Colorectal Cancer Screening 101

NORTH DAKOTA
COLORECTAL CANCER
ROUNDTABLE

NORTH DAKOTA COLORECTAL CANCER ROUNDTABLE

We are a coalition of organizations and individuals dedicated to increasing the use of colorectal cancer screening throughout North Dakota.

We thank the American Cancer Society global headquarters for allowing the use of much of their content to be shared in these slides and be made available for provider champions across the state of North Dakota to share with their peers.

Together, we can save lives from colorectal cancer!

Sneak Peak

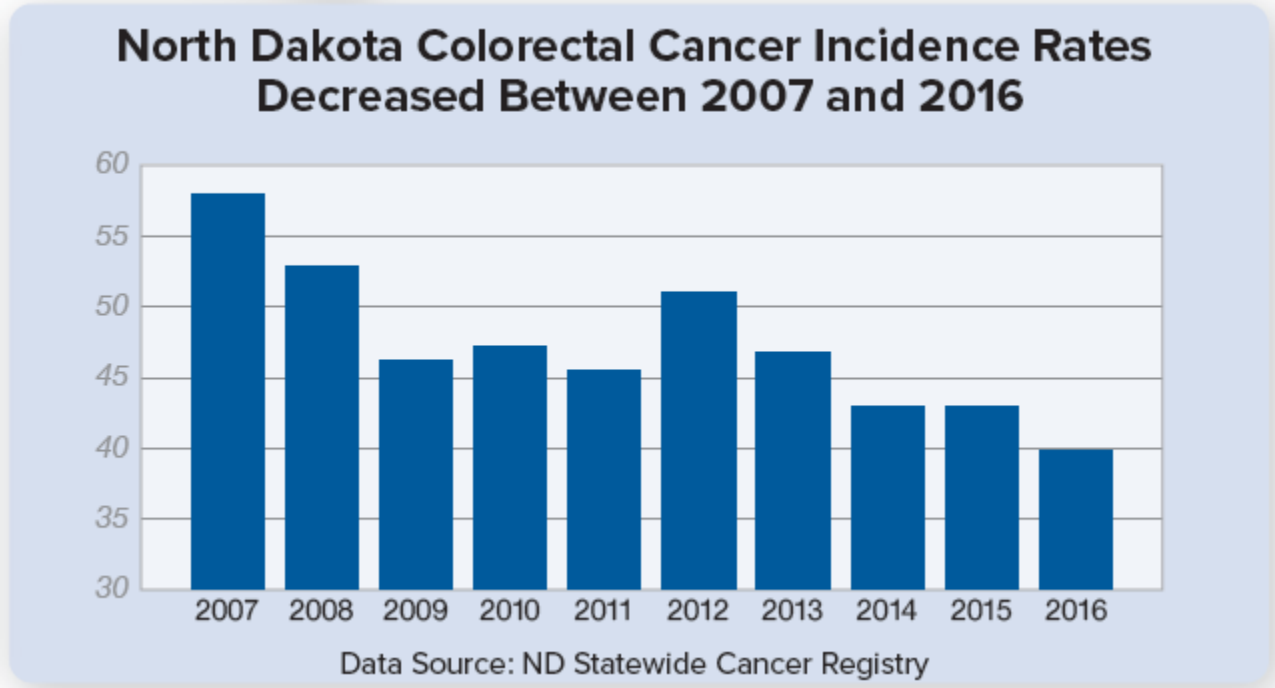
- Colorectal Cancer (CRC) Data
- CRC screening guidelines
  - ACS and USPSTF
- Risk Assessment
- Screening tests overview

Our Belief: *All people should benefit equally from life-saving CRC screening.*

Our Goal: *Achieve an 80% CRC screening rate in every community, regardless of the hurdles that must be crossed.*

Colorectal Cancer (CRC) in North Dakota

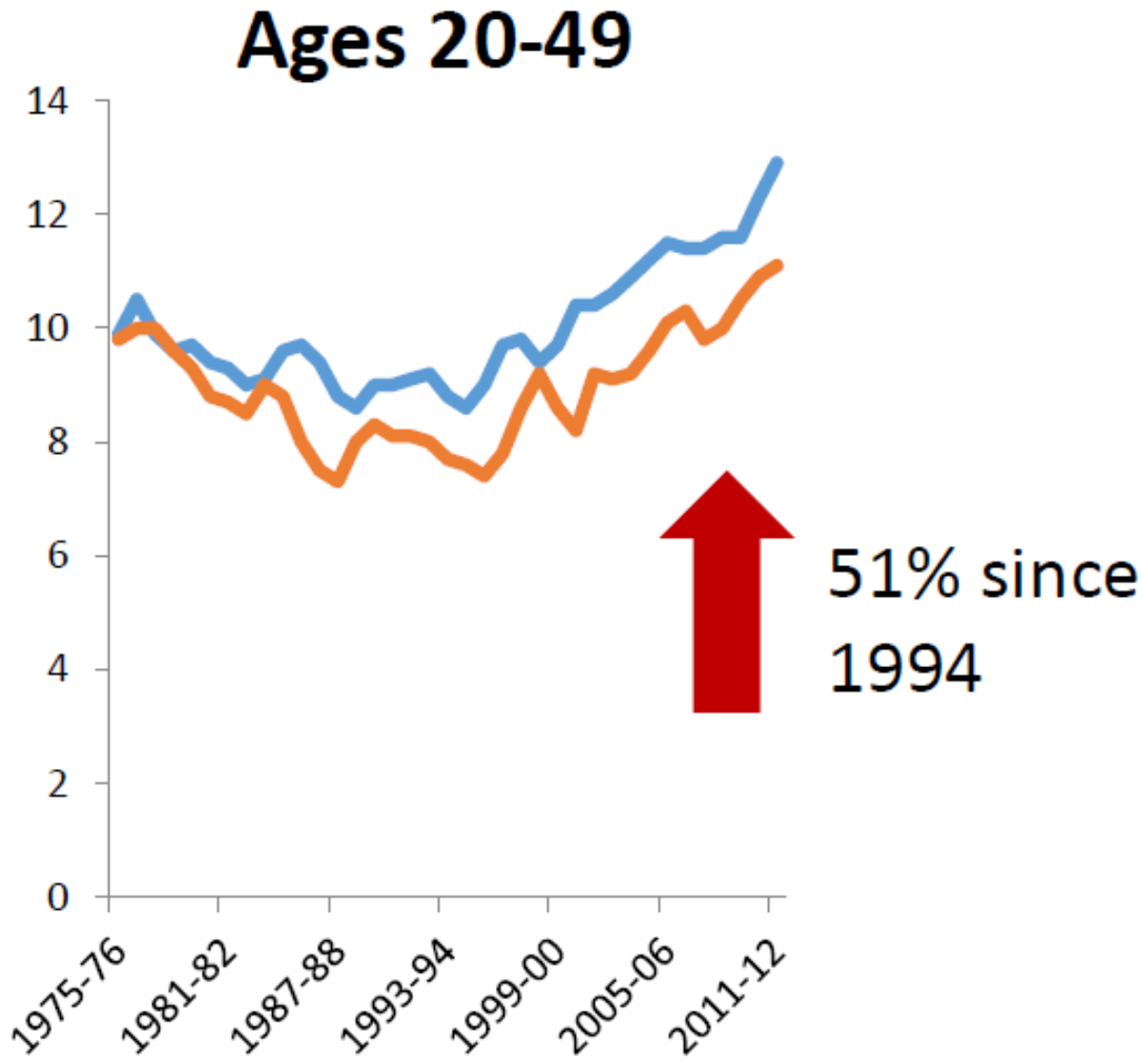
- 2nd leading cause of cancer death in the US and in ND
- Incidence rates have steadily declined over the past 20 years



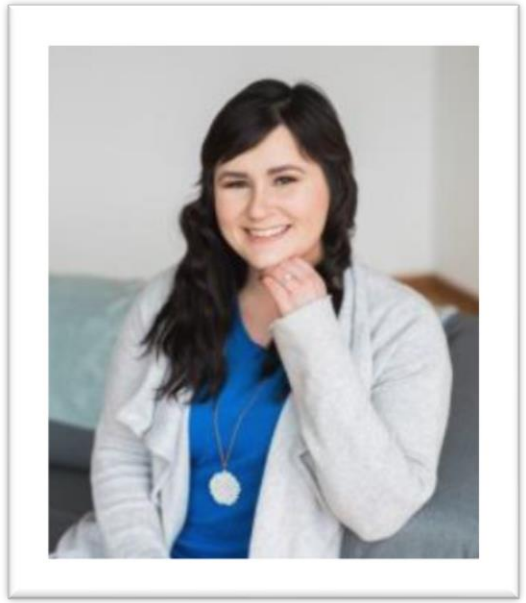
Rising CRC Incidence Among People Under 50

Colorectal Cancer is Occurring in Younger People

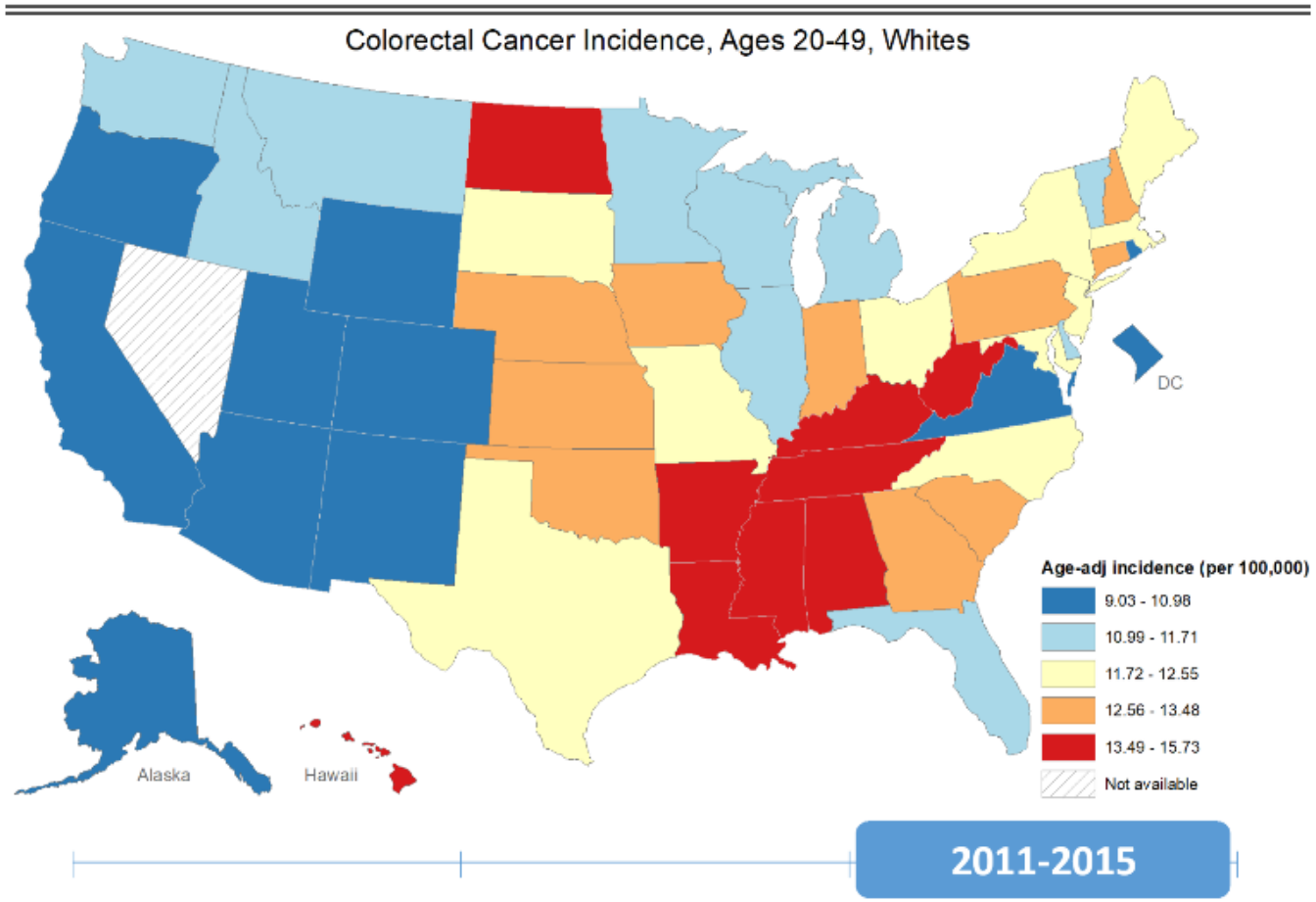
- Early-onset CRC demands a far more deliberate effort to begin screening **no later** than age 50.
- And the ACS has provided compelling data and issued a new guideline to support starting average risk screening at age 45.



Early Onset (age 20 -49) CRC



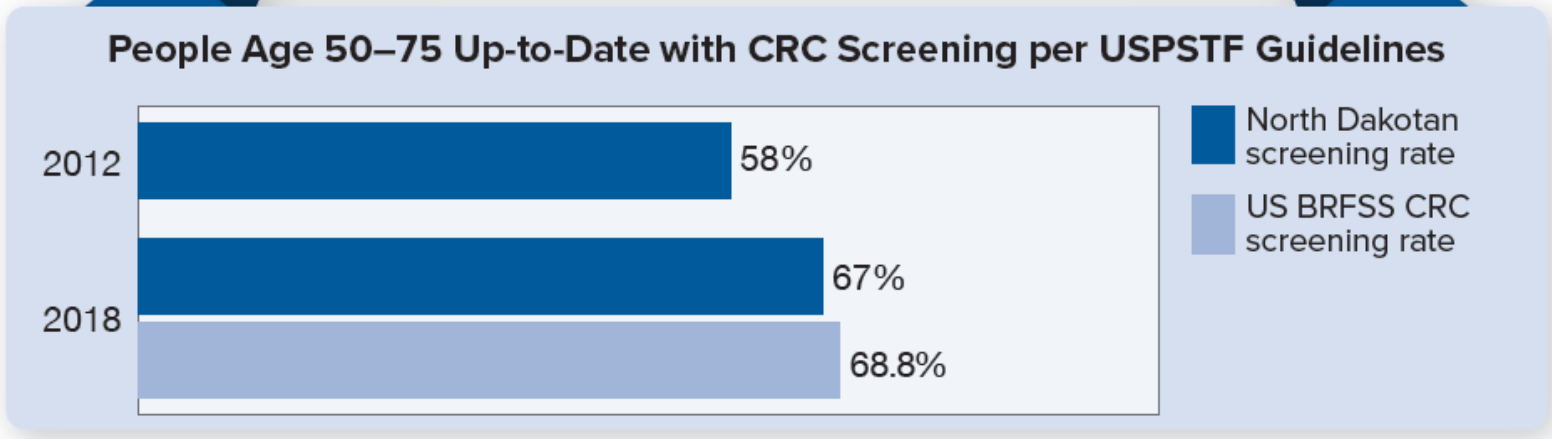
Dena (Fargo, ND) was diagnosed with colon cancer in her 20's.



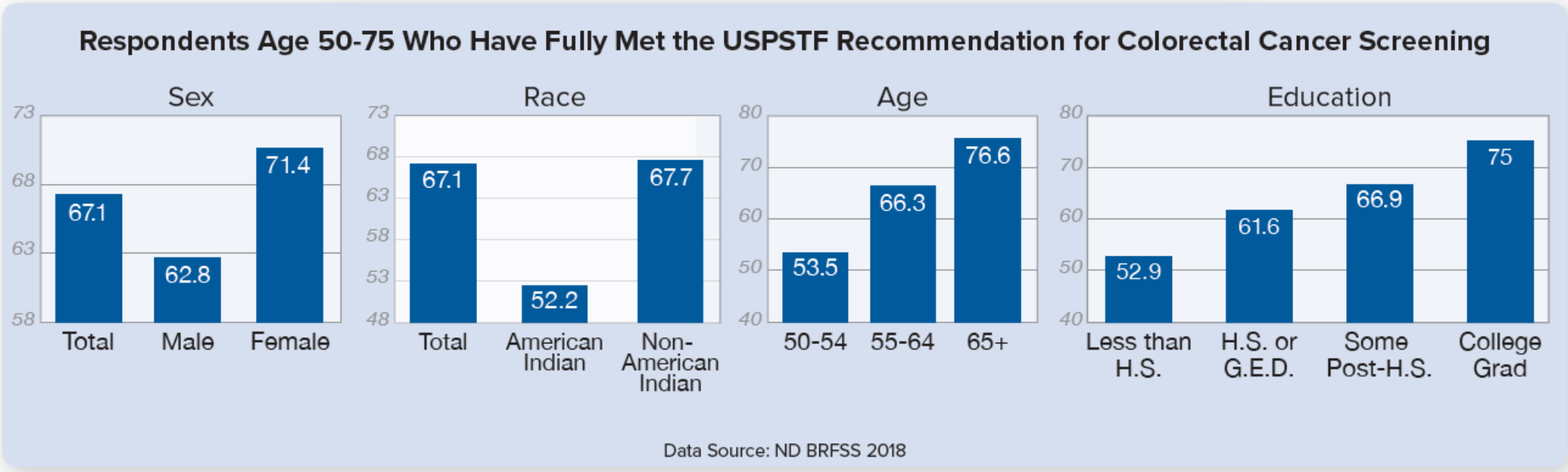
- **North Dakota is a hotspot for early onset colorectal cancers.**
- **Remember:** Screening guidelines apply to *asymptomatic* patients
- ***Symptomatic* patients (including young adults) should be referred for colonoscopy**

CRC Screening in ND

We're making progress!



Despite significant progress in ND screening rates, serious disparities still exist.



SCREENING GUIDELINES FOR AVERAGE RISK ADULTS (ACS & USPSTF)

Recommendations	ACS, 2018	USPSTF, 2016
Age to start screening S-strong Q-Qualified	Age 45y Starting at 45y (Q) Screening at aged 50y and older - (S)	Aged 50y (A)
Choice of test	High-sensitivity stool-based test or a structural exam.	Different methods can accurately detect early stage CRC and adenomatous polyps.
Acceptable Test options	• FIT annually • HSgFOBT annually • mt-sDNA every 3y • Colonoscopy every 10y • CTC every 5y • FS every 5y **All positive non-colonoscopy tests should be followed up with colonoscopy.**	• HSgFOBT annually • FIT annually • sDNA every 1 or 3y • Colonoscopy every 10y • CTC every 5y • FS every 5y • FS every 10y plus FIT every year
Age to stop screening	Continue to 75y as long as health is good and life expectancy 10+y (Q) 76-85y individual decision making (Q) >85y discouraged from screening (Q)	76-85 y individual decision making (C)

HIGH RISK INDIVIDUALS MUST BE RECOGNIZED AND ADDRESSED

Personal history

- Adenomatous Polyps
- Colorectal cancer
- Inflammatory bowel disease
  - Ulcerative colitis
  - Crohn's disease

Family history

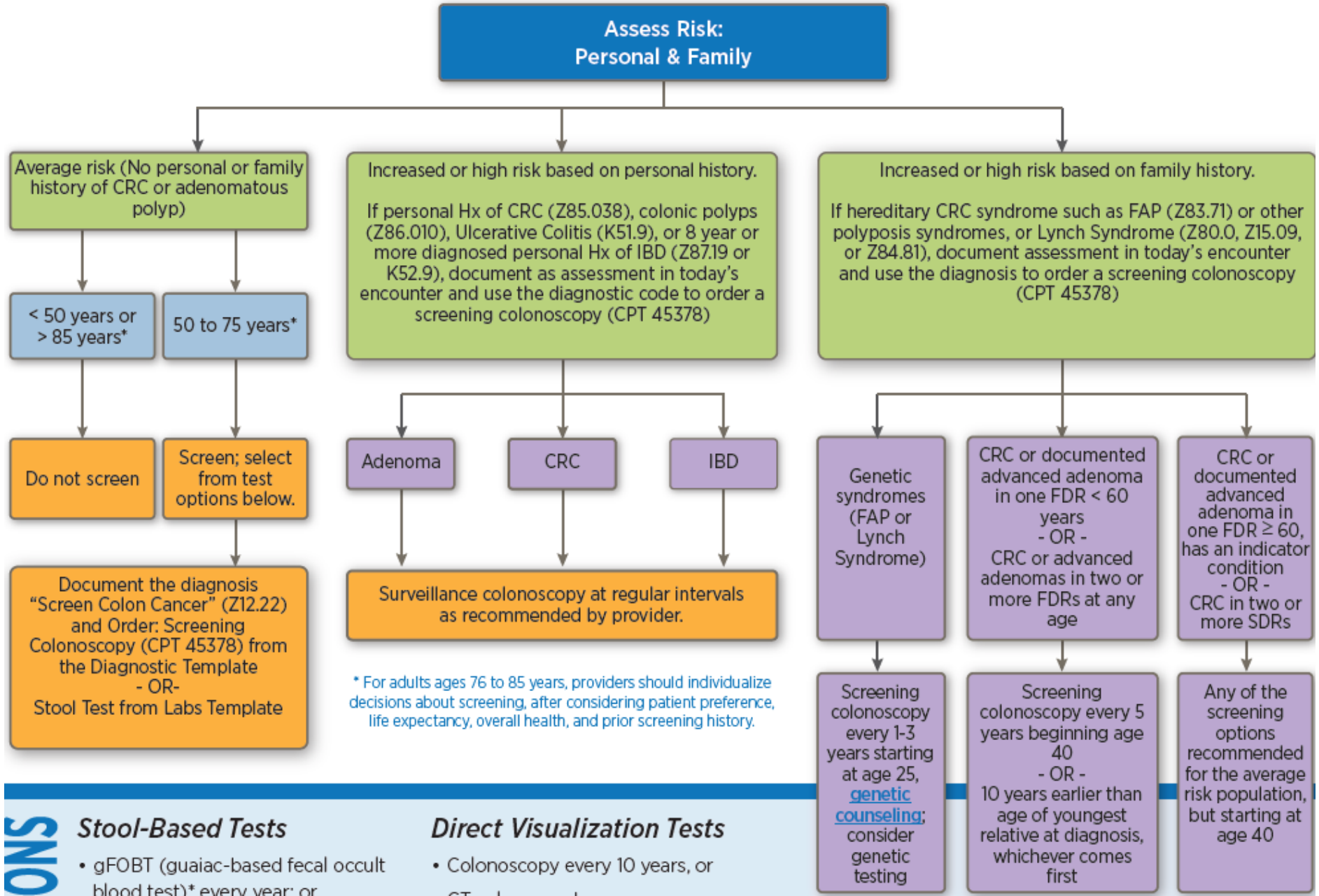
- Colorectal cancer or adenomas
- Hereditary syndrome (FAP, Lynch Syndrome)

Individuals with these conditions should:

- Begin screening earlier (10 years before age at diagnosis of index case)
- Be aware that **colonoscopy** is the only recommended screening test for most

Sample Colorectal Cancer Screening Algorithm

Per Recommendation to Start Screening at Age 50



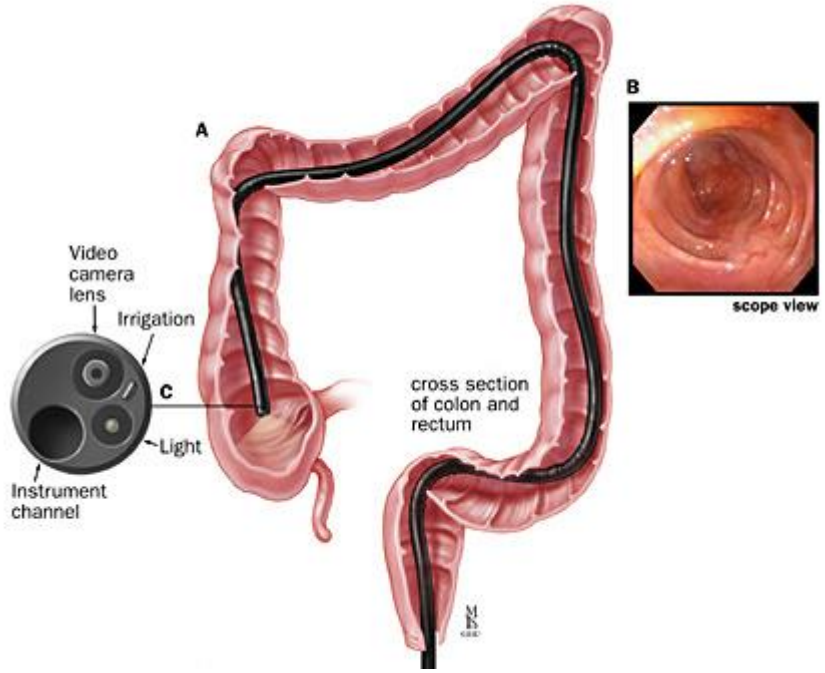
Colorectal Cancer Signs & Symptoms

- A change in bowel habits, such as diarrhea, constipation, or narrowing of the stool, that lasts for more than a few days
- A feeling of needing to have a bowel movement that's not relieved by having one
- Rectal bleeding with bright red blood
- Blood in the stool, which may make the stool look dark
- Cramping or abdominal pain
- Weakness and fatigue
- Unintended weight loss

https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/signs-and-symptoms.html

Colonoscopy

- Allows direct visualization of entire colon lumen
- Screening, diagnostic and therapeutic
- 10 yr interval
- The most common screening test in US and ND



Colonoscopy is a great screening test, but:

- Many patients face barriers or are not willing
  - Requires bowel prep, time off work, caregiver to drive
- More costly, wide variation in quality, invasive
- Practices solely focused on colonoscopy associated with low screening rates

TYPES OF STOOL TESTS

Tests that detect blood (Fecal Occult Blood Tests)

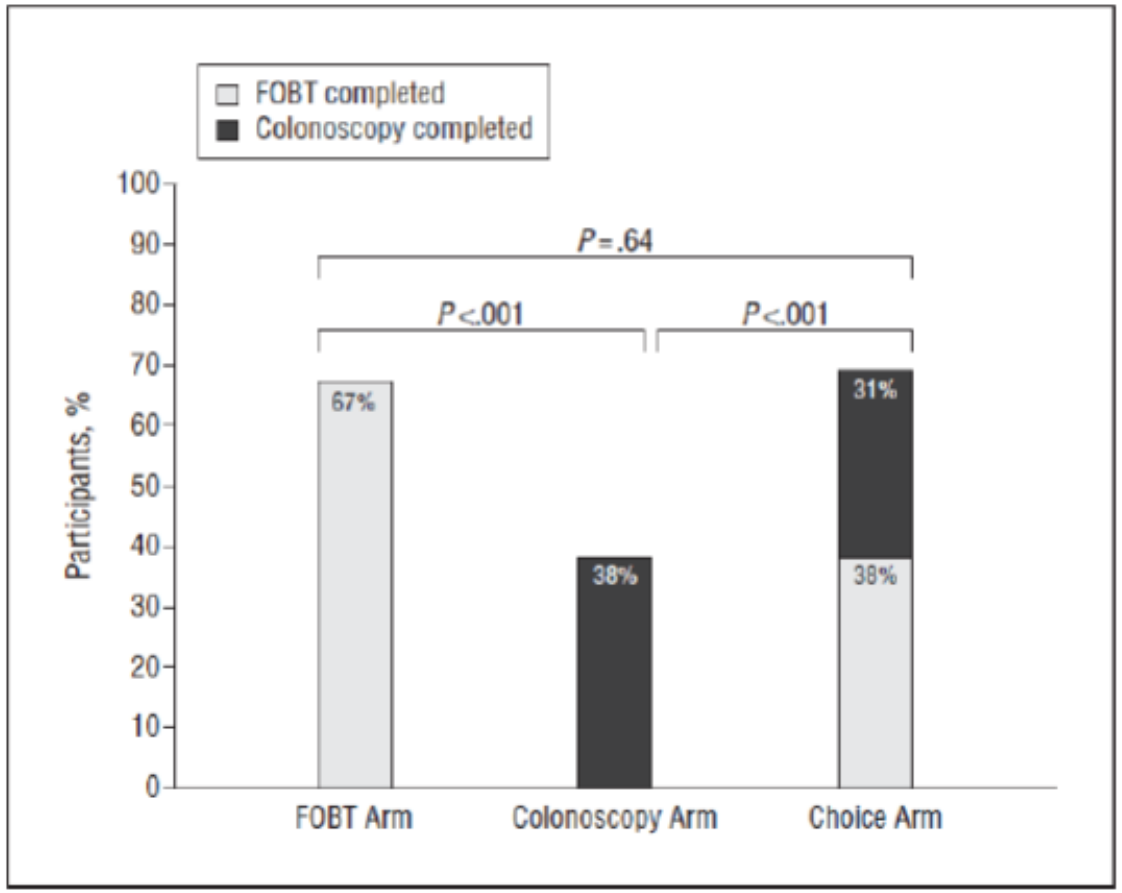
- Two types (but multiple brands, variable performance)
  - Guaiac-based FOBT
  - Fecal Immunochemical Tests (FIT)

Tests that detect aberrant DNA

- One test (Cologuard) available in US
  - Combined DNA mutation test with FIT
  - Referred to as “mt-sDNA” or “FIT-DNA”

> Remember: Stool tests are only appropriate for **average risk** patients

PATIENT PREFERENCES



Inadomi, Arch Intern Med 2012

- Patients who are presented with screening options are more likely complete some form of screening.

GUAIAC FECAL OCCULT BLOOD TESTS

- Historically was most common FOBT in US
- Solid evidence (3 RCTs)
- Requires specimens from three bowel movements
- Non-specific
- Results influenced by foods and medications
- Only high-sensitivity guaiac FOBT (Hemoccult II Sensa) is appropriate for screening
- Older forms (Hemoccult II) are **not recommended by ACS, USPSTF**

FECAL IMMUNOCHEMICAL TESTS (FIT)

- Detect blood by immunoassay
  - An antibody specifically recognizes the globin component of human hemoglobin
- High specificity for **human blood** and for **lower GI bleeding**
- No reported interference by foods or medications
- Most brands require only one or two stool specimens
- Higher sensitivity than guaiac FOBT
  - Cancer sensitivity ~70% with high quality FIT

Patient Navigation is crucial

For take-home stool tests:

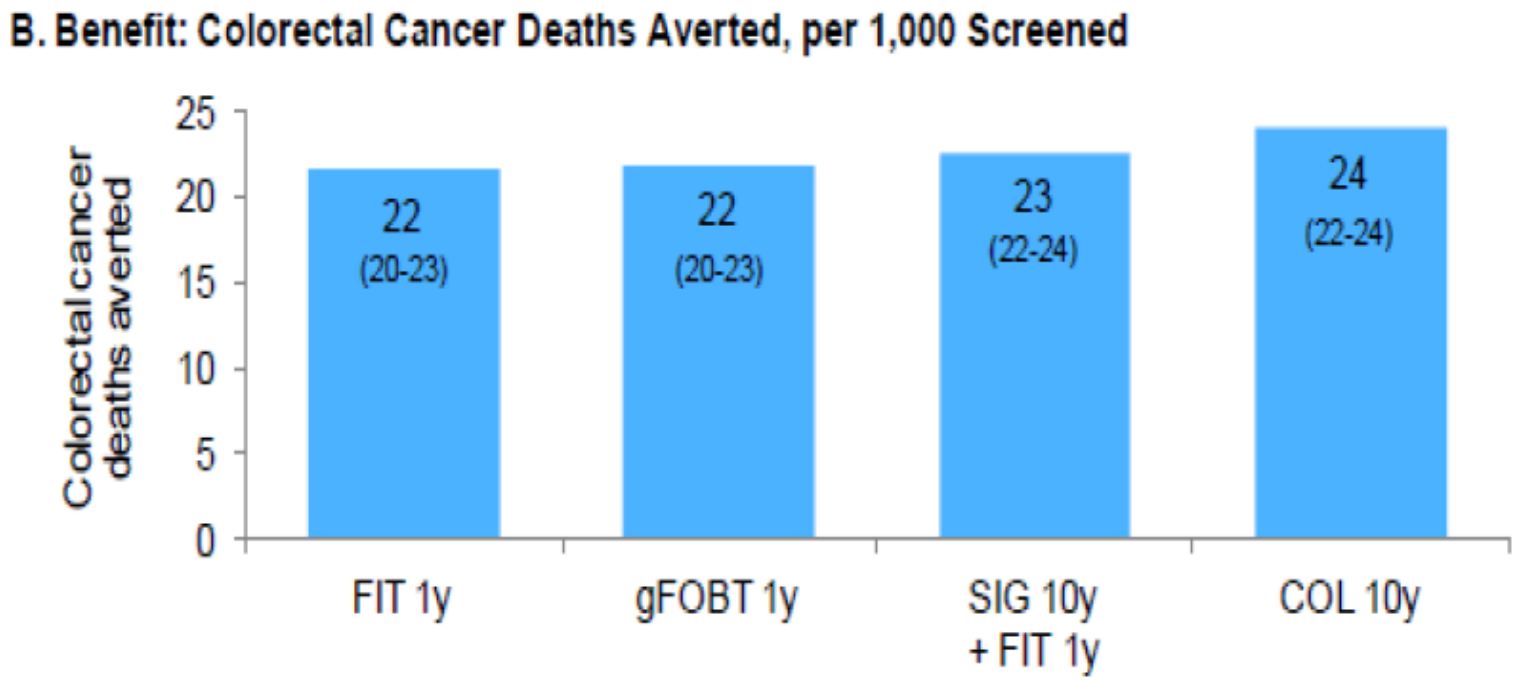
- ✓Ensure patient receives instructions in their own language and at the appropriate literacy level; consider using demos or pictures to enhance comprehension
- ✓Consider offering return postage and a “due by” date
- ✓For patients who have not returned their kits, follow up with a reminder (i.e., phone call, mail, electronic)
- ✓Track returns and results, and refer patients with a positive result to colonoscopy

For colonoscopy:

- ✓Assess possible barriers such as transportation to and from colonoscopy, availability of support person/driver after procedure, cost barriers, time off from work and connect to appropriate resources
- ✓Ensure patient understands the colonoscopy prep process and receives instructions in their own language and at the appropriate literacy level; consider using pictures to enhance comprehension
- ✓Track colonoscopy results and referrals for treatment
- ✓Remove barriers and reschedule colonoscopy if patient did not complete

FOBT/FIT EFFICACY (USPSTF 2015)

- Modeling studies suggest years of life saved through a high-quality stood-based screening program are similar to outcomes with a high-quality colonoscopy screening program



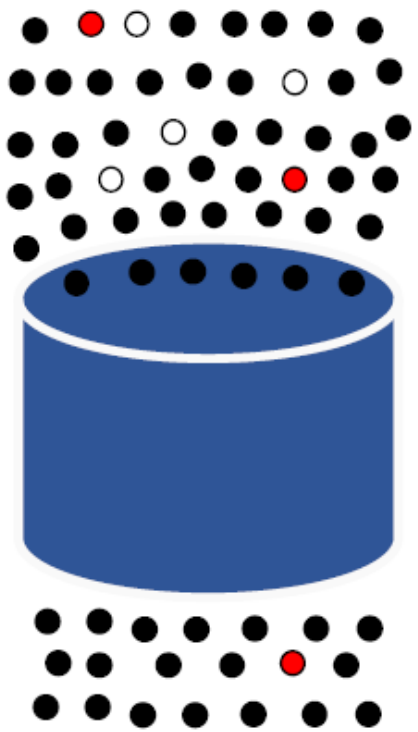
USPSTF, JAMA 2016

ADVANTAGES OF STOOL TESTS

- Far less expensive than colonoscopy
  - Medicare reimbursement $20 - $25 per test
- 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 (refer 1,000 patients)

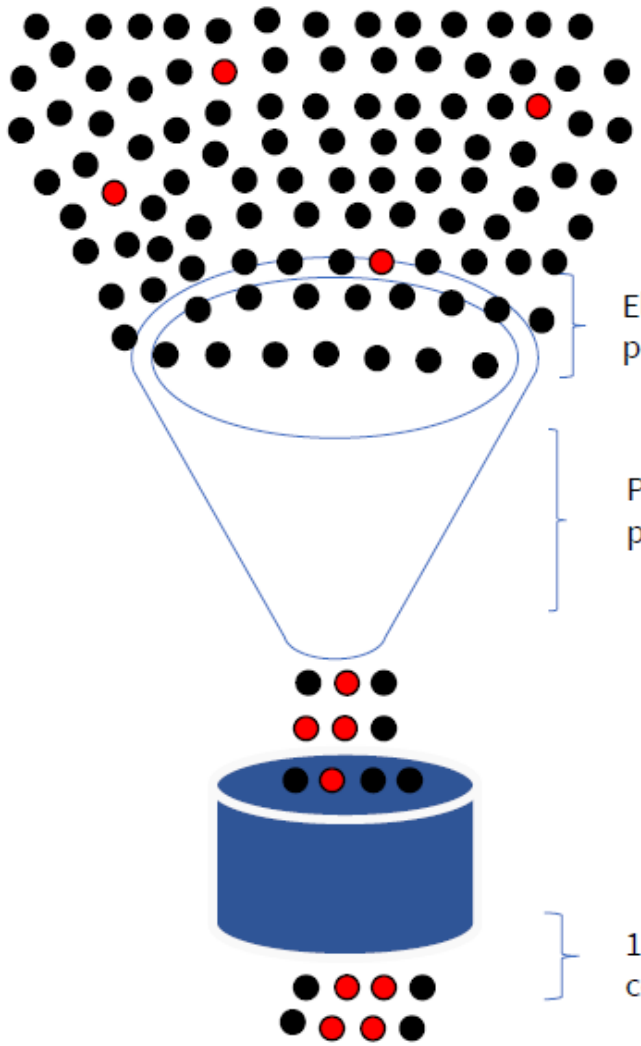


Eligible population, referred

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

- All positive tests must be followed up with colonoscopy
  - Follow up often lacking
    - No documented follow up for **1 in 3** positives in many settings
    - Failure to follow up positive tests in a timely manner is associated with increased risk of future CRC diagnosis and advanced stage disease
  - There is **no value** in repeating a positive stool test!
- Patients should be informed that:
  - A positive stool test requires colonoscopy follow up, and
  - This colonoscopy may be treated as diagnostic → cost sharing

DIGITAL RECTAL EXAM SPECIMENS MISSED 19 OF 21 CANCERS

- DRE is essentially worthless as a screening tool and **should never be used**
- Missed **19 of 21** cancers found at colonoscopy in largest study (DRE with guaiac FOBT)
- No studies showing efficacy of DRE sampling for FIT

“Poop On Demand” (POD)

In-office specimen collection that complies with guidelines:

- Health centers are collecting stool specimens during an office visit by asking patients if they can defecate before leaving the clinic (as opposed to later at home).
- This has earned the label “Poop On Demand” (POD).
  - One-on-one patient education
  - A bathroom designated for POD; includes detailed instructions for proper specimen collection.
- Allows collecting a specimen for FIT analysis from a spontaneously passed stool during an office visit.
- MUST use a “single sample” FIT – an FIT demonstrated to have high sensitivity when analyzing a single stool sample.

ALL FIT ARE NOT CREATED EQUAL

- FDA clears guaiac FOBTs and FITs only for “detection of blood” – no assessment of cancer or adenoma detection capability is required
- Recent study found 60+ FITs cleared for use in US and 26 currently marketed
- Only 6 of these FDA-cleared FITs have published data on their performance for detection of CRC or adenoma
- Some of the tests marketed as “single sample” tests have no performance data on this use

STOOL TEST QUALITY REFERENCE

- Implementation factors required to achieve high quality in practices
- Brand-specific information on published cancer detection performance

FIT BRAND NAME	MANUFACTURER	SENSITIVITY FOR CANCER*,‡	SPECIFICITY FOR CANCER*,‡	NUMBER OF STOOL SAMPLES
Automated (non-CLIA waived) FITs				
OC Auto-FIT*	Polymedco	65%-92.3%[3,4]	87.2%-95.5%[3,4]	1
CLIA-waived FITs				
OC-Light iFOB Test (also called OC Light S FIT)	Polymedco	78.6%-97.0%[3,4]	88.0%-92.8%[3,4]	1
QuickVue iFOB	Quidel	91.9%[3]	74.9%[3]	1
Hemosure One-Step iFOB Test	Hemosure, Inc.	54.5%[3]	90.5%[3]	1 or 2
InSure FIT	Clinical Genomics	75.0%[6]	96.6%[6]	2
Hemoccult-ICT	Beckman Coulter	23.2%-81.8%[3]	95.8%-96.9%[3]	2 or 3

*Used with OC-Sensor DIANA and OC-Auto Micro 80 automated analyzers.

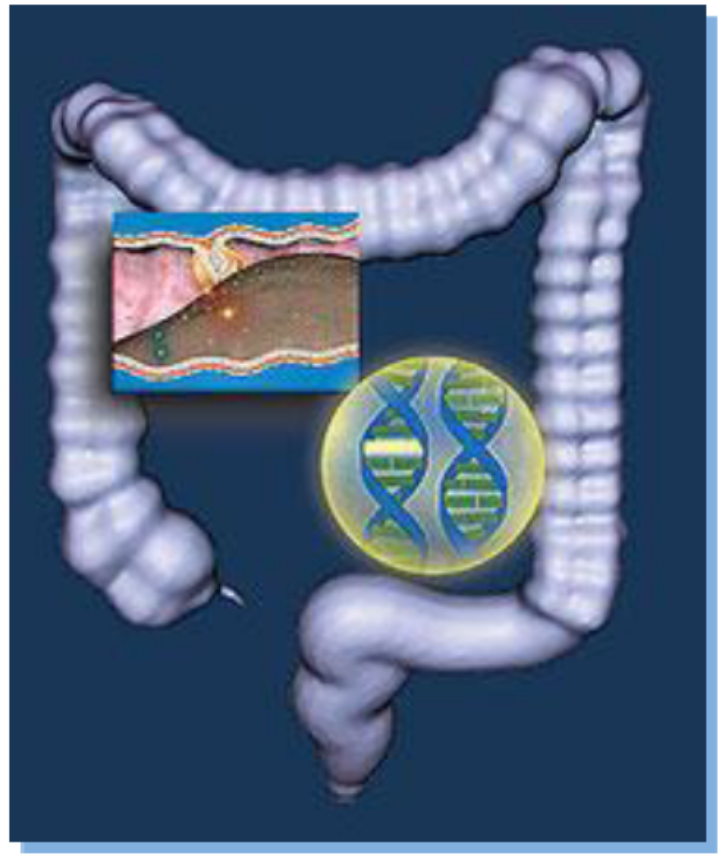
†Detection limits for cancer vary across FIT brand and by study such that direct comparison between FIT brands is not possible.

‡Cited studies should be interpreted in the full context of the published literature given variation in study size and quality.

http://nccrt.org/resource/fobt-clinicians-reference-resource

STOOL DNA TEST (sDNA)

- Guaiac tests and FIT detect blood in the stool; bleeding 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 require follow-up colonoscopy

Cologuard/mt-sDNA TEST

- Only one test (Cologuard) currently available
- Combines tests for stool DNA markers associated with cancer and adenomas **plus** a high quality FIT
- Referred to as a “multi-target stool DNA test” (“mt-sDNA”)

- 3 year screening interval
- All positives require colonoscopy
- Company mails test directly to patients and does reminder calls (60-65% completion rate)
- More costly than FIT

Research-Tested Messaging

The Most Preferred Screening Message

#1 MOST PREFERRED

A colonoscopy isn't the only option for colorectal cancer screening. There are simple, affordable options, including tests that can be done at home. Talk to your doctor about which option is right for you. Ask which tests are covered by your health insurance.

The Second-Most Preferred Screening Message

#2 MOST PREFERRED

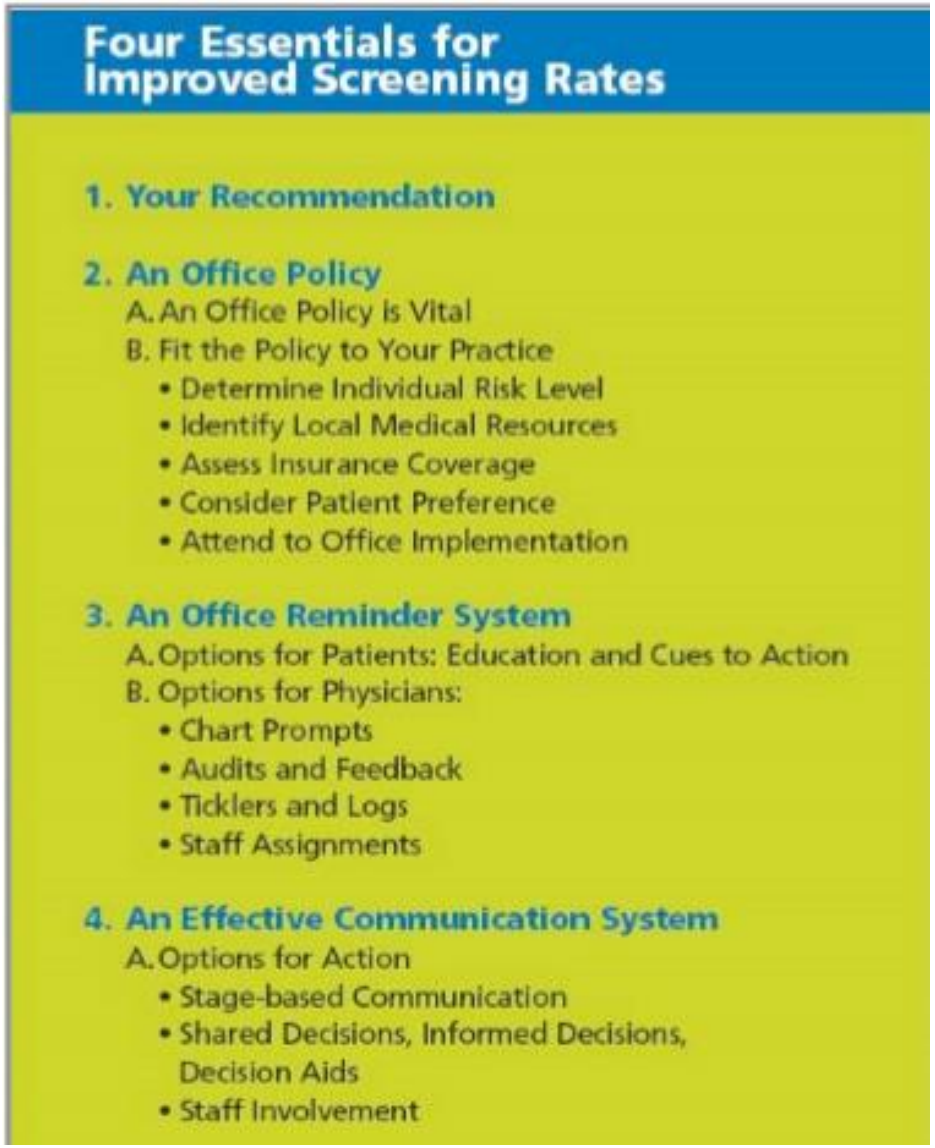
Right now, you could have a polyp, a small growth in your colon or rectum. Right now, your polyp may be harmless, but over time it could develop into colorectal cancer. Right now, through regular screening, you have the power to find and remove precancerous polyps and prevent colorectal cancer. Call your doctor and take control of your health!

The Third-Most Preferred Screening Message

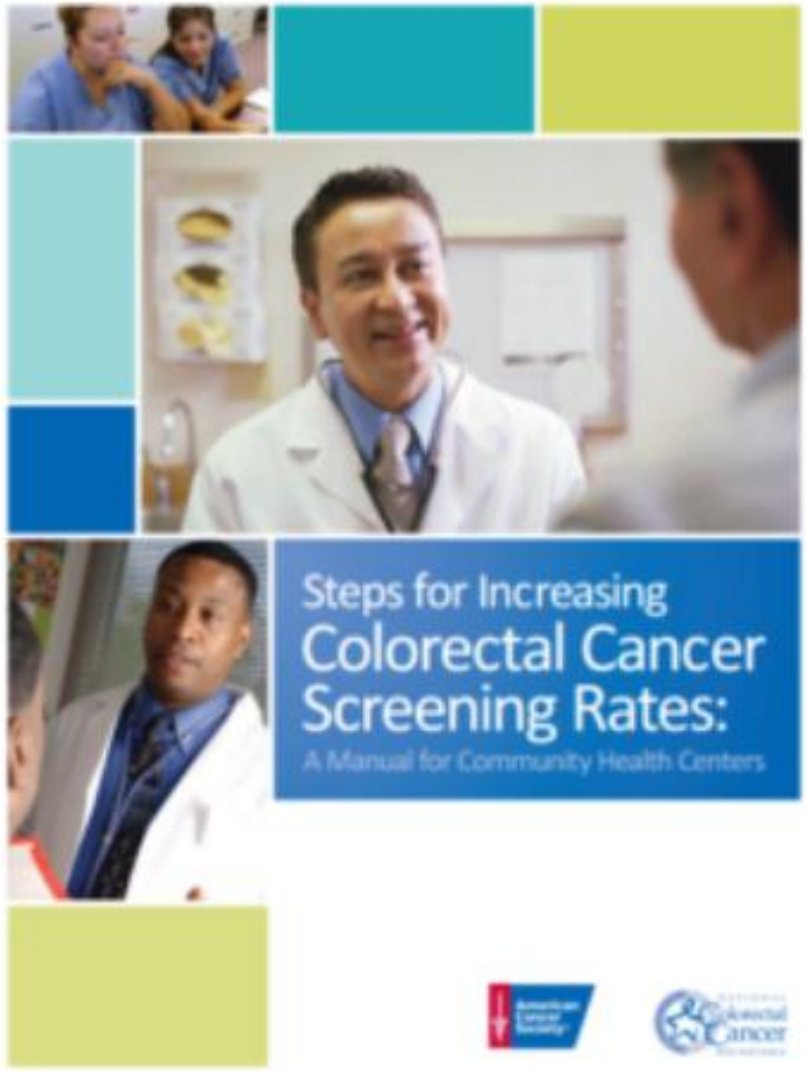
#3 MOST PREFERRED

Preventing colorectal cancer or finding it early is possible through regular screening. There are many test options, including simple, affordable tests. Talk to your doctor about the right option for you and about whether your health insurance covers tests.

The 4 Essentials for Improved Screening Rates



Learn More:



- **ND Clinician FAQ Documents:**
  - Answering Patient Questions
  - Answering Common Clinician Questions
- Steps for Increasing CRC Screening Rates
- Clinician's Reference: Stool-Based Tests
- Research-tested Messaging to Reach the Unscreened
- www.NCCRT.org
- North Dakota Colorectal Cancer Roundtable