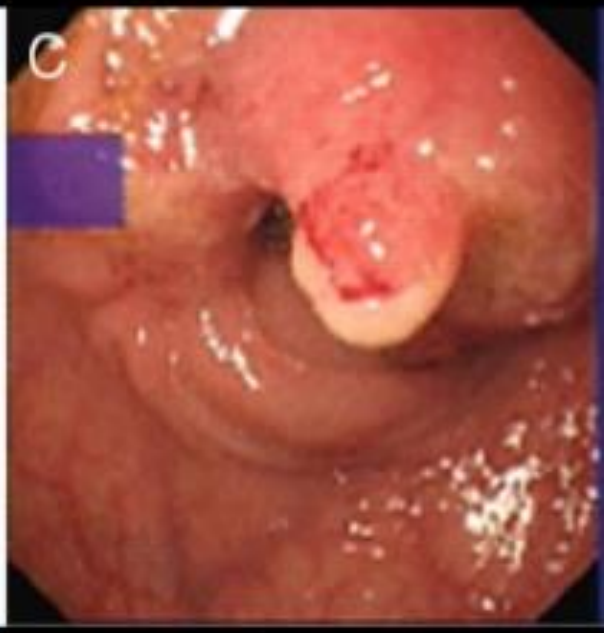
CT Colonography







2-D View

3-D View

Colonoscopy View

Diagnostic Accuracy Studies of Screening Computed Tomographic Colonography (CTC)

Table 2. Prospective Diagnostic Accuracy Studies of Screening Computed Tomographic Colonography (Key Question 2)

Study	Quality[a]	Study Site	Cohort Size	Mean Patient Age, y	Fecal Tag[b]	No. of Readers, Training[c]	Reading Strategy[d]	Reference Standard	Adenoma ≥6 mm, % (95% CI)		Adenoma ≥10 mm, % (95% CI)	
									Sensitivity	Specificity	Sensitivity	Specificity
With Bowel Preparation												
Lefere et al,[89] 2013	Fair	Portugal	496	60	Yes	1, >5000 exams	3D (with 2D)	Repeat colonoscopy if indicated	98 (91-100)	91 (88-93)	NR	NR
Graser et al,[82] 2009	Good	Germany	307	60	No	3, >300 exams	3D (with 2D)	Colonoscopy, segmental unblinding[e]	91 (80-97)	93 (90-96)	92 (76-98)	98 (96-99)
Johnson et al,[85] 2008 (ACRIN)[f]	Good	United States	2531	58	Yes	15, >500 exams	3D (with 2D)	Repeat colonoscopy if indicated	78 (72-83)	90 (88-91)	90 (83-95)	86 (85-87)
Kim et al,[87] 2008	Fair	South Korea	241	58	No	2, >100 exams	2D (with 3D)	Single colonoscopy	68 (55-80)[g]	89 (84-93)[g]	87 (64-97)[h]	97 (95-99)[h]
Johnson et al,[86] 2007	Fair	United States	452	65	No	3, >1000 exams	3D (with 2D)[i]	Single colonoscopy	NR	NR	67 (45-84)	98 (96-99)
Macari et al,[93] 2004	Fair	United States	68	55	No	1, 5 y	NR	Single colonoscopy	NR	NR	100 (46-100)[j]	98 (93-100)[j]
Pickhardt et al,[99] 2003	Good	United States	1233	58	Yes	6, >25 exams	3D (with 2D)	Colonoscopy, segmental unblinding[e]	89 (83-93)	80 (77-82)	94 (84-98)	96 (95-97)

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Action Items

- Join Idaho CRC RT Member Listserv
- Sign and submit Letter of Support
- Know you NUMBERS! Share with your clinicians and Idaho Roundtable
  - Megan.Mackey@dhw.Idaho.gov
- Review your system's screening options– do they cover all patients?
- Register for August 23rd Webinar
  - *Colon Alert: Providers Need Reminders Too!*