Housekeeping

- Welcome to the **Colorectal Cancer Screening Webinar Series!**
- If you are having trouble hearing audio through your computer, please dial in using the audio conference information sent in your registration email.
- A Question and Answer period will take place at the end. Feel free to enter your questions via the chat box

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New York State Cancer Consortium

Colorectal Cancer Screening Webinar Series

New York State Colorectal Cancer Screening Partnership

Michael Seserman, MPH
Manager, State Health Systems
American Cancer Society

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New York State Cancer Consortium

Colorectal Cancer Screening:

The Best Test is the One That Gets Done

Heather Dacus, DO, MPH
Director, Bureau of Cancer Prevention and Control
New York State Department of Health

Durado Brooks, MD, MPH
Vice President, Cancer Control Interventions
American Cancer Society

- **Almost 10,000 men and women in NYS are diagnosed with colorectal cancer each year.**
- **Over 3,200 men and women die of colorectal cancer every year in NYS.**

NYS Cancer Registry, 2011-2015

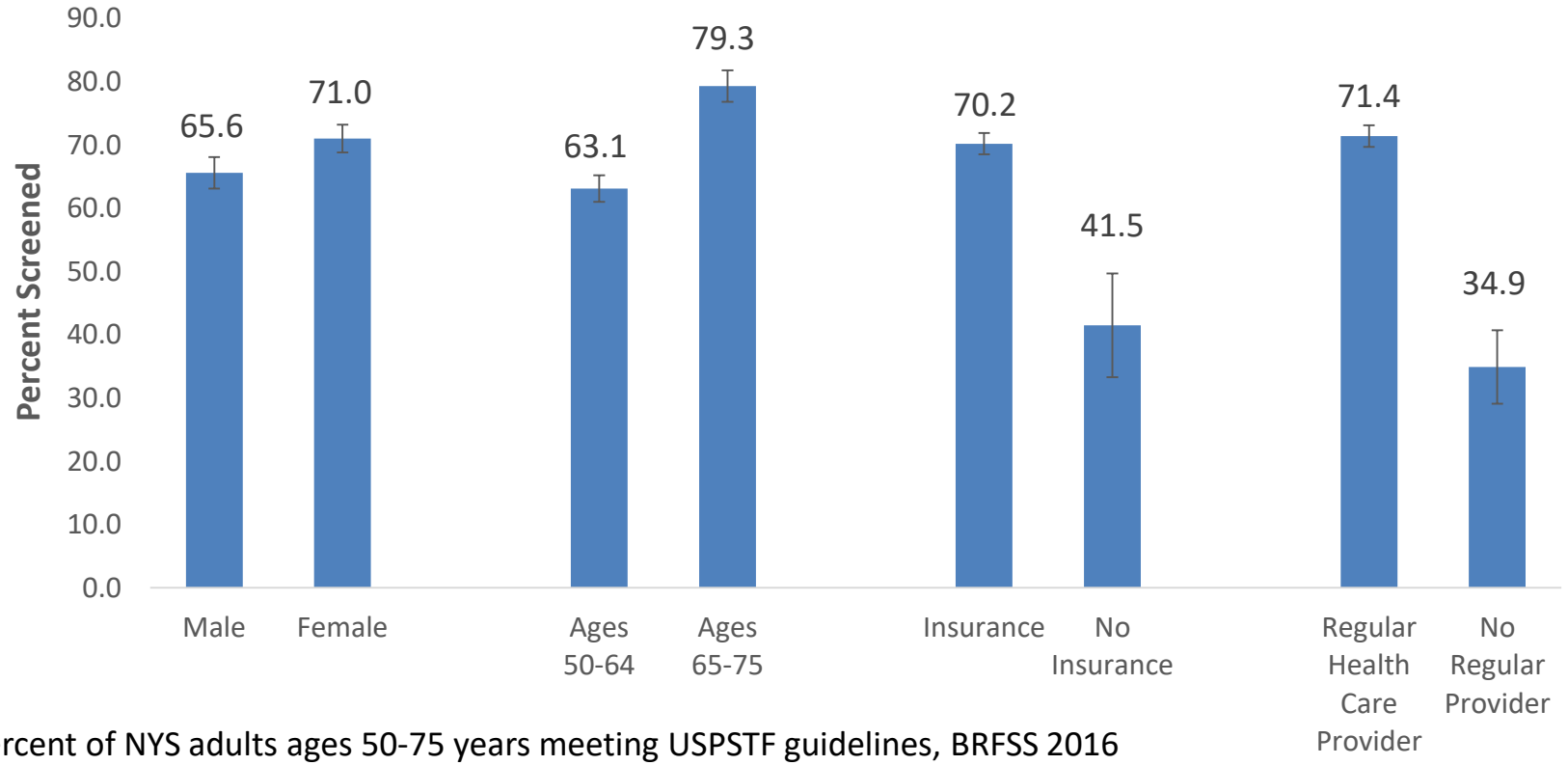
What Contributes to Higher Rates of Death Due to Colorectal Cancer?

Article in Press

Modifiable Failures in the Colorectal Cancer Screening Process and Their Association with Risk of Death

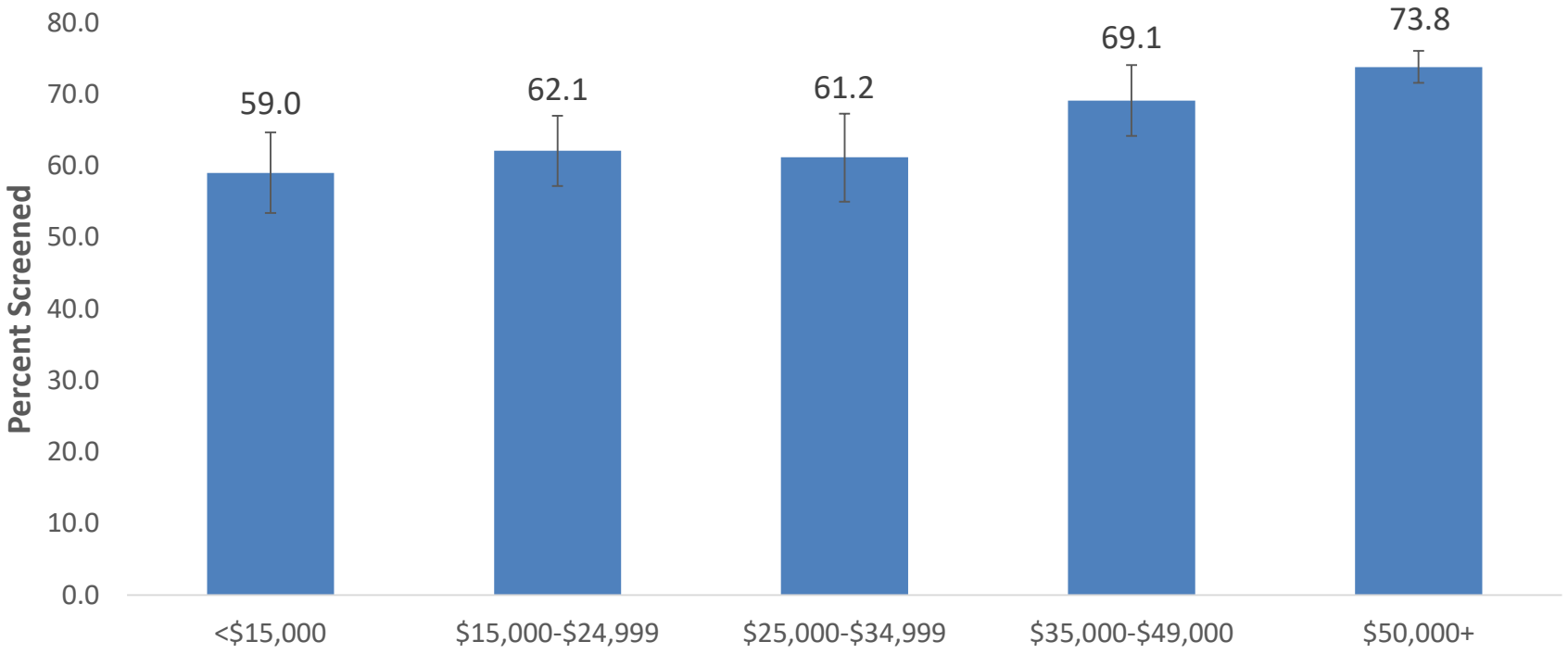
Failure to screen at all, **failure to screen at appropriate intervals** and **not following up on abnormal screening findings** all contribute to higher rates of death due to colorectal cancer

CRC Screening by Demographic Group*



*Percent of NYS adults ages 50-75 years meeting USPSTF guidelines, BRFSS 2016

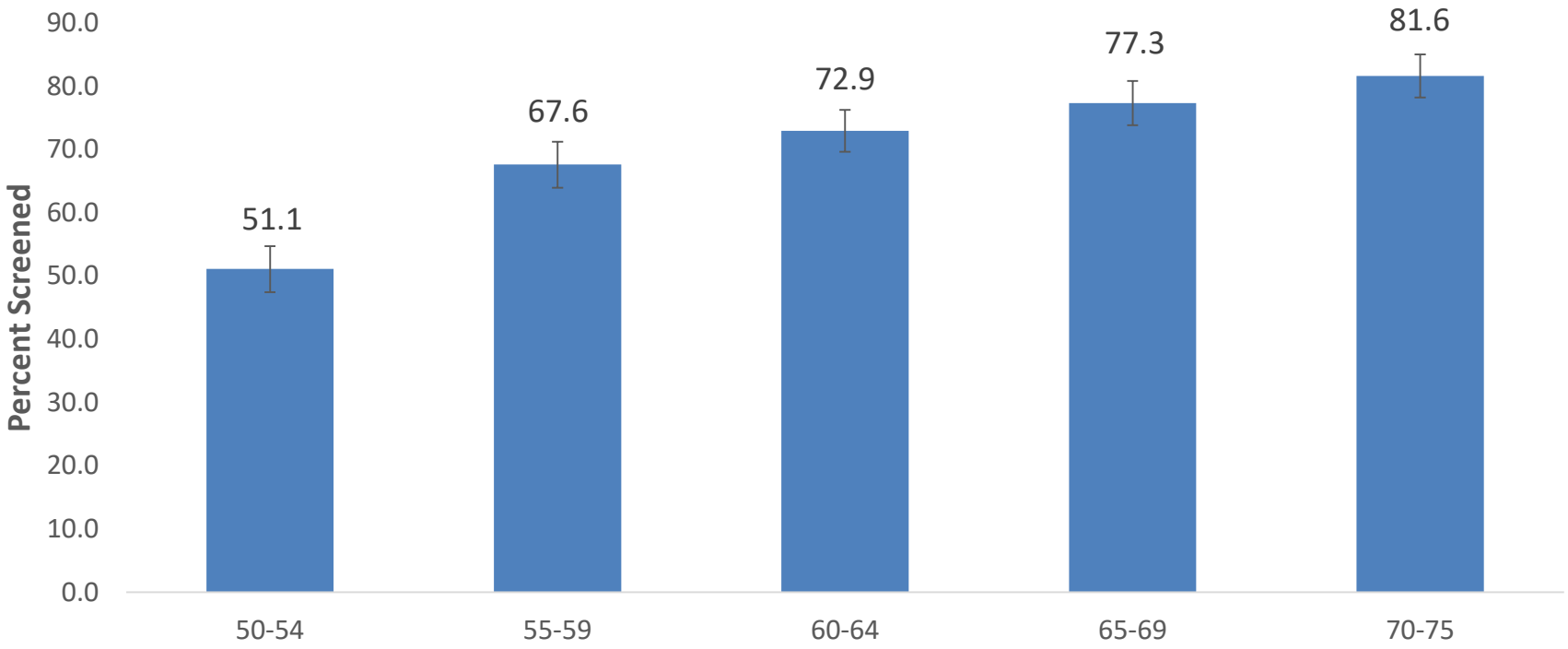
CRC Screening by Household Income*



*Percent of NYS adults ages 50-75 years meeting USPSTF guidelines, BRFSS 2016

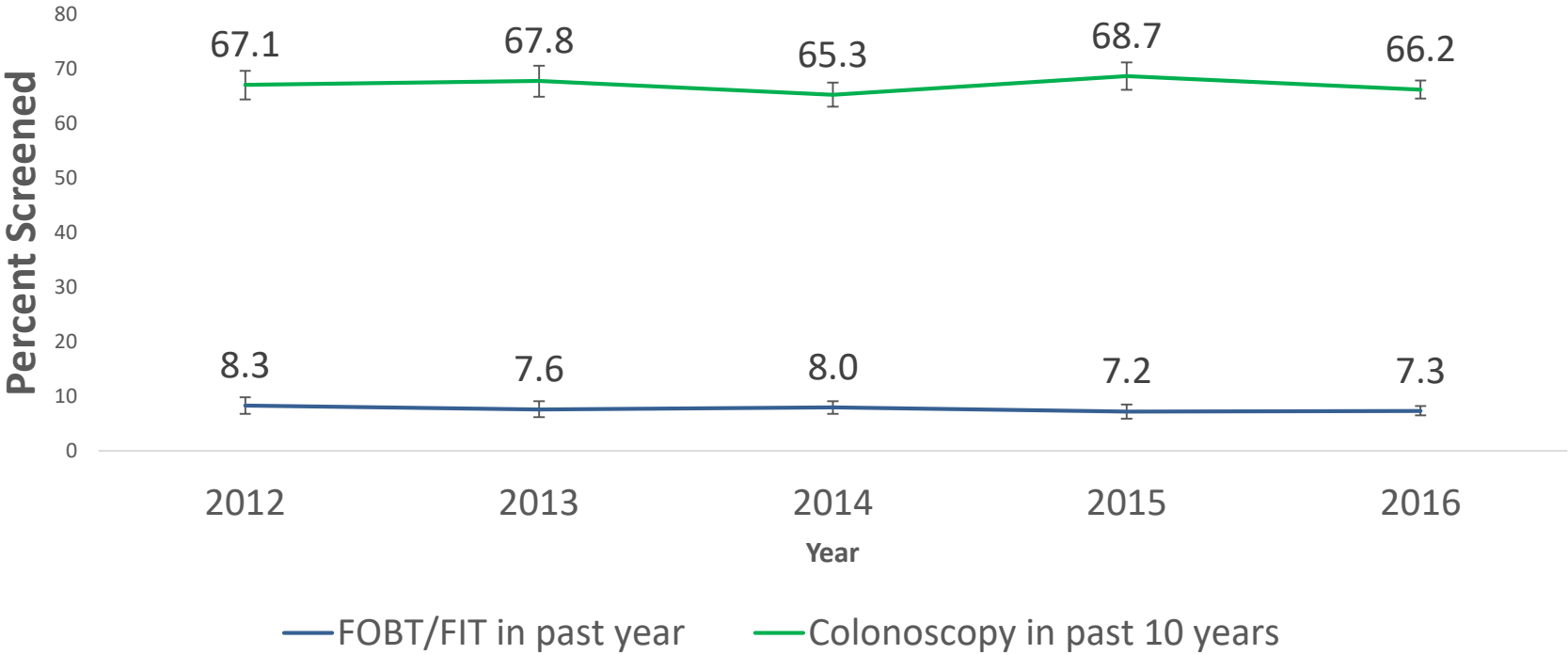
NEW YORK STATE OF OPPORTUNITY. Department of Health

CRC Screening by Age*

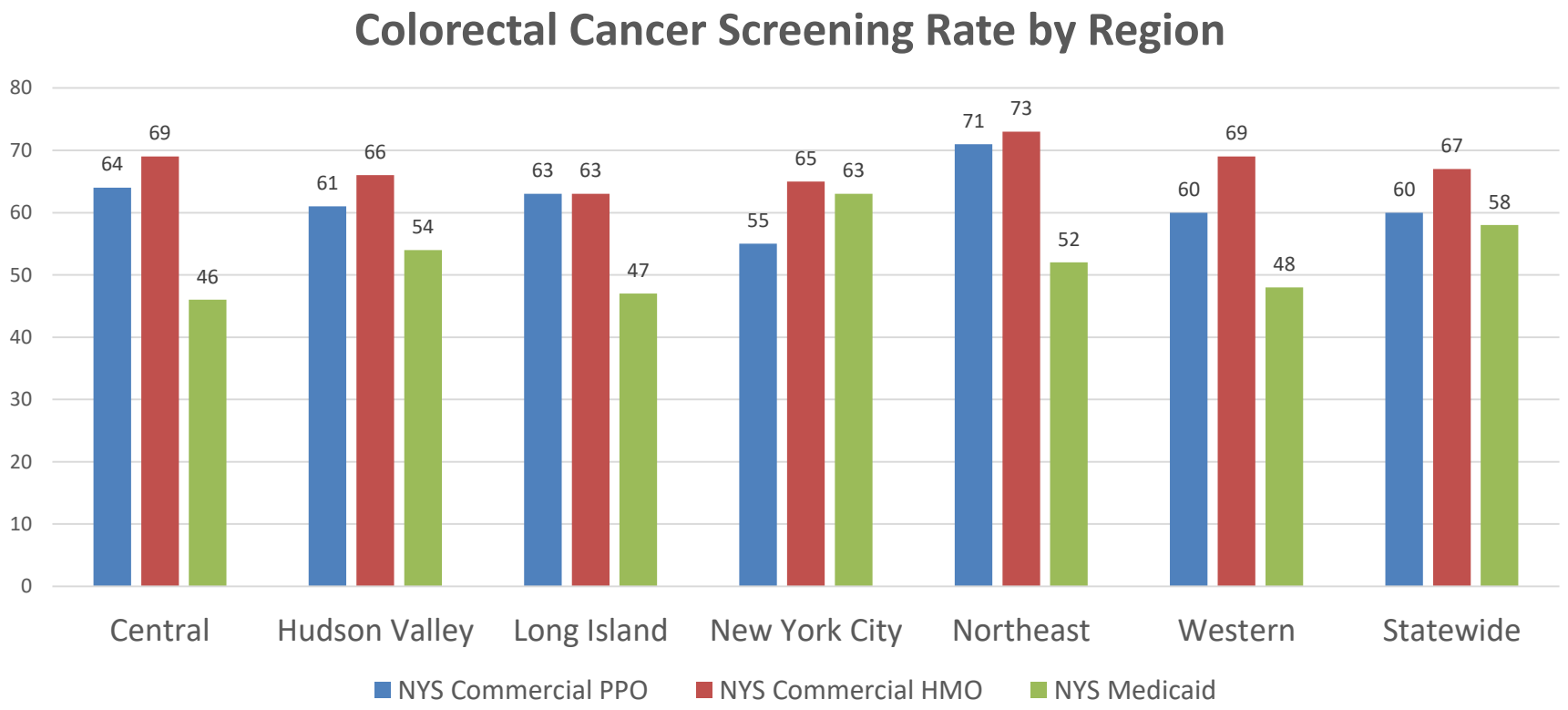


*Percent of NYS adults ages 50-75 years meeting USPSTF guidelines, BRFSS 2016

NYS Trends by Test Type



CRC Screening in NYS Health Plans: HEDIS/NYS QARR 2017



NEW YORK STATE OF OPPORTUNITY. Department of Health

New York's FQHCs

65 federal grantees

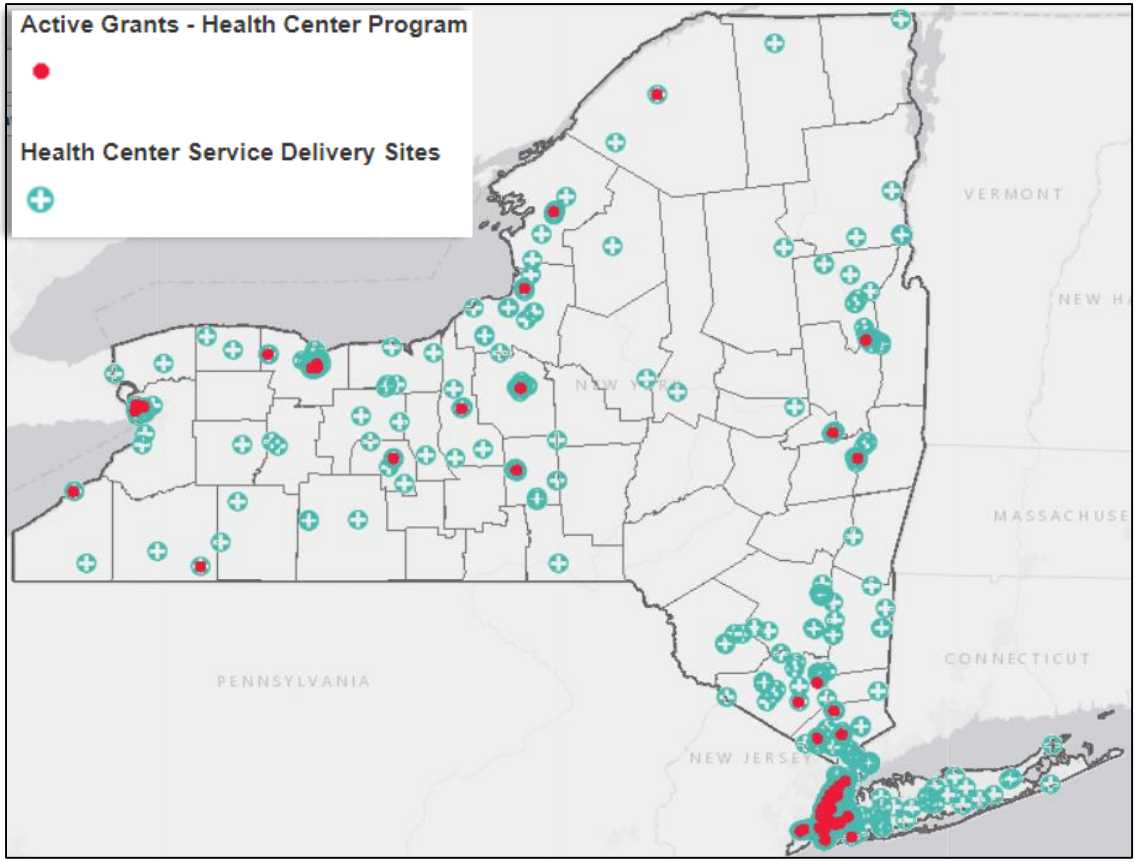
689 service delivery sites in **51** counties throughout NYS

EHR 98%

PCMH 91%

NATIONAL QUALITY LEADER 4.60%

HEALTH CENTER QUALITY LEADER 40.00%



Health Center Service Delivery Site Grantee data as reported in the Uniform Data System calendar year 2017 reporting cycle.

NEW YORK STATE OF OPPORTUNITY. Department of Health

In 2017, NY's FQHC Aggregate CRC Screening Rate Reached Over 46%

- Twenty-three FQHCs above state average
- NYS FQHC screening rates ranged between 2-68%

Source: HRSA, 2017 Health Center Program Grantee Data

NEW YORK STATE OF OPPORTUNITY. Department of Health

All Partners in NYS are Making Progress, But Continued Efforts Are Needed.

- Opportunities for improvement:
  - Across those aged 50-64
  - Across the remaining uninsured
  - Across all health plan products, including Medicaid
  - By test type

Overview of Today's Webinar

Improve Care and Increase Patient Compliance

There are several different recommended stool-based colorectal screening tests available for use with average risk patients (i.e. High Sensitivity FOBT, Fecal Immunochemical Test (FIT), FIT-DNA (Stool DNA Test). Learn about the pros and cons of each to determine the best test to use. Considering stool-based options and patient preference have been shown to increase the number of patients who get screened.

NEW YORK STATE OF OPPORTUNITY. Department of Health

Welcome Dr. Durado Brooks!

Stool Testing for Colorectal Cancer: Efficacy, Quality and Outcomes

New York State Department of Health

November 13, 2018

Durado Brooks, MD, MPH
Vice-President, Cancer Control Intervention

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New Resource

Clinicians Information on Modern Stool Tests

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

Objectives

- Review current evidence on role of stool-based tests in colorectal cancer (CRC) screening, and potential impact on outcomes
- Describe concerns related to performance and utilization of a variety of stool tests cleared for marketing in the US

CRC Screening Guidelines for Avg Risk Adults: ACS (2018); USPSTF (2016)

Recommendations	ACS, 2018	USPSTF, 2016
Age to start screening **S-strong Q-Qualified**	**Starting at age 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 annully • sDNA every 1 or 3 y • 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)

Increased Risk for CRC

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

People with these conditions:

- *Usually need to begin screening before age 50*
- *Are not candidates for stool testing (in most cases)*

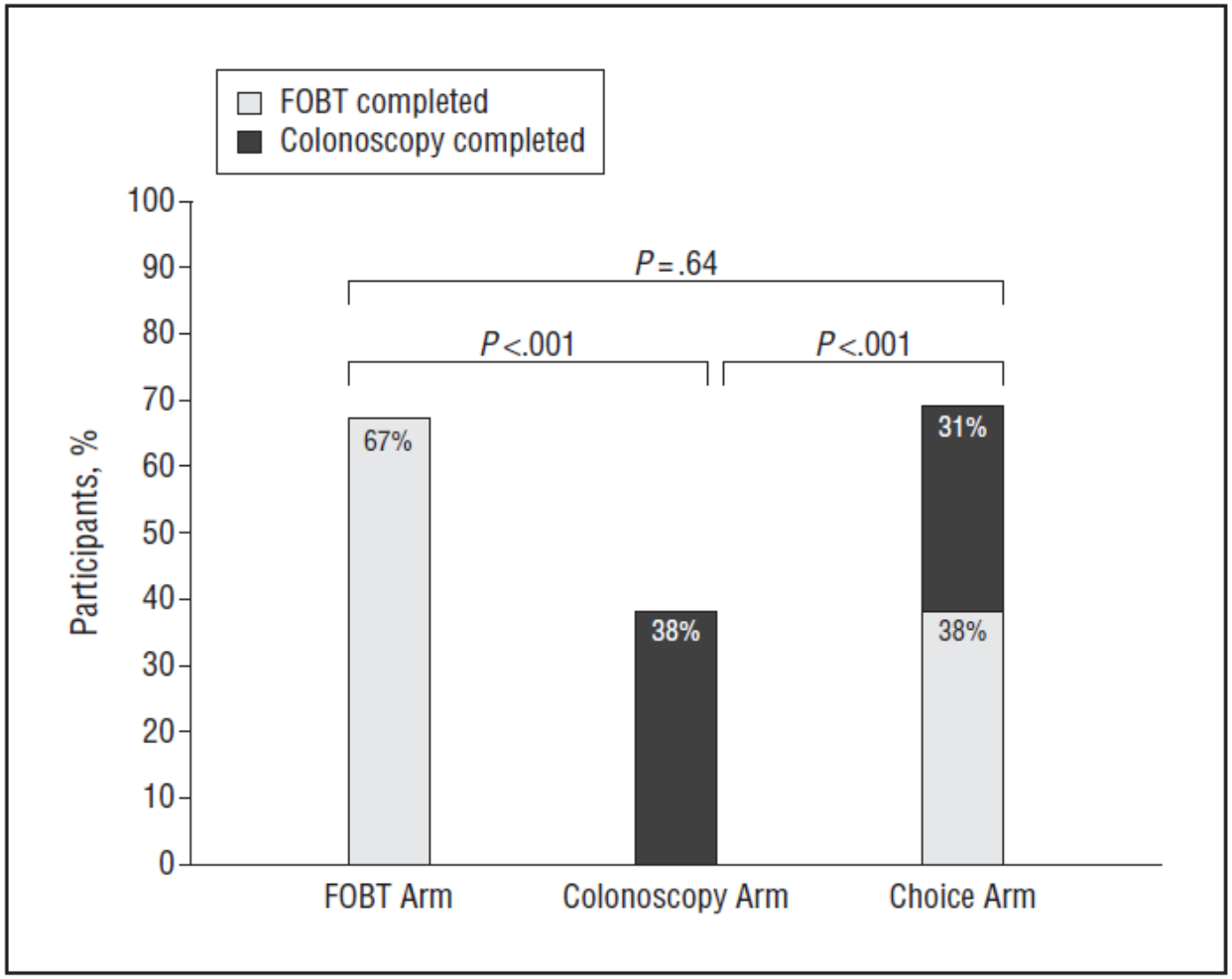
Most Commonly Used Screening Tests

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

PCP Beliefs and Preferences

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

Patient Preferences



Inadomi, Arch Intern Med 2012

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 testing for altered DNA biomarkers with a high-quality FIT
  - Referred to as “FIT-DNA” test or multi-target stool DNA test (“mt-sDNA”)
  - Included in CRC guidelines from ACS and USPSTF

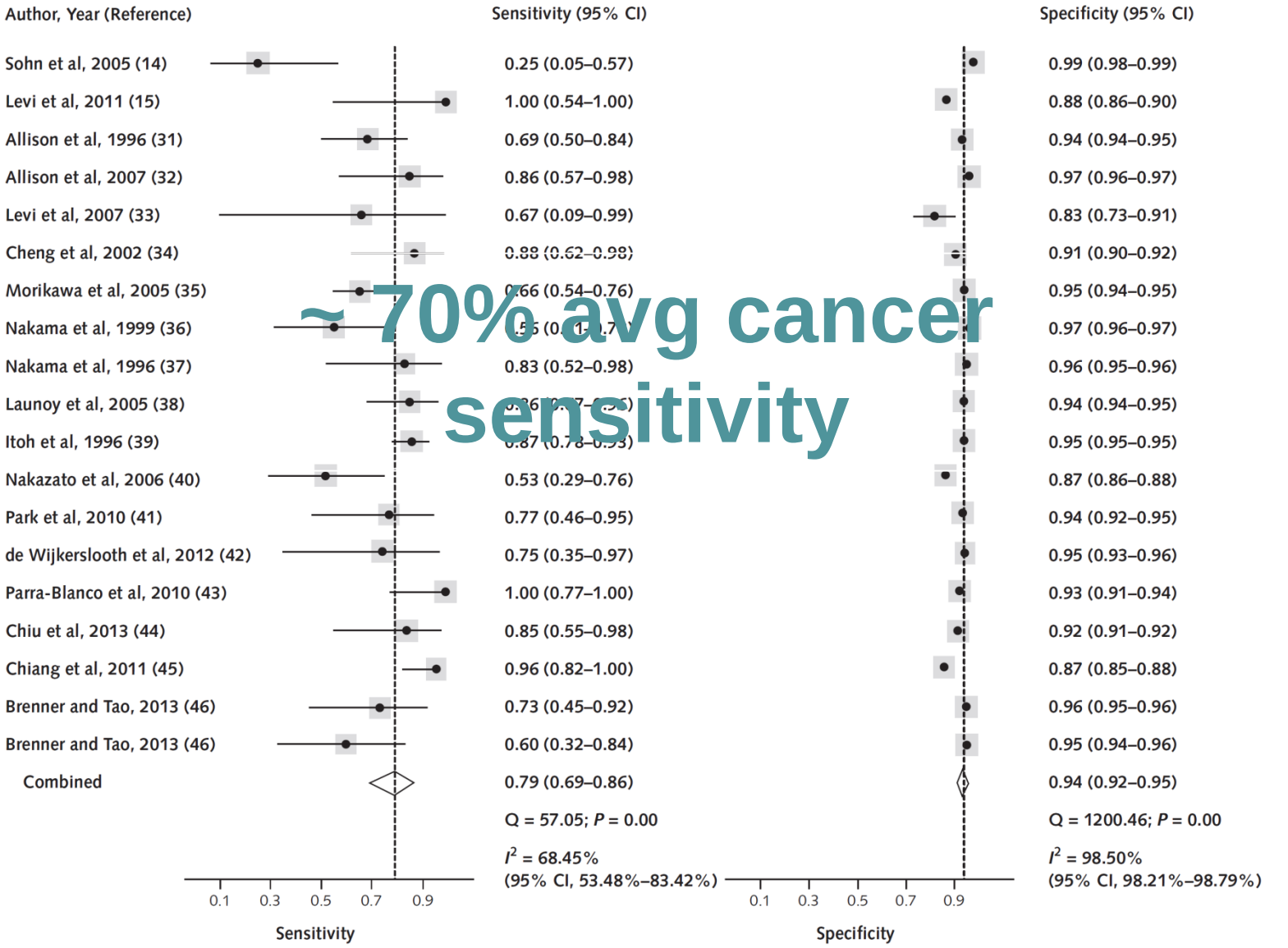
Guaic-based Fecal Occult Blood Tests (gFOBT)

- Most common type in U.S.
- Solid evidence (3 RCT's)
- Need specimens from 3 bowel movements
- Non-specific
- Results influenced by many foods and medications
- **Hemoccult II Sensa** is only brand with documented cancer sensitivity close to that of high quality FIT ($\geq$ 50%)
- Older forms (Hemoccult II) have low cancer sensitivity (<25% in most studies) and **not recommended** by ACS or USPSTF

Fecal Immunochemical Tests (FIT)

- Detect blood by immunoassay
- Antibody specifically recognizes the globin component of human hemoglobin
- High specificity for human blood and for lower GI bleeding
- No interference from food, medications
- Most brands require only 1 or 2 stool specimens
- Well-studied, high-quality brands demonstrate higher sensitivity than guaiac FOBT

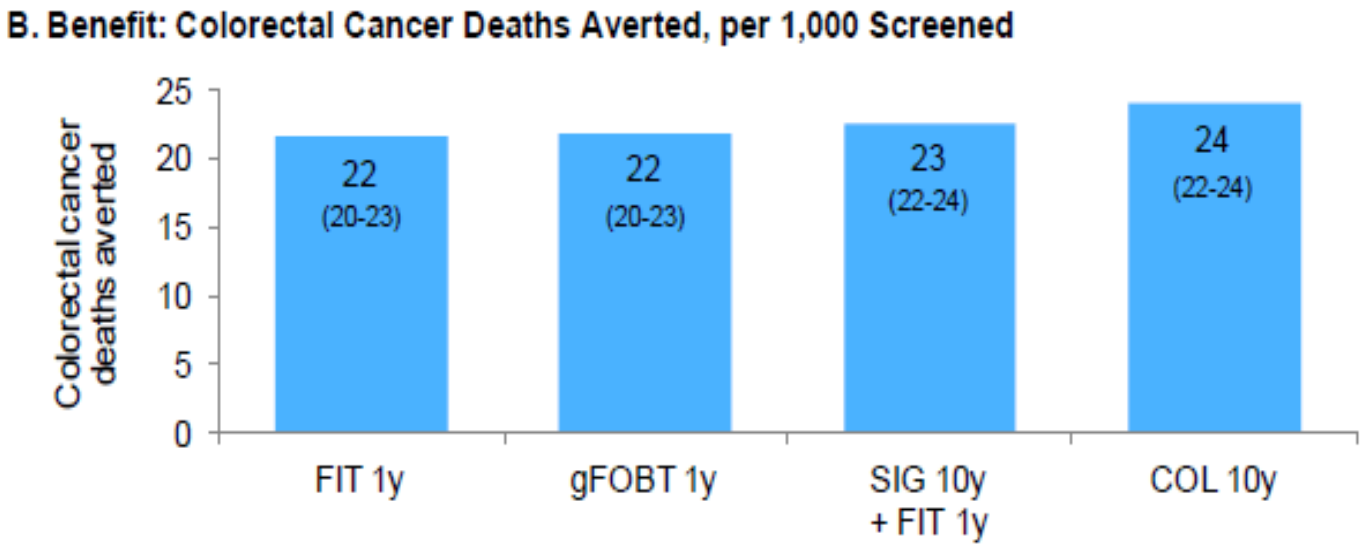
Figure 2. **Pooled sensitivity and specificity for fecal immunochemical tests for the detection of colorectal cancer for all included studies.**



~70% avg cancer sensitivity

FOBT Efficacy (USPSTF 2015)

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



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

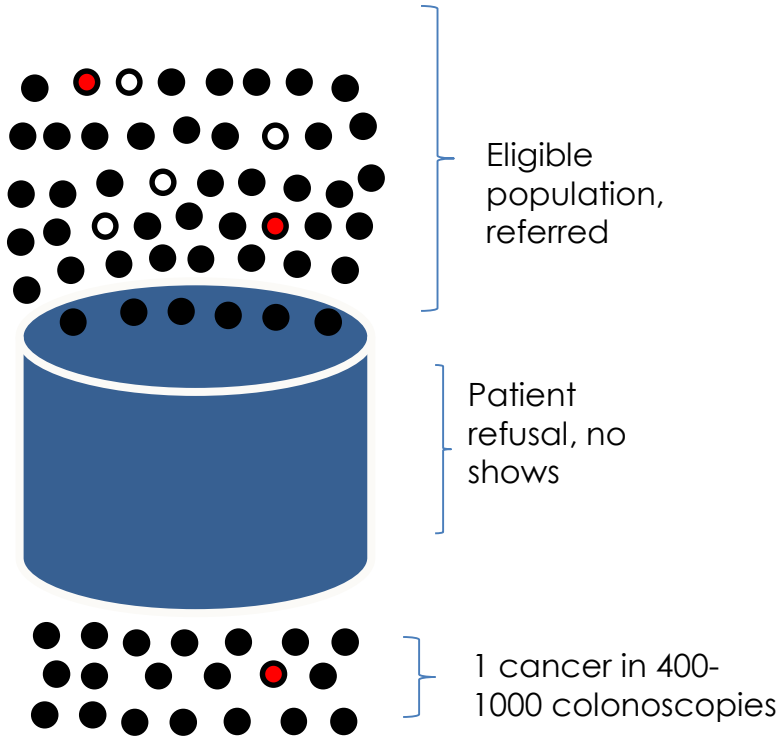
Advantages of Stool Tests

- 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.

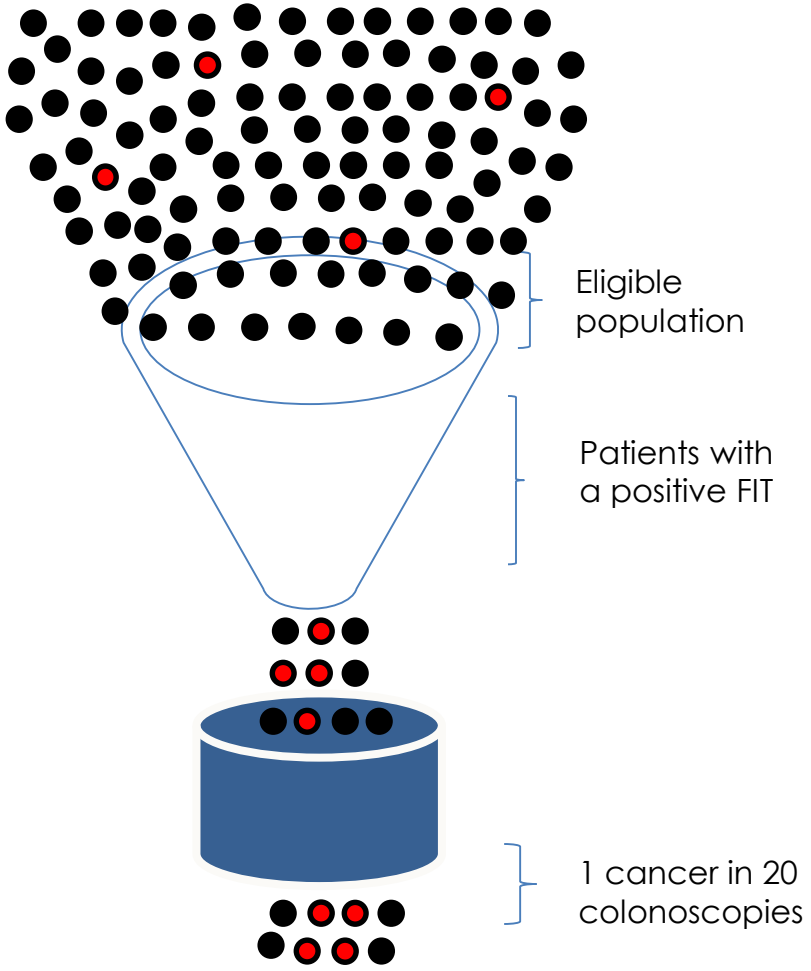
Making the Best Use of Scarce Resources:
Screening colonoscopy vs. FIT

- Represents 20 patients

Screening colonoscopy (refer 1,000 patients)



FIT testing (2,000 patients)



Slide courtesy of Dr. G. Coronado

FIT Quality Issues

All FIT are not created equal

- Current FDA guidance requires assessment of gFOBTs and FITs only for "detection of blood" – no data on cancer or adenoma detection capability is required
- Recent study found 65 FITs cleared for use in US, and 23 currently marketed*
  - Published data on detection of CRC or adenoma found for only **6** marketed FITs

*Daly et al. J Primary Care & Comm Hlth (2017)

FIT and gFOBT with Published Performance Data

(Supported by Endoscopy Findings)

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.

GFOBT BRAND NAME	MANUFACTURER	SENSITIVITY FOR CANCER	SPECIFICITY FOR CANCER	NUMBER OF STOOL SAMPLES
Hemoccult II SENSA	Beckman Coulter	61.5%-79.4%[4]	86.7%-96.4%[4]	3

DRE collection is NOT Evidence-Based

DRE Specimens

Essentially *worthless* as a screening tool for CRC and should NEVER be used.

Missed 19 of 21 cancers in largest study (gFOBT[1])

- Up to 25% of PCPs still use DRE sampling for CRC screening[2]
- No quality studies available re: FIT on DRE specimens
  - No FDA approvals based on this collection method
  - Not included in consumer directions from any brand
- However, some manufacturer reps reportedly endorsing

Collins et al. Annals Int Med (2005); 2. Levy et al. J Primary Care & Comm Hlth (2012)

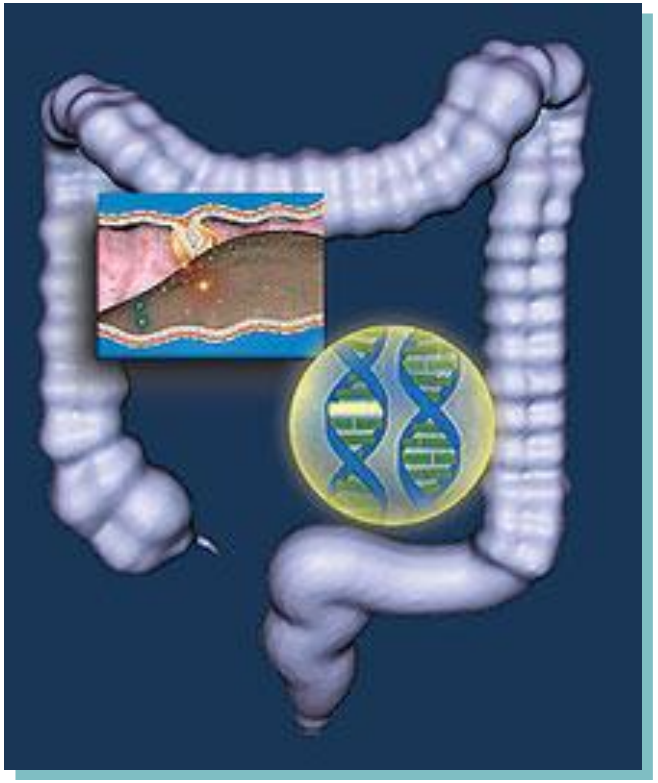
Other gFOBT/FIT Quality Issues

Clinicians and consumers should be aware that:

- Stool tests are generally appropriate only for *average risk* (no strong family history, no personal risks,…)
- Must be repeated annually
- All positive stool tests must be followed up with colonoscopy
  - No follow up colonoscopy documented for ~ **1 in 3** abnormal stool tests within 12 months in most studies
  - Failure to follow up positive tests in a timely manner is associated with **increased risk** of future **CRC diagnosis** and **advanced stage disease**

Stool DNA Test (sDNA)

- Fecal occult blood tests detect blood in the stool – which is intermittent and non-specific
- Colon cells are shed continuously
- Adenoma and cancer cells contain abnormal DNA
- Stool DNA tests look for DNA mutations in cells that are passed in the stool*



Only recommended or appropriate for **average risk patients*

“FIT-DNA” Test

- One test (Cologuard) currently available

- Combines tests for stool DNA markers associated with cancer and adenomas **plus** an FIT (OC FIT-CHEK, Polymedco)

Cologuard (FIT-DNA) Performance

Table 1. Sensitivity and Specificity of the Multitarget Stool DNA Test and the Fecal Immunochemical Test (FIT) for the Most Advanced Findings on Colonoscopy.

Most Advanced Finding	Colonoscopy (N = 9989)	Multitarget DNA Test (N = 9989)		FIT (N = 9989)	
		Positive Results	Sensitivity (95% CI)	Positive Results	Sensitivity (95% CI)
	no.	*no.*	%	*no.*	%
Colorectal cancer					
Any	65	60	92.3 (83.0–97.5)	48	73.8 (61.5–84.0)
Stage I to III*	60	56	93.3 (83.8–98.2)	44	73.3 (60.3–83.9)
Colorectal cancer and high-grade dysplasia	104	87	83.7 (75.1–90.2)	66	63.5 (53.5–72.7)
Advanced precancerous lesions†	757	321	42.4 (38.9–46.0)	180	23.8 (20.8–27.0)
Nonadvanced adenoma	2893	498	17.2 (15.9–18.6)	220	7.6 (6.7–8.6)
			Specificity (95% CI)		Specificity (95% CI)
All nonadvanced adenomas, non-neoplastic findings, and negative results on colonoscopy	9167	1231	86.6 (85.9–87.2)	472	94.9 (94.4–95.3)
Negative results on colonoscopy	4457	455	89.8 (88.9–90.7)	162	96.4 (95.8–96.9)

* 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.

NEJM 2014

FIT-DNA/Cologuard

- Included in ACS and USPSTF guideline
- FDA-cleared for marketing as CRC screening test
- 3 year testing interval (based on limited evidence)
- Medicare reimbursement for beneficiaries age 50 – 85
  - Medicare reimbursement ~ $500 q 3 yrs
- Private insurance coverage reportedly increasing since added to USPSTF recommendation
- All positive tests must be evaluated by colonoscopy (may be subject to cost sharing)
- Manufacturer provides “patient navigation” in current payment model (improves completion rates)

Clinicians Information on Modern Stool Tests

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

Questions

- Please type any questions into the chat box
- We will do our best to answer your questions in the remaining time.
- Thank you for participating!