FIGHT

COLORECTAL CANCER

LEARNING SERIES

FIGHT COLORECTAL CANCER

Stool-Based Colorectal Cancer Screening

State of the science and implications for screening management among the 45-49 year old population

Tuesday, March 9th

1:00 PM Eastern

ANN ZAUBER PHD
Attending Biostatistician
Memorial Sloan Kettering

THEODORE R. LEVIN MD
Research Scientist
Kaiser Permanenate Northern California

FIGHT™
COLORECTAL CANCER

Fight Colorectal Cancer (Fight CRC) is a leading patient-empowerment and advocacy organization in the United States, providing balanced and objective information on colon and rectal cancer research, treatment, and policy.

We are relentless champions of hope, focused on funding promising, high impact research endeavors while equipping advocates to influence legislation and policy for the collective good.

Learn more at
FightColorectalCancer.org

FIGHT COLORECTAL CANCER

Early-Age Onset Workgroup Research Learning Session #5 Agenda

12:00-12:10p ET	Welcome and Introductions: Elsa Weltzien and Andrea (Andi) Dwyer
12:10 - 12:40p ET	Dr. Ann Zauber: State of the science of stool-based testing
12:40-1:10p ET	Discussion with Dr. Theordore R. Levin: implementation of stool-based testing
1:10-1:55p ET	Discussion
1:55-2:00p ET	Close out and next steps: Andi Dwyer

EAO Workgroup: Upcoming Opportunities

01 Research Learning Series – Session #5

May 4, 2021 – 12-2 pm EST
Pt. 2: Equitable access to screening among 45-49
Registration coming soon!

02 2021 EAO CRC International Symposium

June 24 & 25, 2021. 11:30-3:30 EST
The 2021 symposium will include action-based dialogue between patients, advocates, clinicians, and researchers, and collaborative discussion of the successes and gaps in EAO CRC research and clinical care.

Registration and abstract submissions opening March 31, 2021


CALL ON CONGRESS
F!GHT COLORECTAL CANCER
KICKOFF EVENT
MARCH 15
CALLONCONGRESS.ORG

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"Strategies to Screen Ages 45-49 for Colorectal Cancer: The Case for Implementing Stool-Based Screening at a Younger Age"

Fight CRC Early Age Onset Workgroup

March 9, 2021

Ann G. Zauber, PhD

Memorial Sloan Kettering Cancer Center

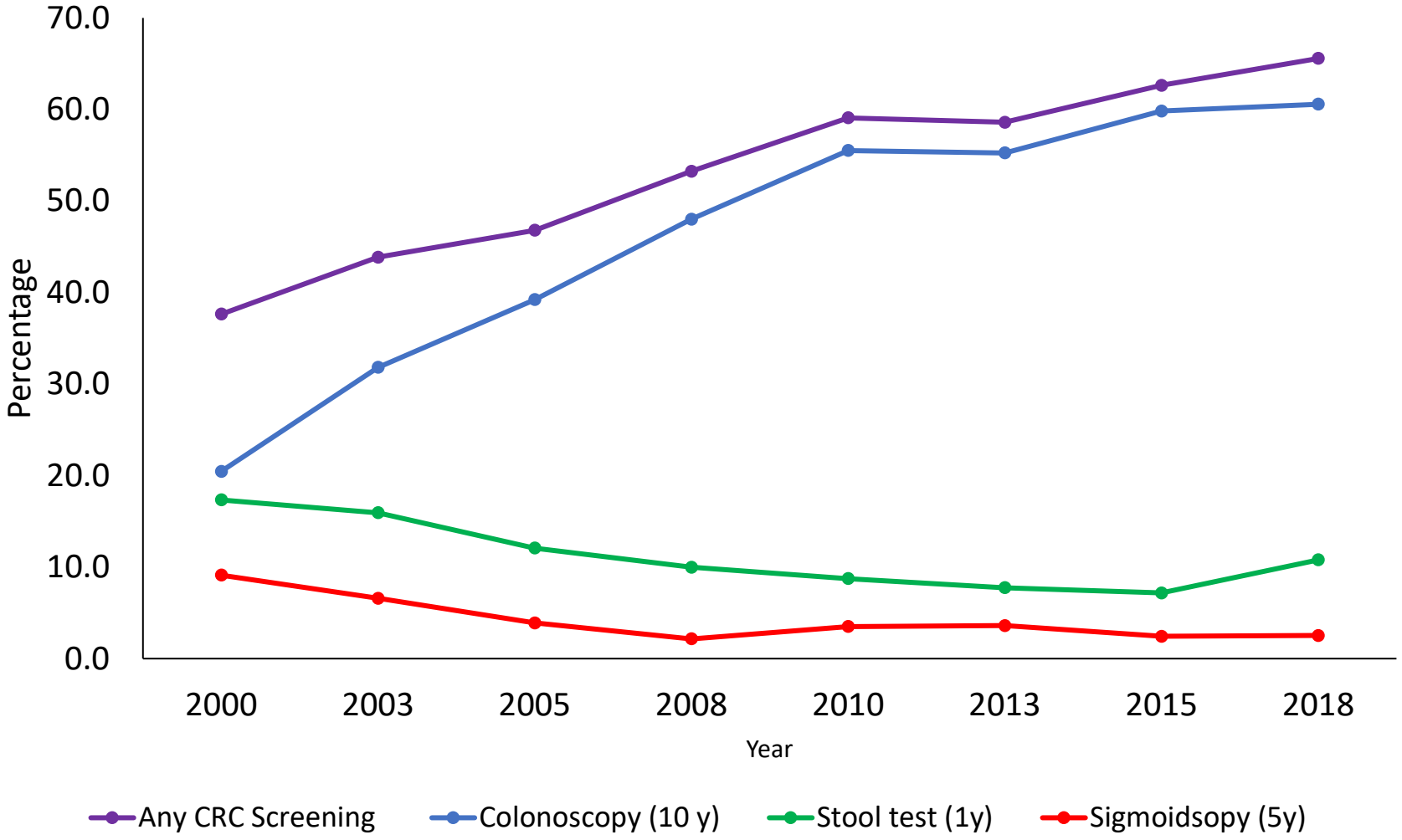
CISNET-Colon Coordinating Chair

Outline

- Background
- Characteristics of Stool Based Screening
- Diagnostic Accuracy of Stool Based Screening
- Adherence to Stool Based Screening
- USPSTF 2020 Draft Recommendations

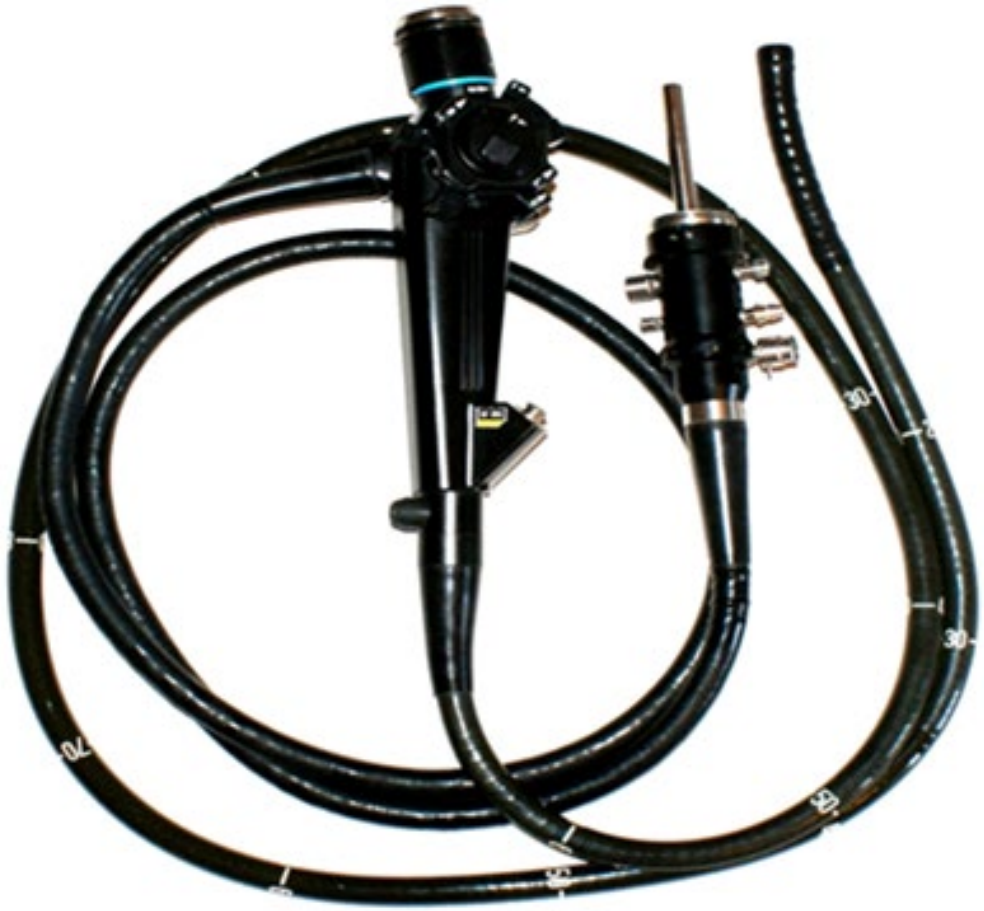
Background

CRC Screening from 2000 - 2018



Source: National Health Interview Survey (2018) Stacey Fedewa

In the United States, 90% of CRC Screening is Colonoscopy



PROS:

- Done every 10 years
- Removes adenomas and detects CRC

CONS:

- Bowel prep
- Sedation
- Potential perforation
- Companion is needed after exam

Getting Vetted As a Running Mate? Like a Colonoscopy, Only Worse…

POLITICAL MEMO

Life on the Vice-Presidential Short List

It's exciting. It can also feel like a colonoscopy.

Joseph R. Biden Jr. initially declined President Barack Obama's request to vet him for the vice presidency. Gabriella Demczuk for The New York Times

Evan Bayh, a former Democratic senator from Indiana and a repeat vice-presidential contestant, somewhat famously ***compared the vetting process to a colonoscopy*** — "except they use the Hubble telescope on you."

-New York Times
July 4, 2020

The New York Times

THE NEW OLD AGE

A Colonoscopy Alternative Comes Home

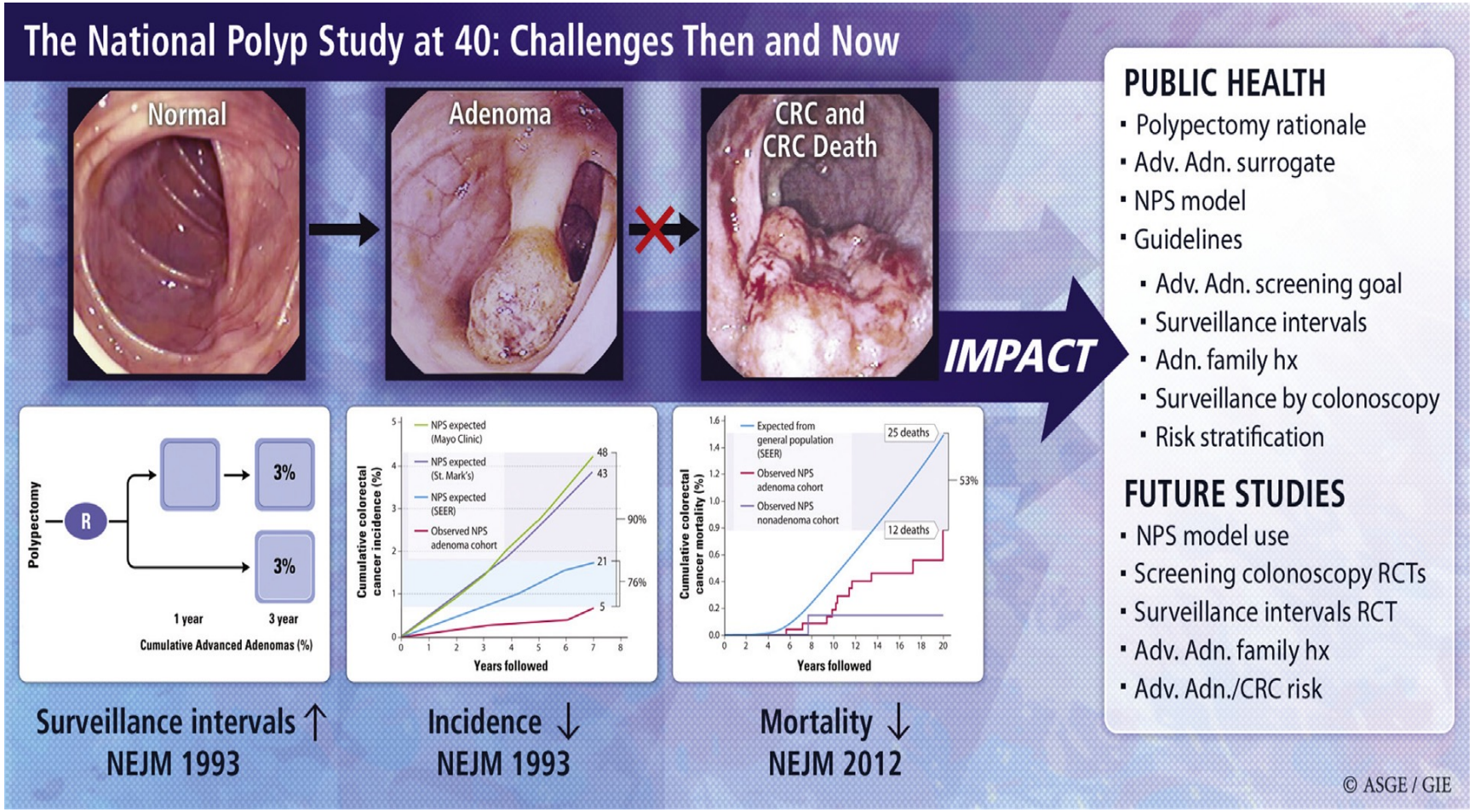
An at-home test for colon cancer is as reliable as the traditional screening, health experts say, and more agreeable.

601

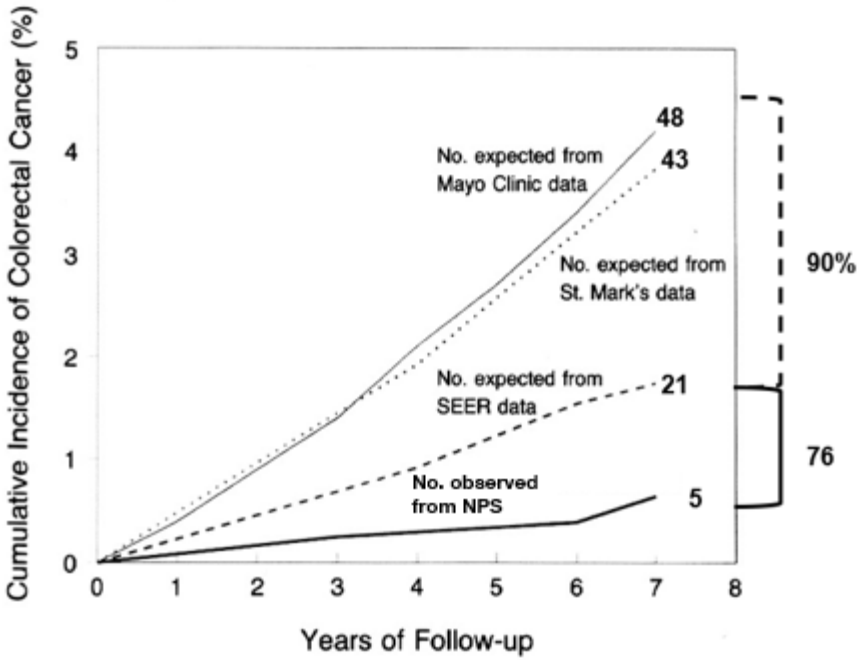
"Many of my own patients are surprised to learn that ***there's another way***," said Dr. Alex Krist, also a family physician at Virginia Commonwealth University. "As they age, they want ***less invasive methods"*** and may be happy to switch.

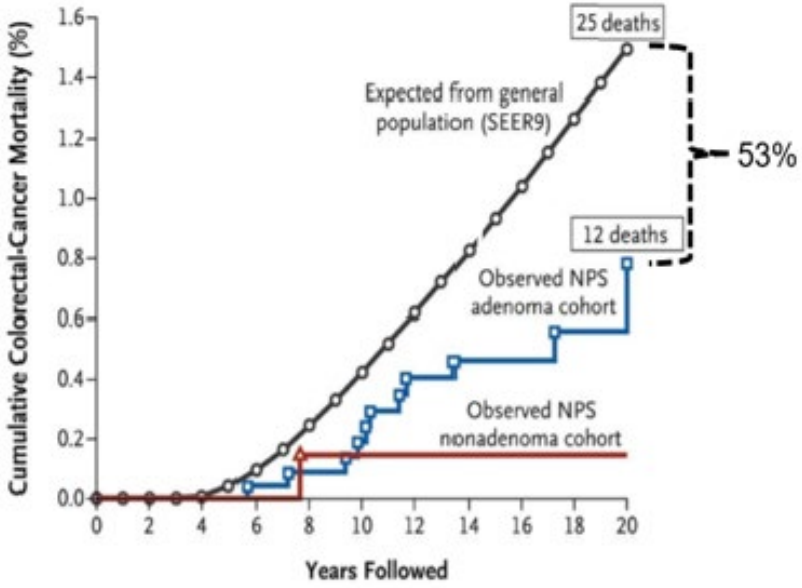
-New York Times
January 11, 2021

Adenoma-Carcinoma Sequence



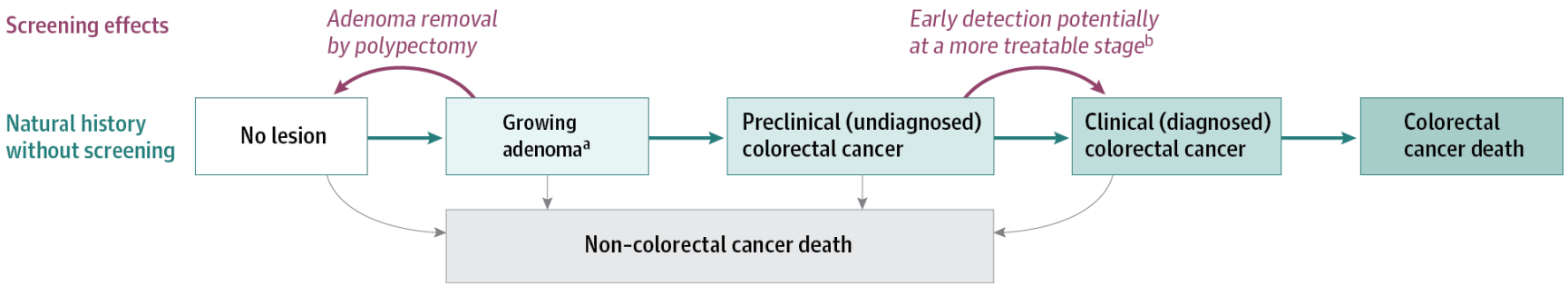
National Polyp Study: Colonoscopy Polypectomy Reduces CRC Incidence and CRC Mortality





Colonoscopic polypectomy reduces burden of disease

Natural History of Colorectal Cancer



- The opportunity to intervene in the natural history through screening is noted in red. Screening can either remove an adenoma, thus moving a person to the “no lesion” state, or diagnose a preclinical cancer, which, if detected at an earlier stage, may be more amenable to treatment (Knudsen, JAMA 2016)

Suggested screening CRC

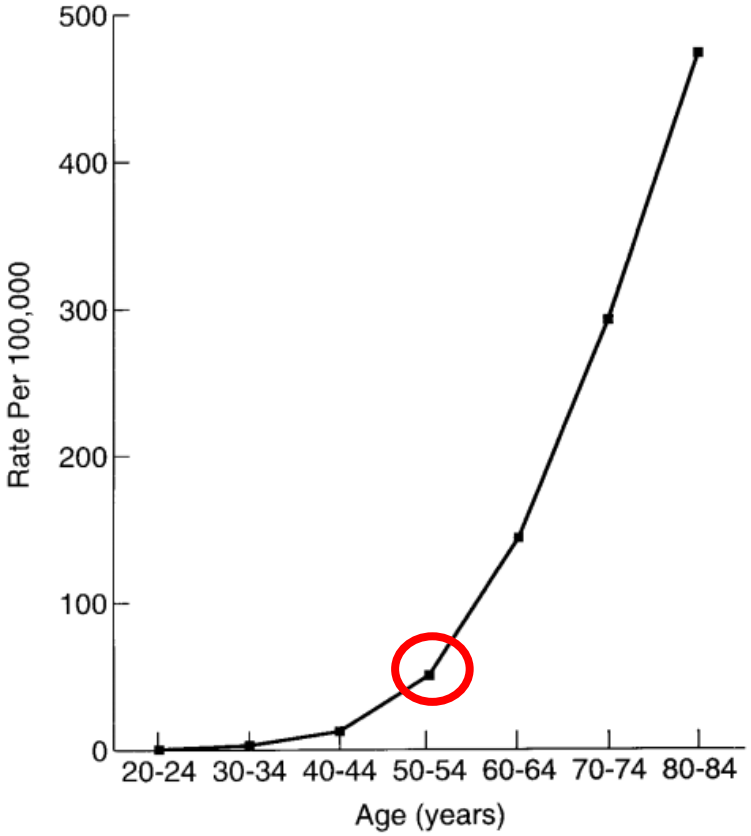


Figure 3. Age-specifi incidence of CRC in the general population; SEER Program (total, male and female, all races, colon and rectum. 1988 – 1992). (Reprinted with permission.[217])

- SEER Data of 1988-1992 SEER

Gastroenterology
Volume 112, Issue 2, February 1997, Pages 594-642

Colorectal cancer screening: Clinical guidelines and rationale

SJ Winawer, RH Fletcher, L Miller, F Godlee, MH Stolar, CD Mulrow, SH Woolf, SN Glick, TG Ganiats, JH Bond, L Rosen, JG Zapka, SJ Olsen, FM Giardiello, JE Sisk, R Van Antwerp, C Brown-Davis, DA Marciniak, RJ Mayer

Familial Risk is Associated with CRC

- Evidence to begin CRC screening earlier for familial risk.

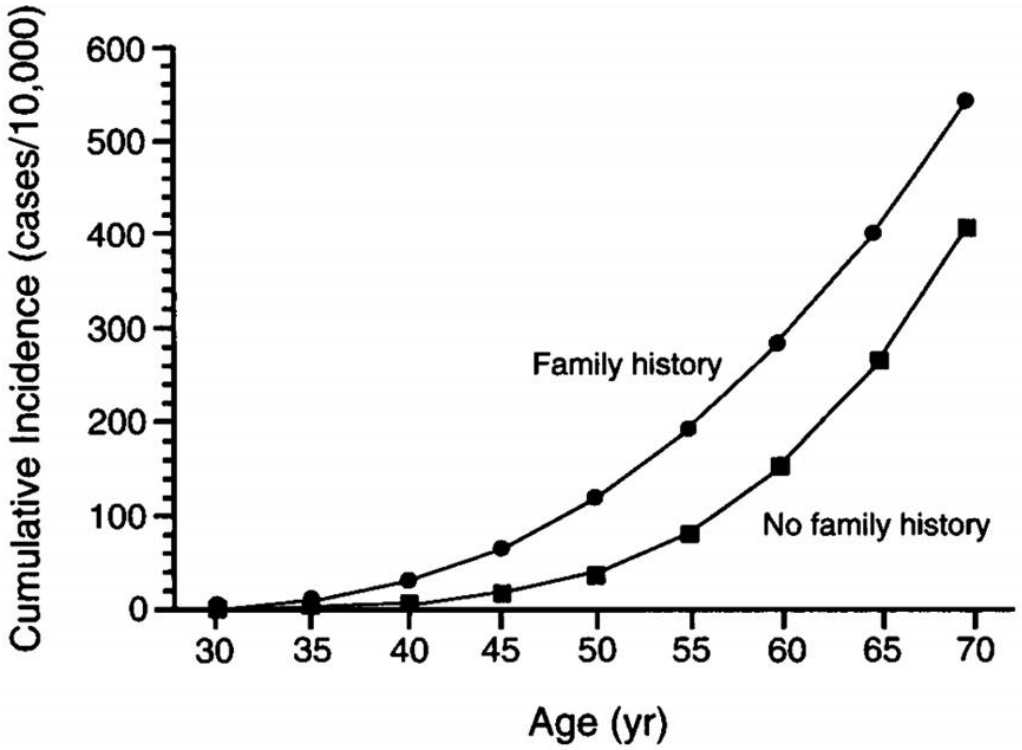
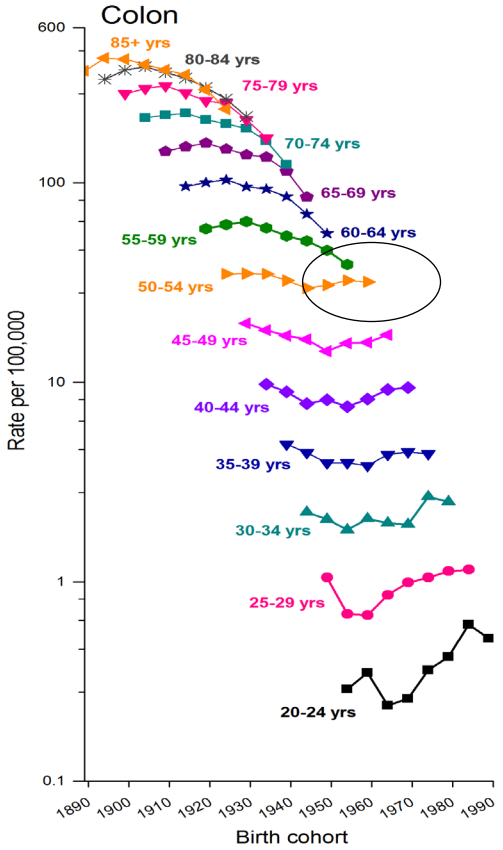


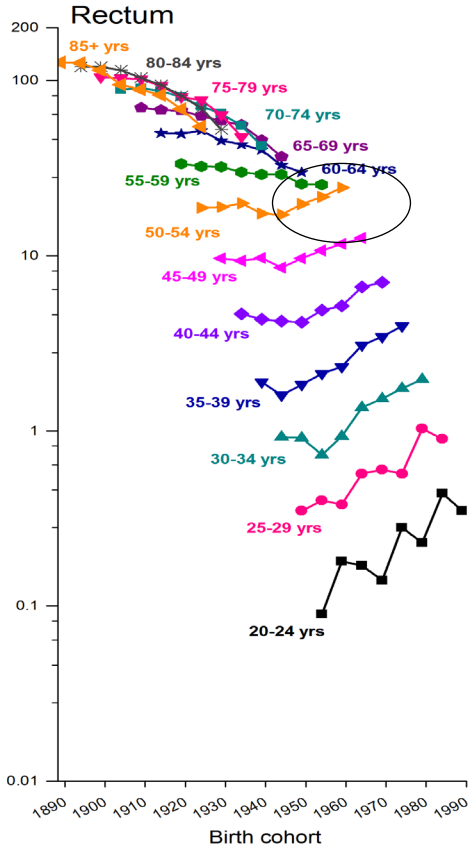
Figure 1. Cumulative Incidence of Colorectal Cancer According to Age and the Presence or Absence of a Family History of the Disease.

Fuchs CS et al, NEJM 1994

Trends in CRC Incidence by Age and Year of Birth

Among adults younger than 55 years, there was a 51% increase in the incidence of CRC from 1994 to 2014 and an 11% increase in mortality from 2005 to 2015.



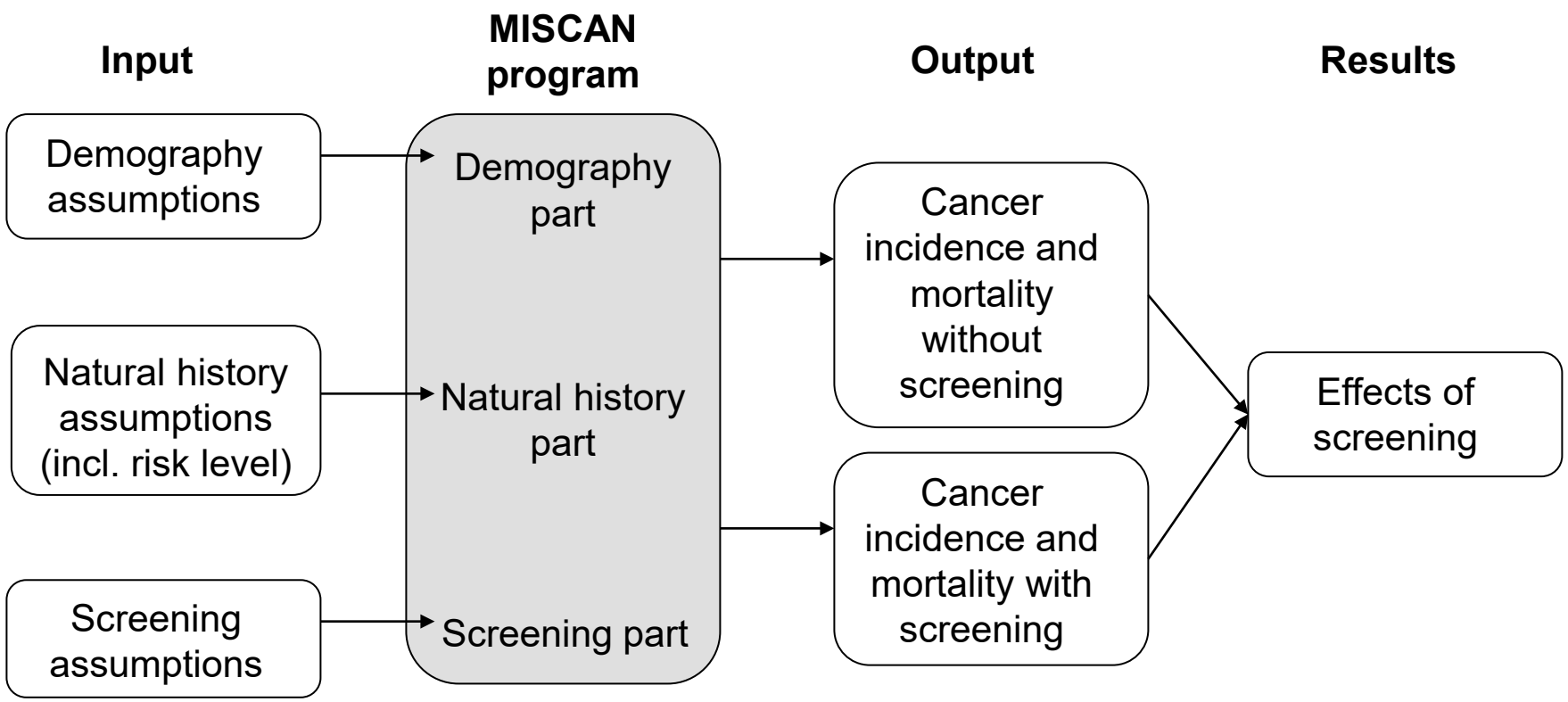


Source: Siegel RL, Fedewa SA, Anderson WF, et al. Colorectal cancer incidence patterns in the United States, 1974-2013. JNCI 2017;109;djw322.

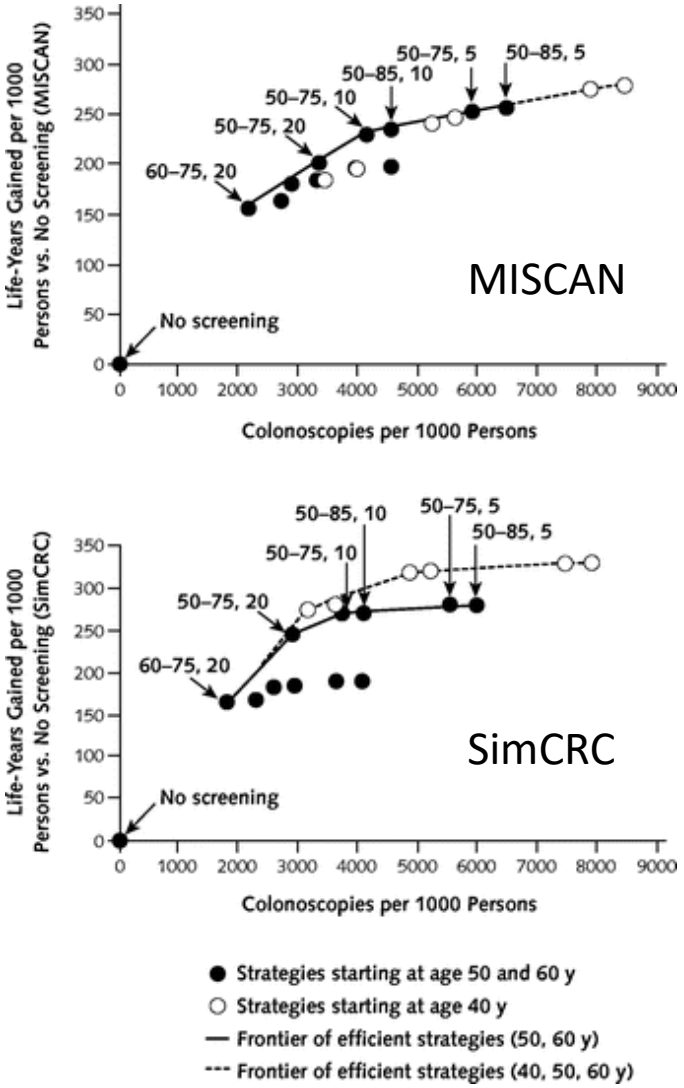
American Cancer Society®

CISNET Modeling and Past Recommendations

Population Simulation Model

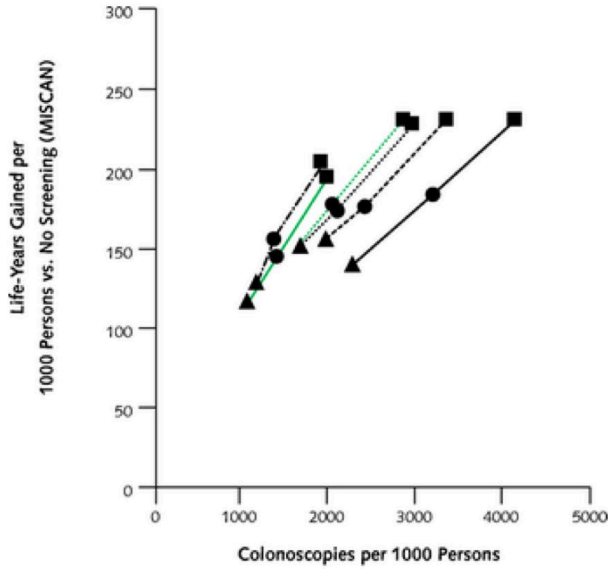


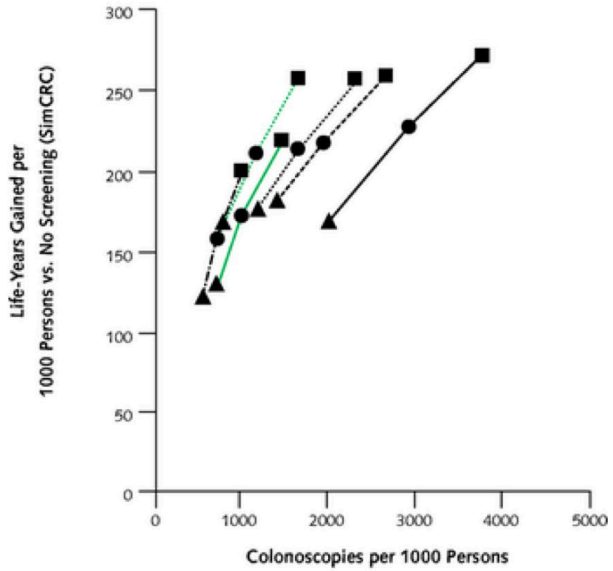
USPSTF CISNET Decision Analysis 2008



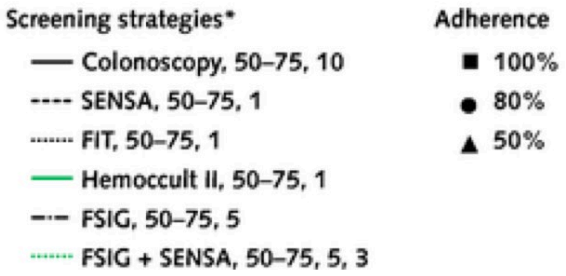
- Age to begin of **40,50,60**
- Comparative modeling with MISCAN and SimCRC
- SimCRC found a higher benefit by beginning at age 40 than MISCAN
- No empiric data to start at 40

USPSTF Decision Analysis 2008
Adherence Affects Life Years saved

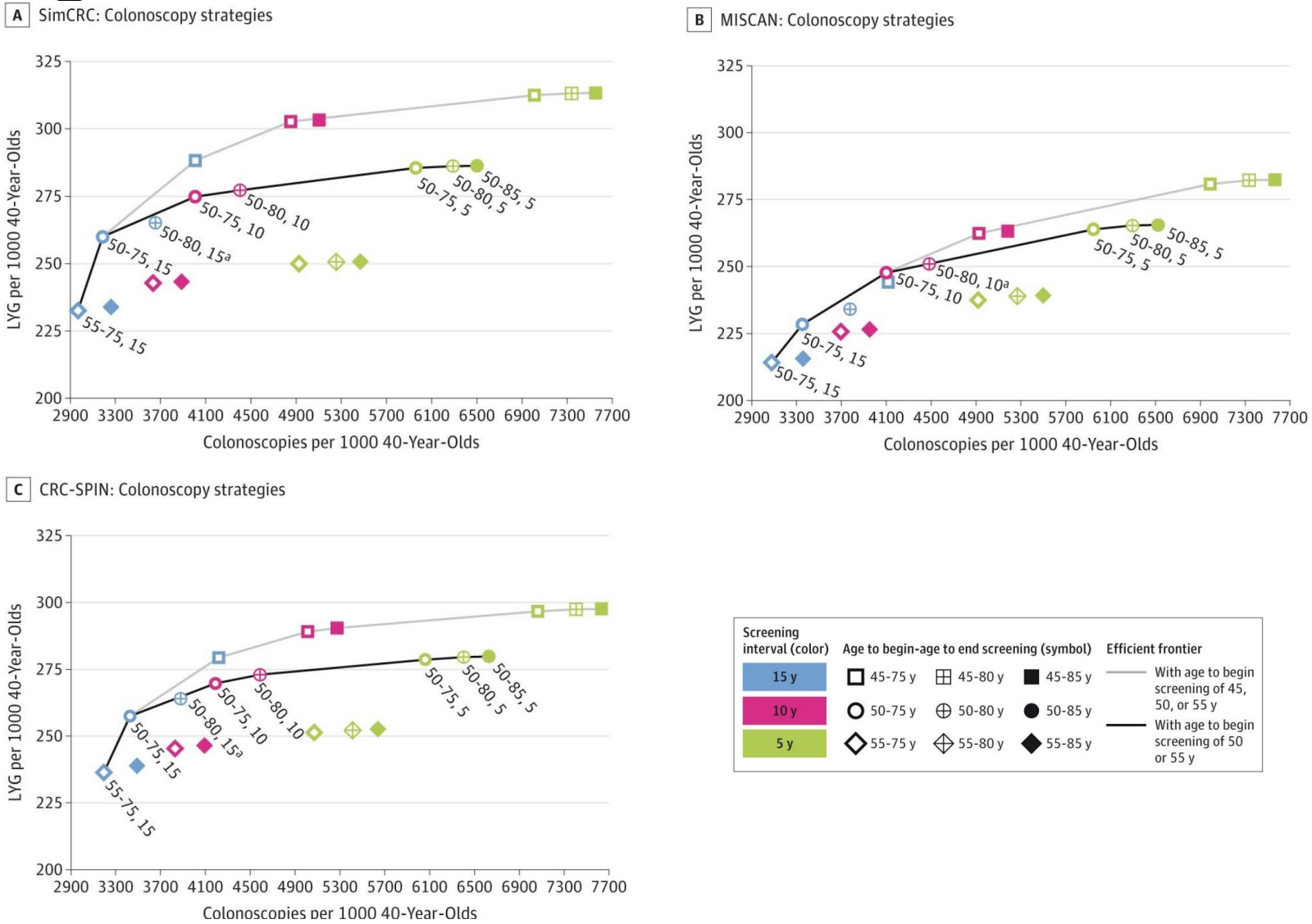




- Considered 100%, 80% and 50% adherence to screening program
- As expected lower adherence has lower life years gained than full adherence for both MISCAN and SimCRC models



USPSTF Decision Analysis 2016 Ages 45,50,55



Knudsen AB, Zauber AG, Rutter CM, et al. Estimation of Benefits, Burden, and Harms of Colorectal Cancer Screening Strategies: Modeling Study for the US Preventive Services Task Force. JAMA. 2016;315(23):2595-2609. doi:10.1001/jama.2016.6828.

USPSTF Recommendations 2016

- In **2016,** the CISNET models performed analyses for the United States Preventive Services Task Force

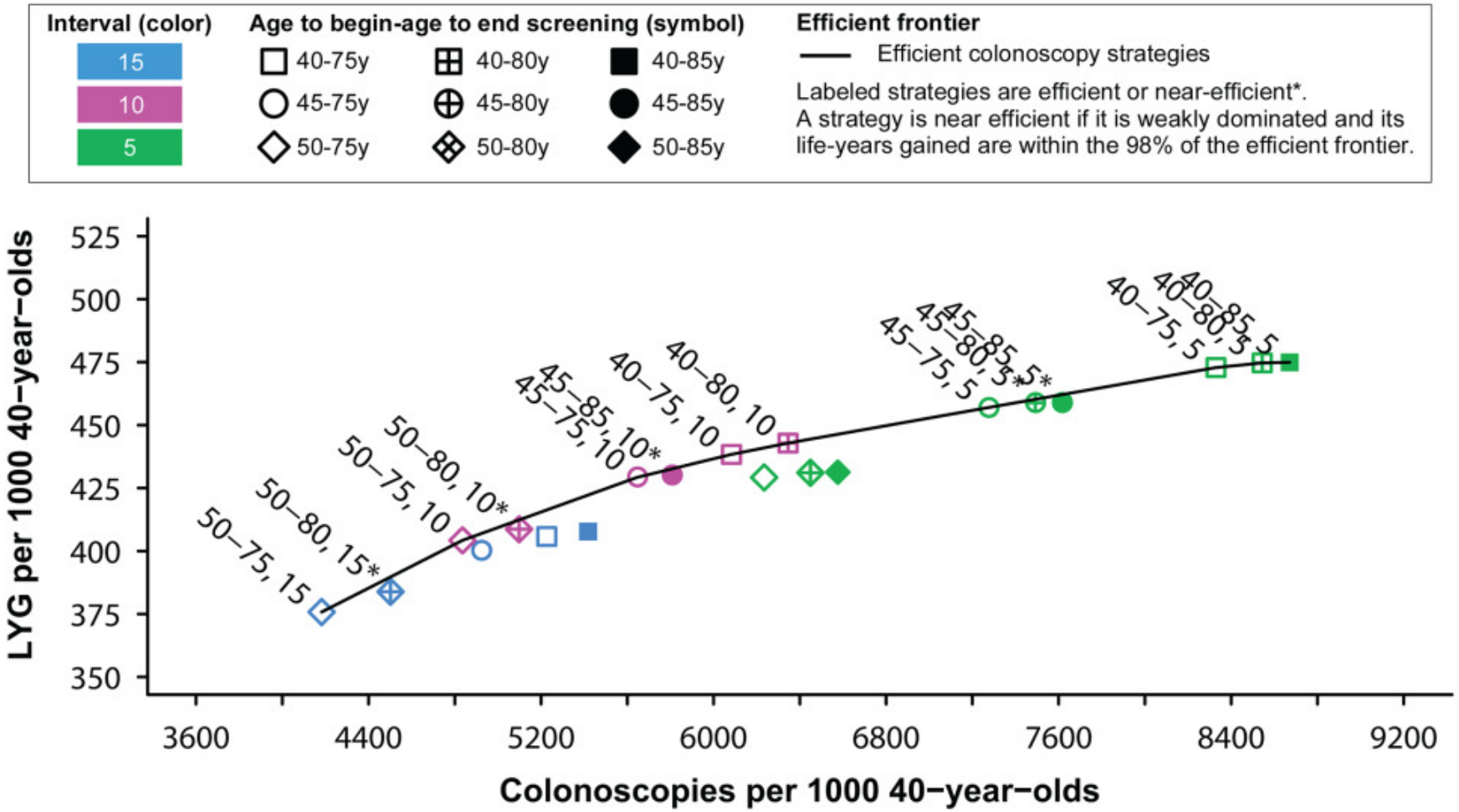
US Preventive Services Task Force | MODELING STUDY

Estimation of Benefits, Burden, and Harms of Colorectal Cancer Screening Strategies
Modeling Study for the US Preventive Services Task Force

Amy B. Knudsen, PhD; Ann G. Zauber, PhD; Carolyn M. Rutter, PhD; Steffie K. Naber, MSc; V. Paul Doria-Rose, DVM, PhD; Chester Pabiniak, MS; Colden Johanson, BA; Sara E. Fischer, MPH; Iris Lansdorp-Vogelaar, PhD; Karen M. Kuntz, ScD

- Two out of three CISNET models recommended screening from age 45 to 75 years with a 15 year colonoscopy interval.
- MISCAN recommended screening from age 50 to 75 years with a 10 year colonoscopy interval.
- ***Lacking empiric data on age to begin***

ACS 2018: Impact of *Rising CRC* in Young Adults (MISCAN Model)



Cancer, Volume: 124, Issue: 14, Pages: 2964-2973, First published: 30 May 2018, DOI: (10.1002/cncr.31543)

ACS: 2018 Guideline with Qualified Recommendation for Begin at Age 45

ACS 2018 Recommendations:
The ACS recommends that adults aged 45 y and older with an average risk of CRC undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) examination, depending on patient preference and test availability. As a part of the screening process, all positive results on non-colonoscopy screening tests should be followed up with timely colonoscopy.
The recommendation to begin screening at age ***45 y is a qualified recommendation.***
The recommendation for regular screening in adults aged 50 y and older is a strong recommendation.
The ACS recommends that average-risk adults in good health with a life expectancy of greater than 10 y continue CRC screening through the age of 75 y (qualified recommendation).
The ACS recommends that clinicians individualize CRC screening decisions for individuals aged 76 through 85 y based on patient preferences, life expectancy, health status, and prior screening history (qualified recommendation).
The ACS recommends that clinicians discourage individuals over age 85 y from continuing CRC screening (qualified recommendation).

CA: A Cancer Journal for Clinicians, Volume: 68, Issue: 4, Pages: 250-281, First published: 30 May 2018, DOI: (10.3322/caac.21457)

ACS: 2018 Guideline Recommendations

Options for CRC Screening
Stool-based tests • Fecal immunochemical test every year • High-sensitivity, guaiac-based fecal occult blood test every years • Multitarget stool DNA test every 3 years
Structural examinations • Colonoscopy every 10 years • CT colonography every 5 years • Flexible sigmoidoscopy every 5 years

CA: A Cancer Journal for Clinicians, Volume: 68, Issue: 4, Pages: 250-281, First published: 30 May 2018, DOI: (10.3322/caac.21457)

Informing the Young Onset CRC Debate: Unintended and Intended Con

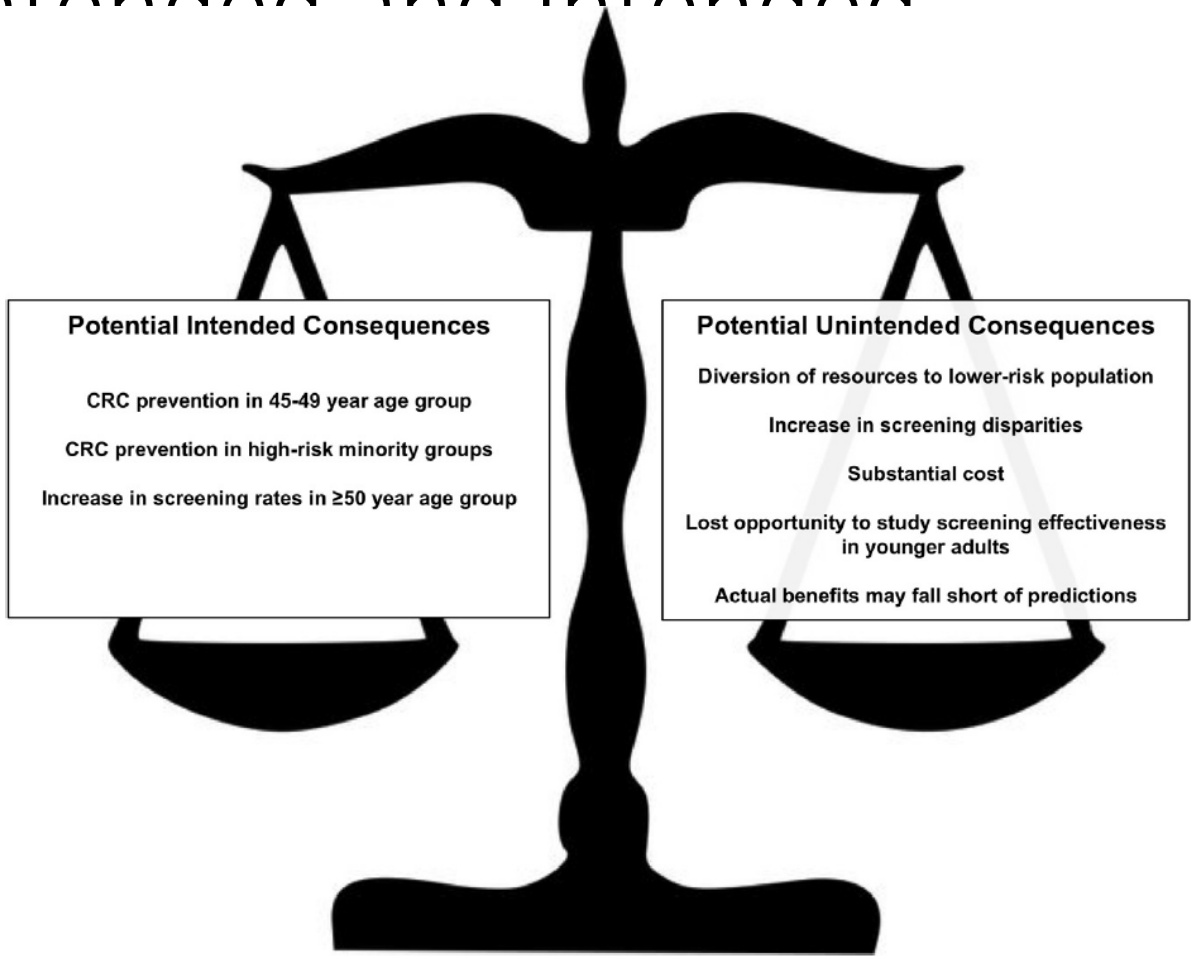
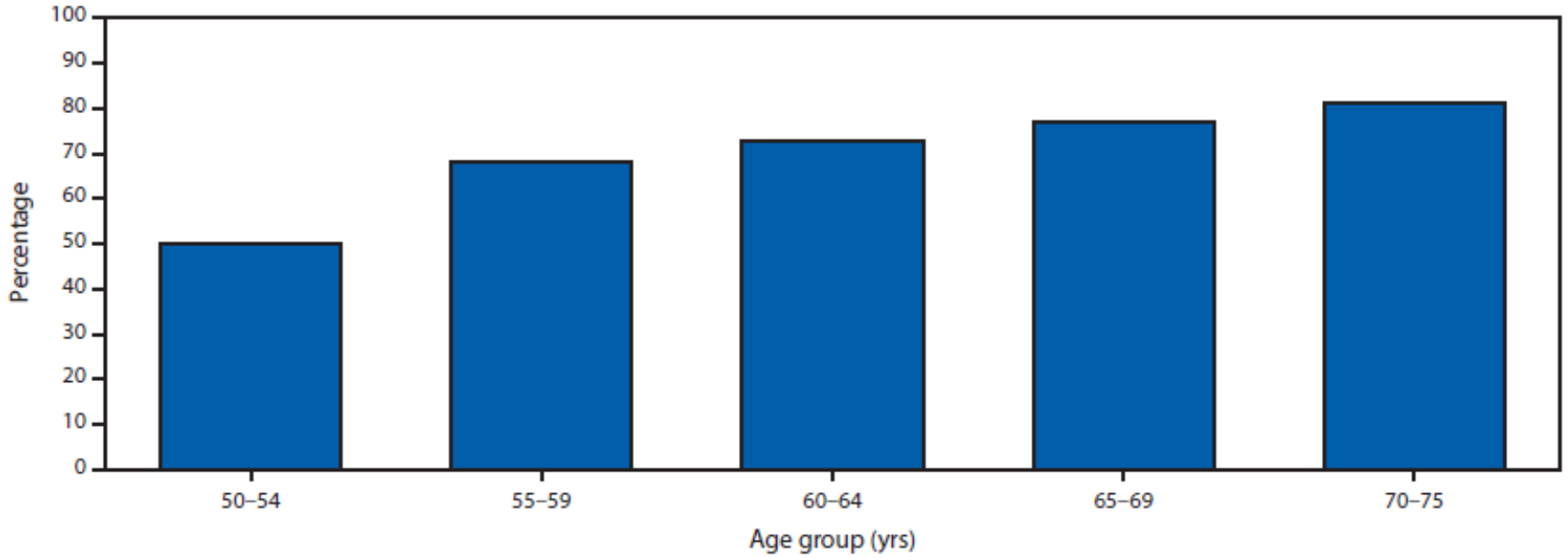


Figure 1. Potential consequences of recommending colorectal cancer (CRC) screening initiation at age 45 instead of age 50 years.

Liang et al, Gastro 2018

Who is *Actually* Getting Screened >50?

FIGURE. Percentage of respondents aged 50–75 years who reported being up to date* with colorectal cancer screening, by age — Behavioral Risk Factor Surveillance System (BRFSS), United States, 2018†,§



* Blood stool test within the past 1 year, sigmoidoscopy within the past 5 years, and/or colonoscopy within the past 10 years.
† Data were weighted to the age, sex, and racial/ethnic distribution of each state's adult population using intercensal estimates and age-standardized to the 2018 BRFSS population.
§ Test for trend is significantly different ($p<0.005$).

CDC, 2018

Who is Getting Screened After the ACS 2018 Recommendations?

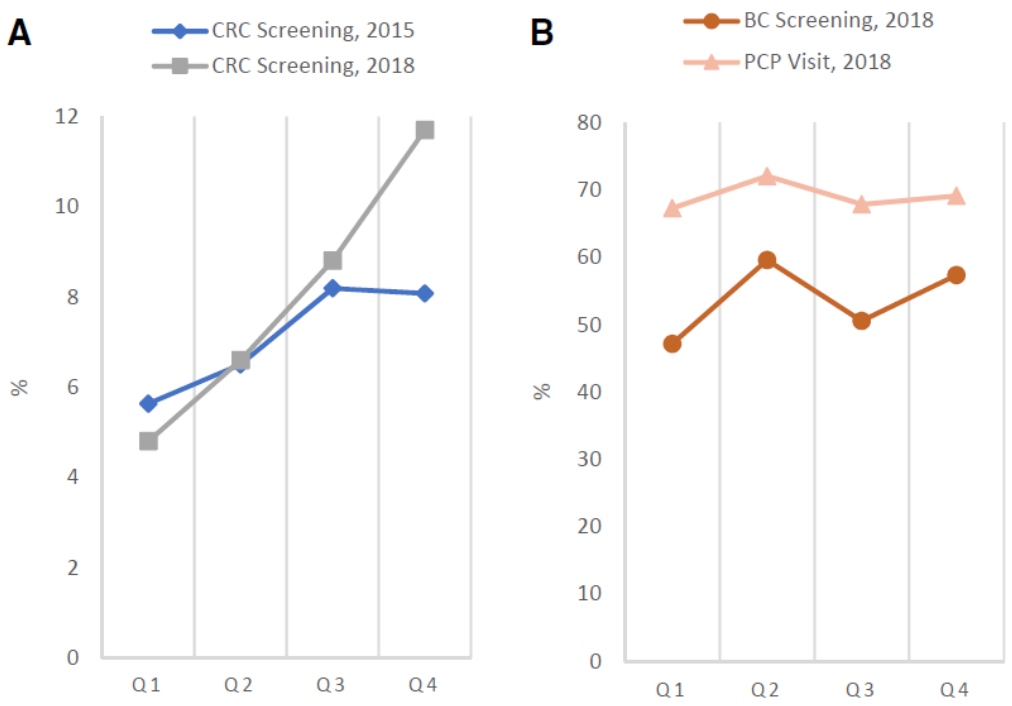


Figure 1. Colorectal cancer (CRC) and breast cancer (BC) screening and primary care provider (PCP) visits within the past year among adults aged 45 to 49 years in the National Health Interview Survey for 2015 and 2018. Colorectal cancer screening included colonoscopy, sigmoidoscopy, computed tomography colonography, and stool testing within the past year. Breast cancer screening included mammogram within the past year among females only. Q indicates interview quarter.

Fedewa et al, 2019 *Cancer*

Just in Time:
American College of Gastroenterology Clinical Guideline
Begin Screening Ages 45-49 Conditional

Recommendations

1. We recommend CRC screening in average-risk individuals between ages 50 and 75 years to reduce incidence of advanced adenoma, CRC, and mortality from CRC.

Strong recommendation; moderate-quality evidence

2. We suggest CRC screening in average-risk individuals between ages 45 and 49 years to reduce incidence of advanced adenoma, CRC, and mortality from CRC.

Conditional recommendation; very low-quality evidence

Shaukat et al, **March 1, 2021** *Am J Gastro*

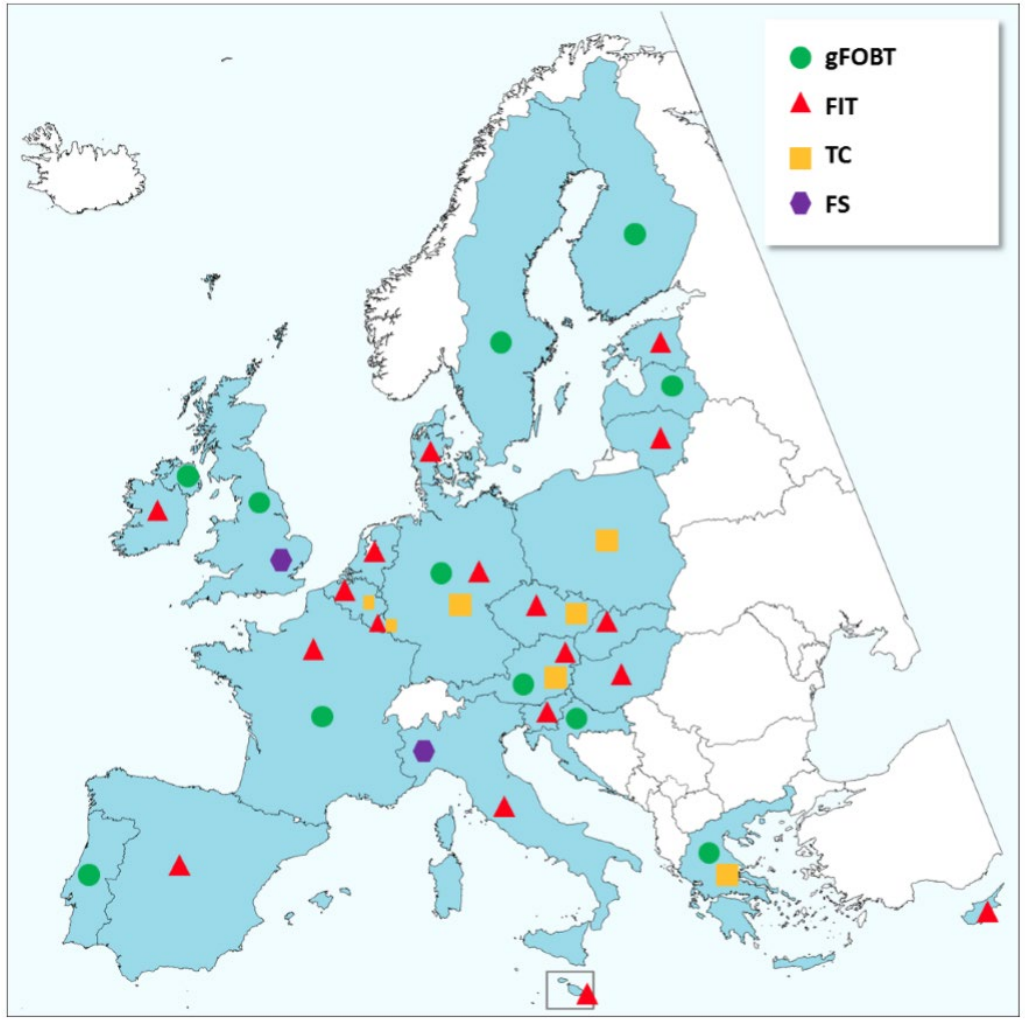
Characteristics of Stool Based Screening

“The best test is the one that gets done, and done well.”

-Dr. Sidney Winawer

FIT Screening Programs Worldwide

Testing Modalities in Europe (2016)

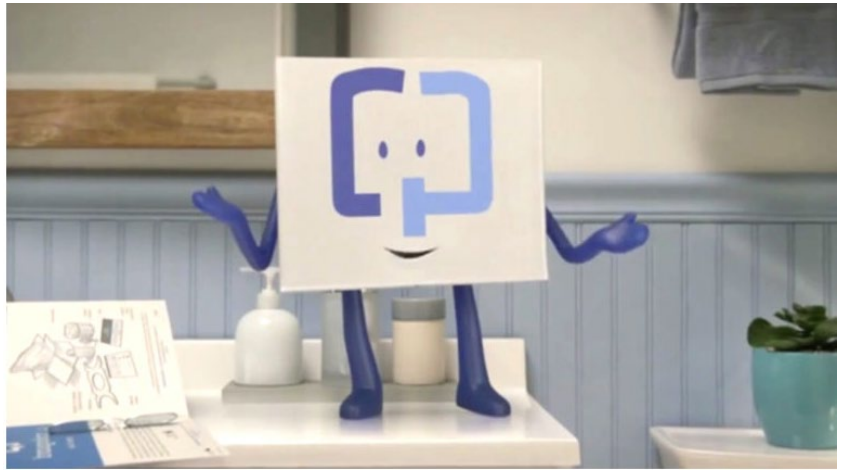


IARC, Against Cancer, 2017 (Linda Rabeneck)

RCTs for FIT vs Colonoscopy:

- CONFIRM (VA)
- COLONPREV (Quintero)
- TARGET-C (China)

Colorectal Cancer Screening: Stool Tests
FOBT, FIT, and Cologuard

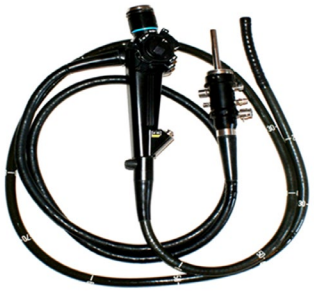


Steps of Stool-Based Testing

Stool Based Test: (gFOBT, FIT or mt-sDNA)

Negative Finding → Repeat screening at next interval

Positive Finding → Colonoscopy



Negative Consequences of Increasing Colonoscopy Time After Positive FIT

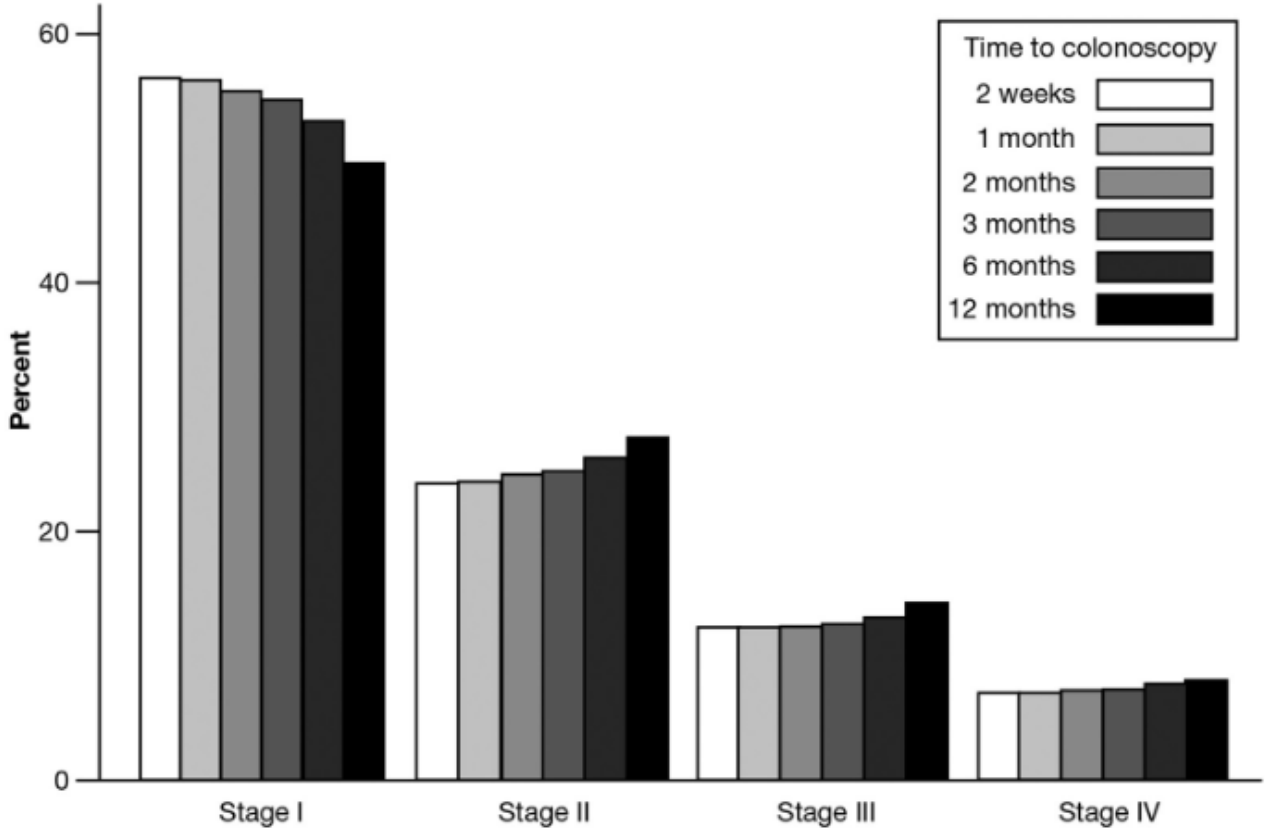
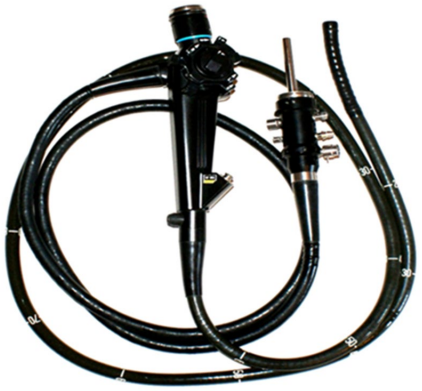


Figure 2. Stages of newly diagnosed CRC cases in FIT-positive patients according to time to diagnostic colonoscopy.

Meester et al, 2016 *Clinical Gastroenterology and Hepatology*

What Will it Cost?

$ ~800- 1,000*



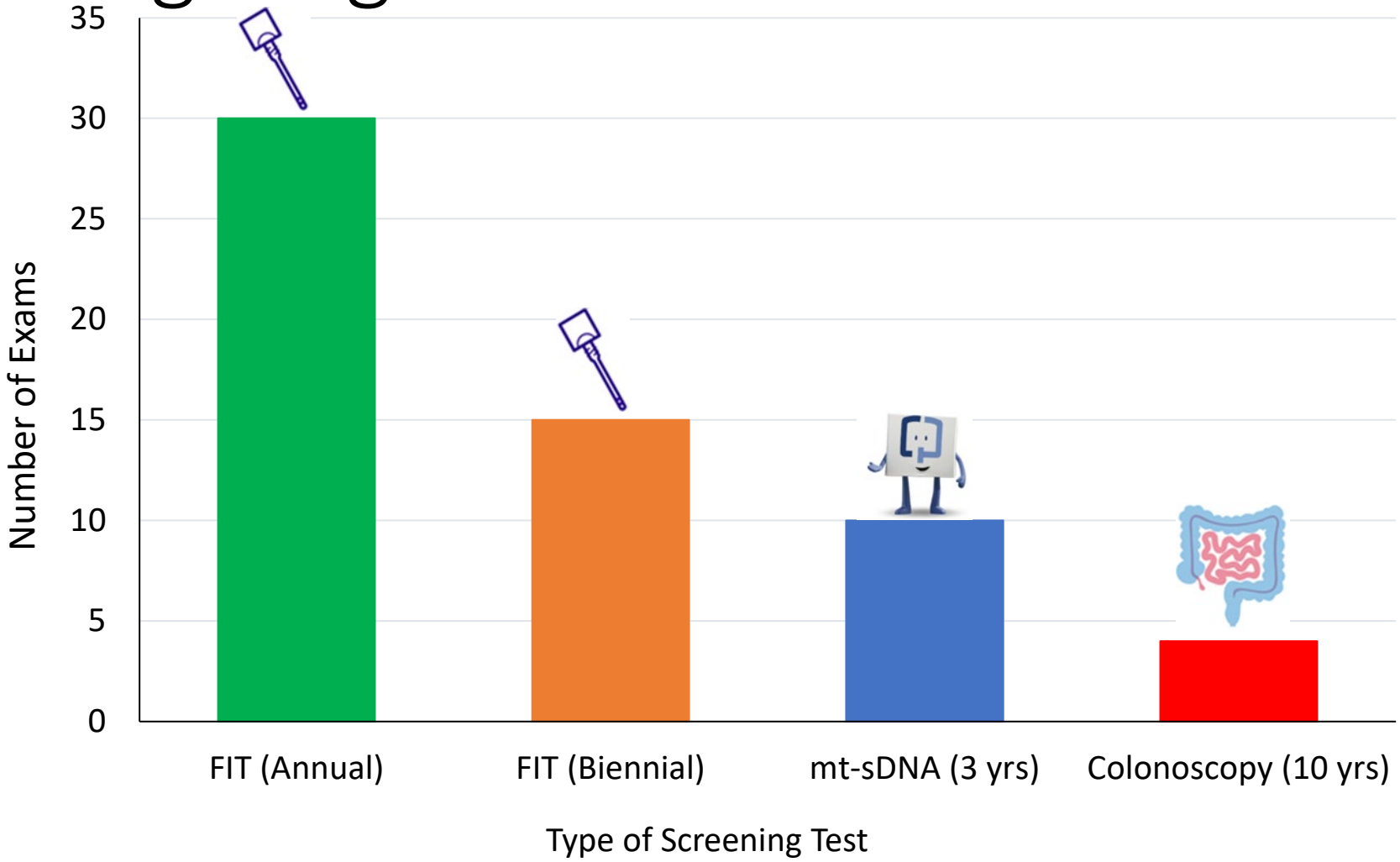
Costs with Medicare*

$ 595 - 695+

$ 25 - 35 +

Cost as Imperiale et al, 2021+
Funded by Exact Sciences

Screening Intervals and the Intensity of Screening – Ages 45-75



Hemoccult II:

- **Qualitative test**
- **Evidence Source:** RCTS
- **Reduction in CRC Incidence:** 17-20 %
- **Reduction in CRC Mortality:** 9-22%
  - 33% for hydrated slides

Ladabaum et al., 2020 *Gastro*

How Do Stool-Based Test Detect Hemoglobin?

- **gFOBT** uses the *pseudoperoxidase activity* of heme to detect the presence of blood in stool
  - Dietary modification, avoidance of nonsteroidal anti-inflammatory drugs and vitamin C are recommended to avoid false-positives and false-negatives, respectively
  - Three stool samples per each screening round

Ladabaum et al., 2020 *Gastro*

FIT Screening:

- **Evidence Sources:** observational studies and test characteristic studies
- **Reduction in CRC Incidence:** 10%
- **Reduction in CRC Mortality:** 22-62%

Ladabaum et al., 2020 *Gastro*

How Do Stool-Based Test Detect Hemoglobin?

- **FIT** uses an antibody to detect *hemoglobin* and is *not affected by diet*. It has largely replaced gFOBT
  - Only one stool sample is needed; greater adherence compared to gFOBT

Ladabaum et al., 2020 *Gastro*

Appropriate Messaging for Positive and Negative FITs

NHS SCOTLAND

Scottish Bowel Screening Centre
Kings Cross Hospital
Clepington Road
Dundee
DD3 8EA

Dear Mr. Smith,

Thank you for taking the time to do your bowel screening test.

Your result: We are pleased to tell you that your bowel screening test shows that no further investigation is required at this time.

What happens next?
We will send you another test in two years' time if you are still aged between 50 and 74. It's important that you do your bowel screening test every time you're invited. After that age you can still request a test by contacting the Bowel Screening Centre (details above).

Never ignore symptoms
It's important to remember that this test picks up most but not all bowel cancers. This is because the test looks for blood but not all cancers bleed all of the time. Remember that changes can happen in between your bowel screening tests so please tell your GP if you notice any of these symptoms:

Appropriate Messaging for Positive and Negative FITs

NHS SCOTLAND

Scottish Bowel Screening Centre
Kings Cross Hospital
Clepington Road
Dundee
DD3 8EA

Dear Mr. Smith,

Thank you for taking the time to do the bowel screening test.

Your result: The test you provided shows that further investigation is required.

This result doesn't mean you have cancer but it does mean that we need to check on the cause of the bleeding (the bowel screening test measures the amount of blood in your poo sample).

A colonoscopy is the best way of looking for the cause of bleeding. It can find bowel cancer at the earliest stage of the disease, when it's more treatable. It can also prevent cancer by removing polyps (small growths of cells on the bowel wall) during the test.

Cologuard (mt-sDNA)

- Qualitative test, multiple targets—FIT and DNA mutation:
  - BMP3
  - NDRG4
  - KRAS
  - β-actin
- Adherence support program for patient compliance
- Includes large serrated lesions
- No long-term mortality studies

$$(e^{\text{Sum of Scores}}) / (1+e^{\text{Sum of Scores}})) * 1000 = \text{multi-target stool DNA Composite Score}$$

(Imperiale et al, 2021, *Cancer Prevention Research)*

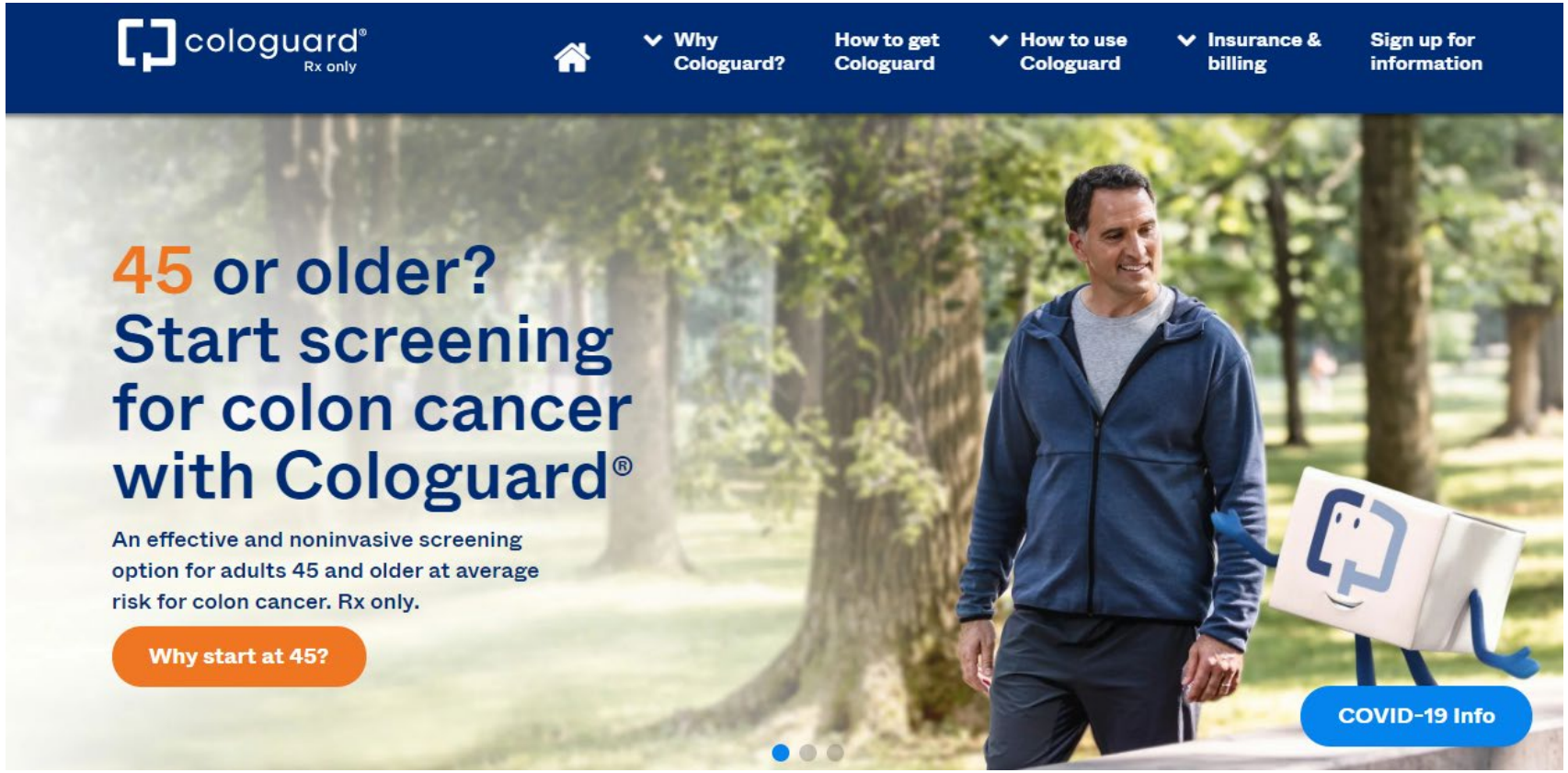
Cologuard:


SHIPPING BOX
SAMPLE CONTAINER
PROBE + TUBE
BRACKET
cologuard
PATIENT GUIDE INSTRUCTIONS
SAMPLE LABELS
BOTTLE OF LIQUID
(PRESERVATIVE)

Cologuard:


1 SIT
Cologuard® is ready to use when you are ready to use it.
2 SCRAPE
Use the kit components to collect your sample.
3 SOAK
Fill the sample container with the liquid preservative.
4 SHIP
Ship your sample to complete the process.

Cologuard:



Specificity 95% Among Age 45-49
(Imperiale et al, 2021, *Cancer Prevention Research)*

www.cologuard.com

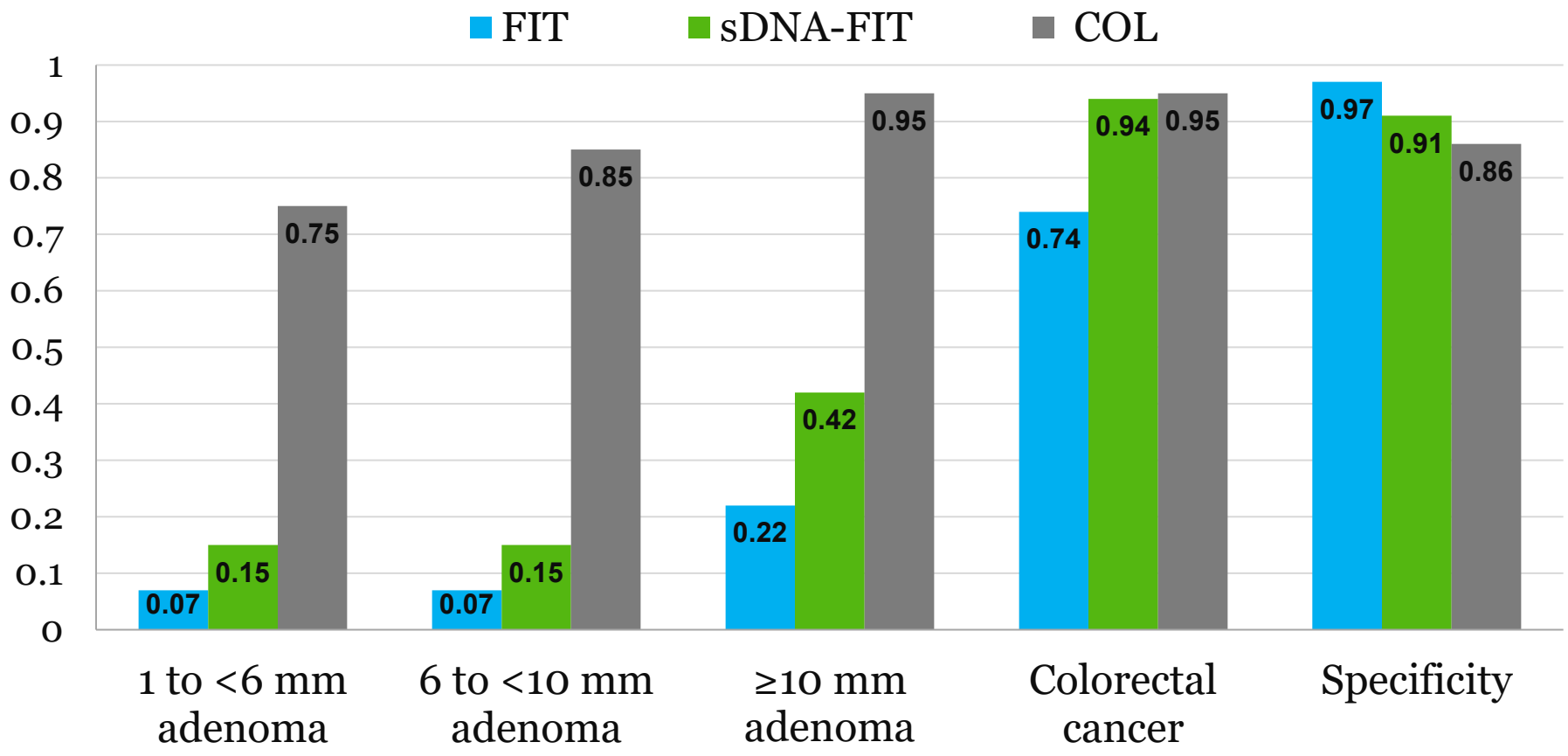
Diagnostic Accuracy of Stool Based Tests

Sensitivity and Specificity

Disease

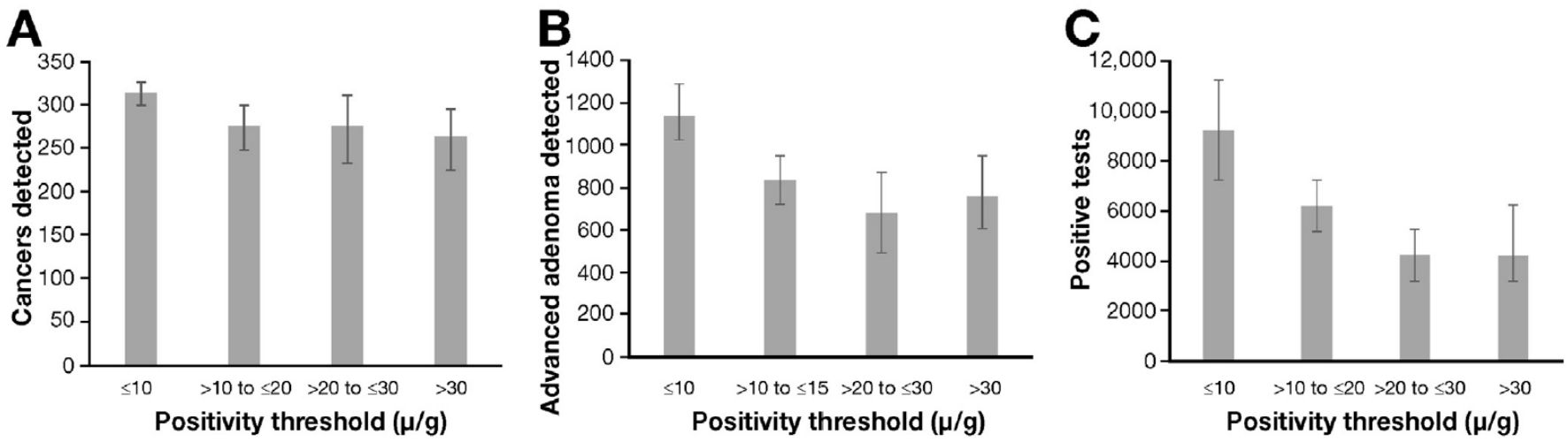
		Cancer	**No Cancer**
Test	**Positive**	Sensitivity (TP) ↓	False Positive →
	Negative	False Negative →	Specificity (TN) ↓

Sensitivity and Specificity (for one time test)



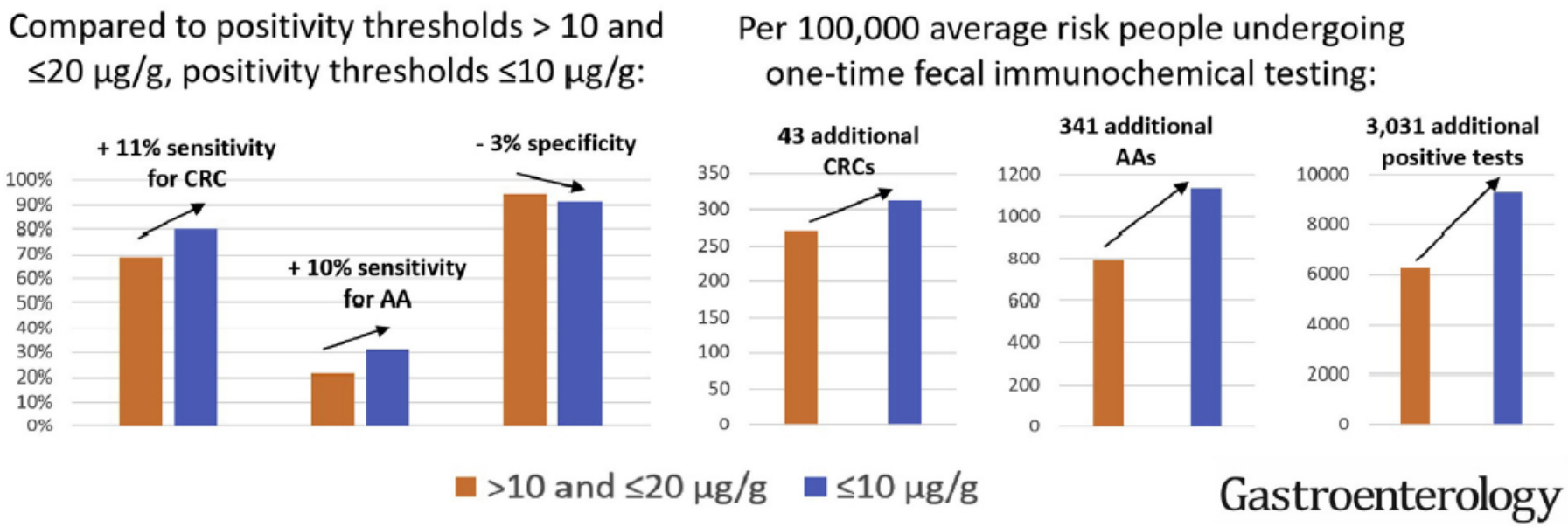
Lin et al, 2020 *Draft Evidence Report*

Quantitative FIT Performance



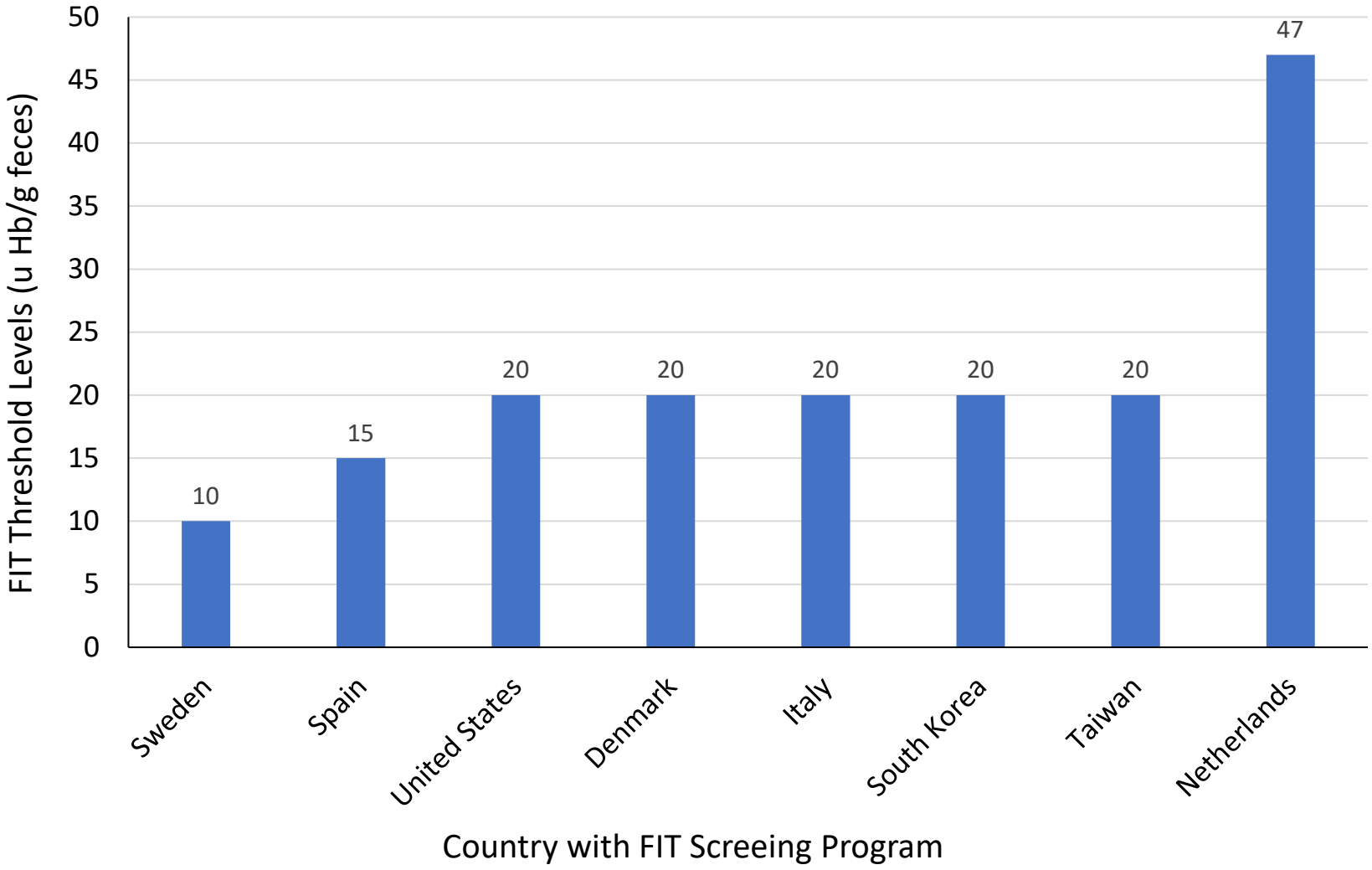
Selby et al, 2019 *Gastro*

Quantitative FIT Performance



Selby et al, 2019 *Gastro*

FIT Cut-Off By Screening Program Country

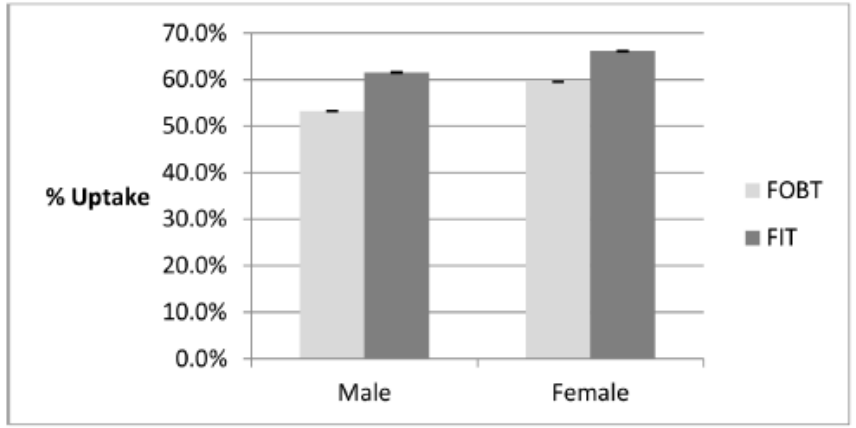


Kaminski et al, 2020 *Gastro*

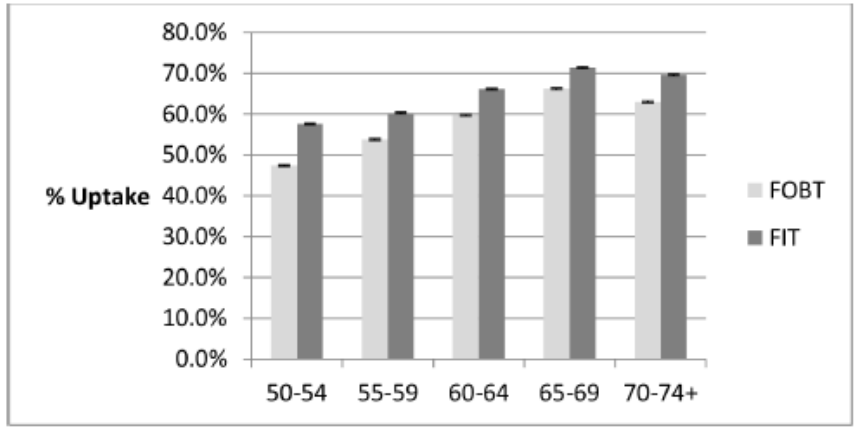
Adherence to Stool-Based Tests

Scottish Bowel Screening Program

Sex



Age



Clark G, et al. Gut 2021

Dutch National Screening Program

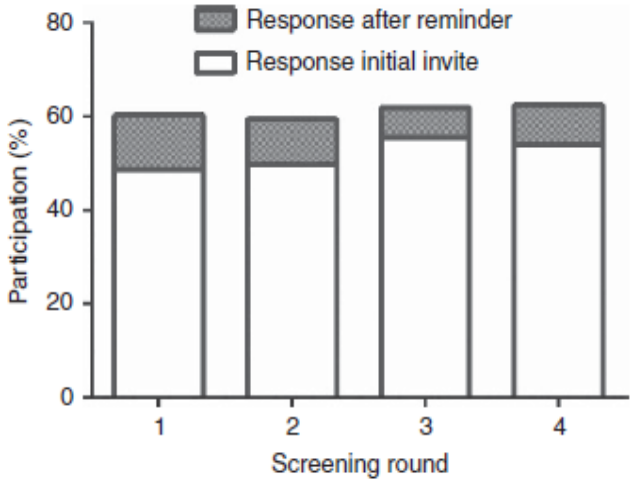


Figure 1. Overall participation per screening round with percentage distribution of type of response to participation (initial response *vs* response after reminder letter).

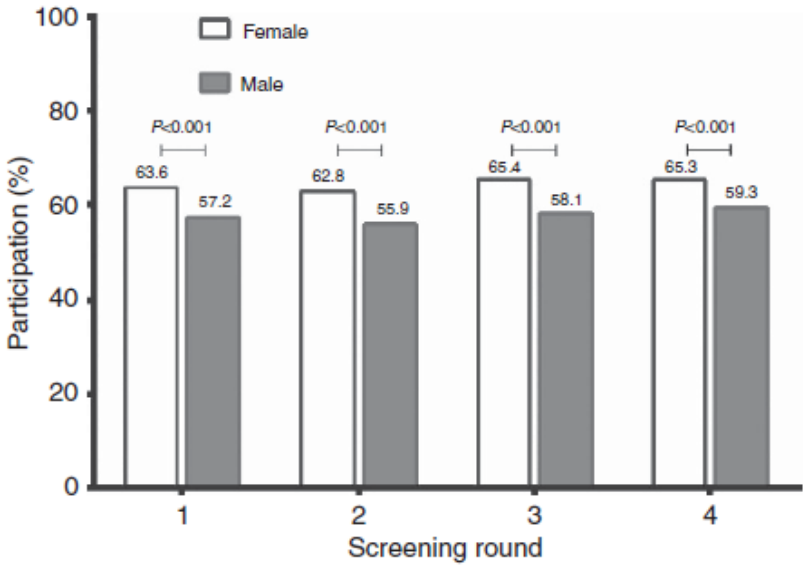
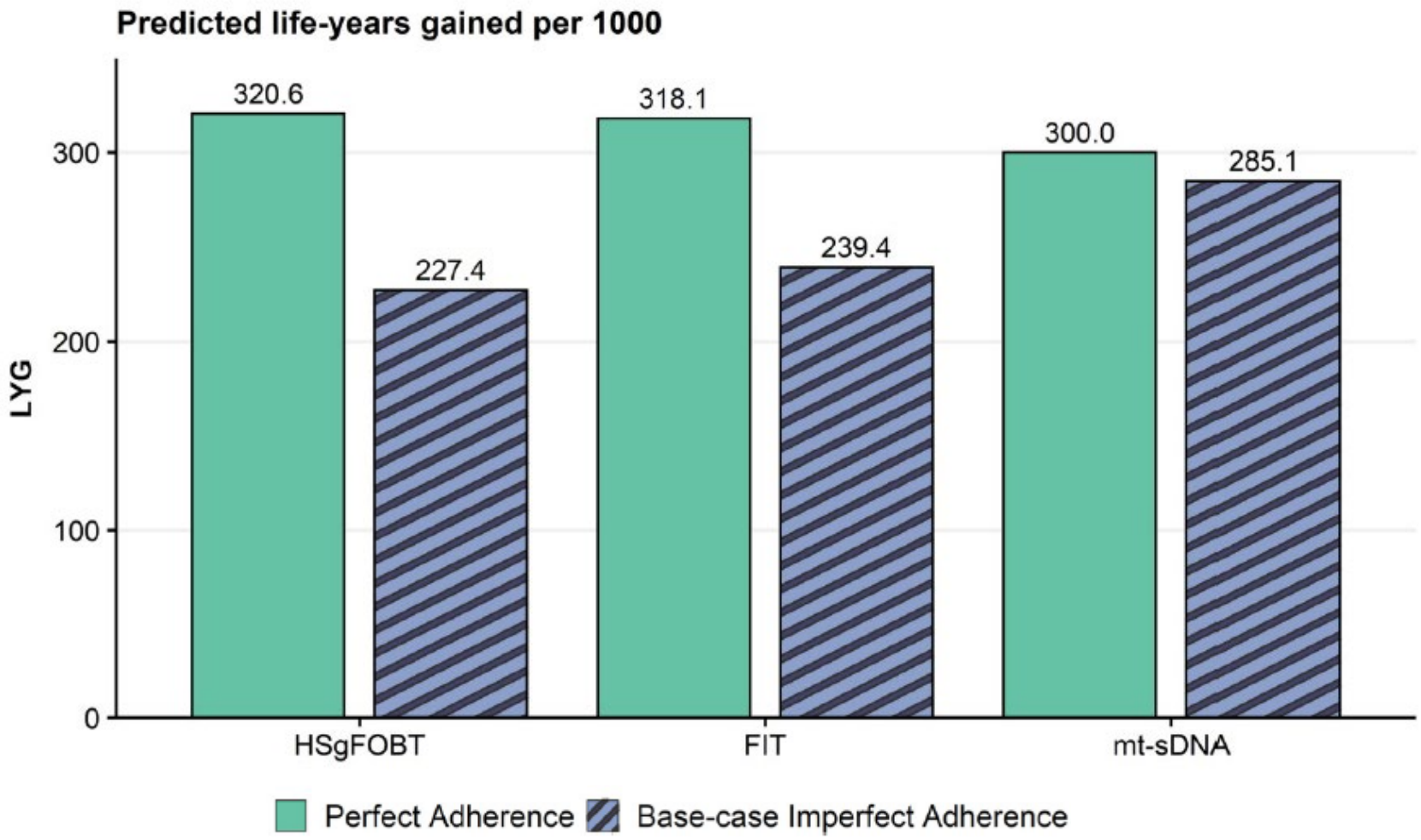


Figure 2. Participation rates per round of FIT-based screening subdivided by sex.

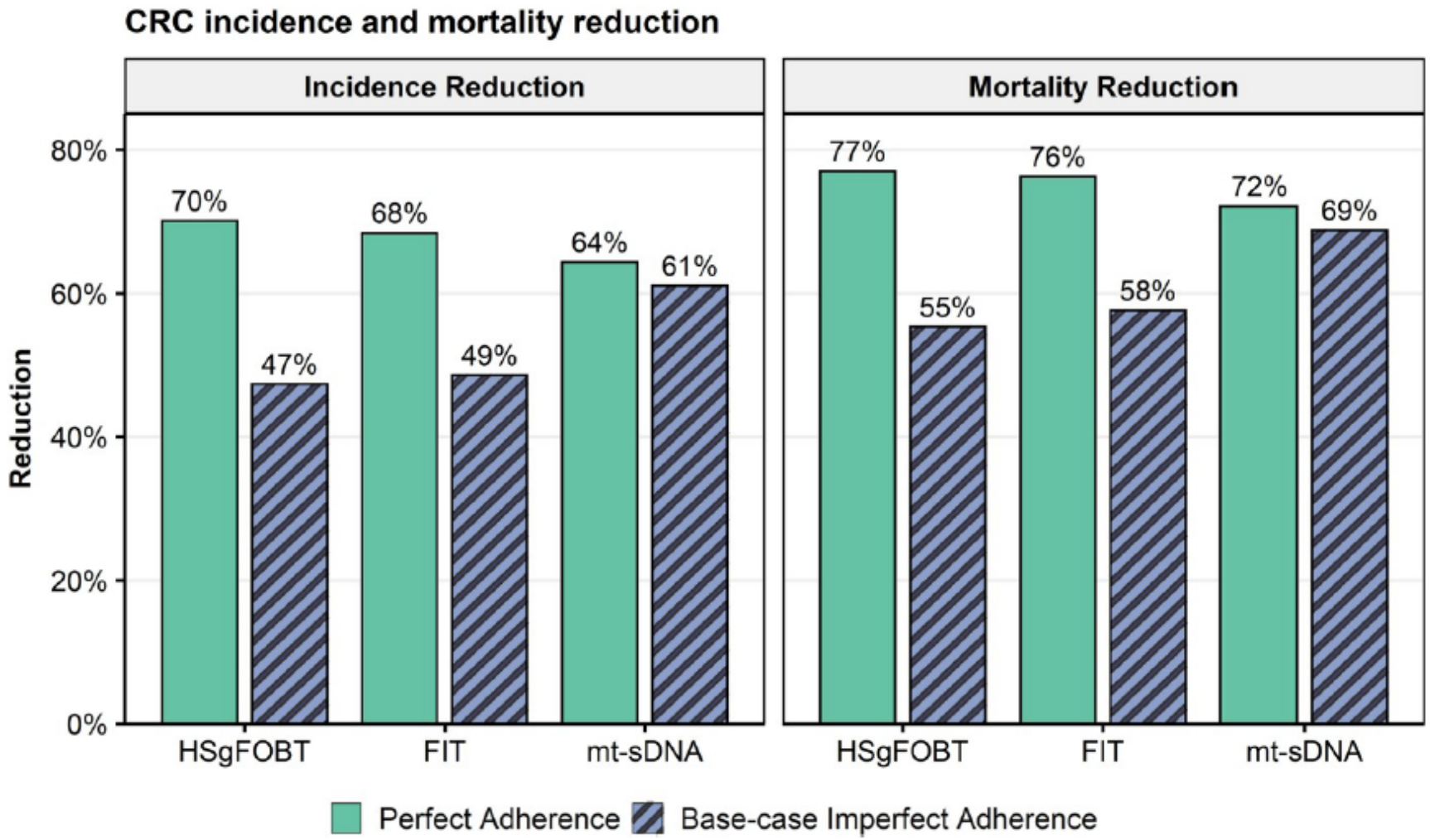
van der Vlugt et al., 2017 BJC

CRC-AIM: 100% Adherence vs. Imperfect Adherence (70% mt-sDNA & 40% FIT)



Piscitello et al., 2020 *PLOS*

CRC-AIM Incidence and Mortality



Piscitello et al., 2020 *PLOS*

2020 United States Preventive Services Task Force
DRAFT Recommendations

USPSTF Draft Age to Begin Screening Recommendations 2020

Recommendation Summary

Population	Recommendation	Grade
Adults ages 50 to 75 years	The USPSTF recommends screening for colorectal cancer in all adults ages 50 to 75 years. See the "Practice Considerations" section and Table 1 for details about screening strategies.	A
Adults ages 45 to 49 years	The USPSTF recommends screening for colorectal cancer in adults ages 45 to 49 years. See the "Practice Considerations" section and Table 1 for details about screening strategies.	B
Adults ages 76 to 85 years	The USPSTF recommends that clinicians selectively offer screening for colorectal cancer in adults ages 76 to 85 years. Evidence indicates that the net benefit of screening all persons in this age group is small. In determining whether this service is appropriate in individual cases, patients and clinicians should consider the patient's overall health and prior screening history.	C

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IN PROGRESS

USPSTF Draft Screening Tests Recommendations 2020

Stool Based Exam	Frequency
HsgFOBT	Annual
FIT	Annual
mt-sDNA	1 or 3 years*
Direct Visualization Exam	**Frequency**
Colonoscopy	Every 10 years
CTC	Every 5 years
Flex-sig	Every 5 years
Flex-sig with FIT	Flex-sig every 10 years and yearly FIT

*suggested by manufacturer

USPSTF Draft Screening Tests Recommendations 2020

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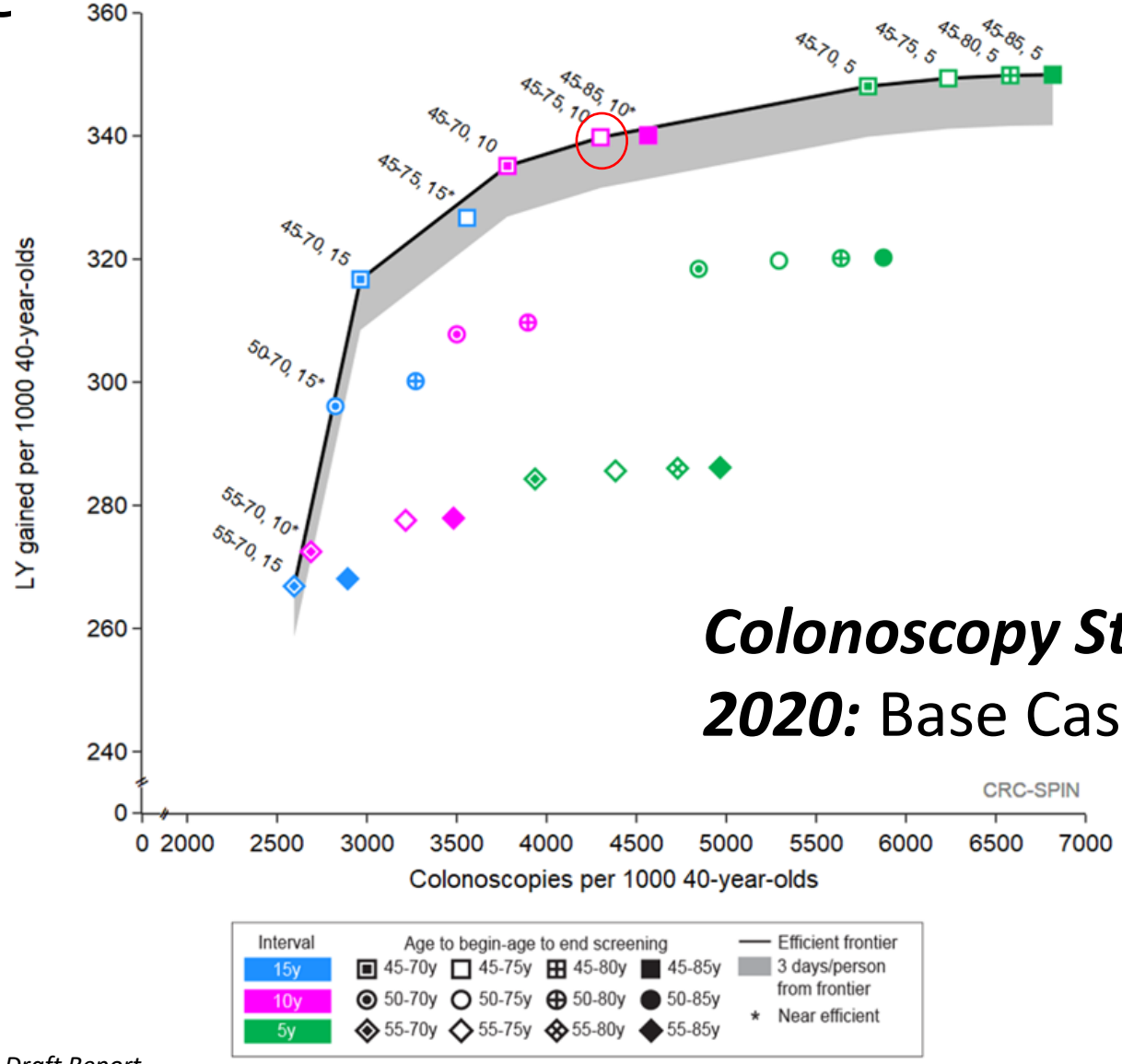
*suggested by manufacturer

IN PROGRESS

US Preventive Service Task Force

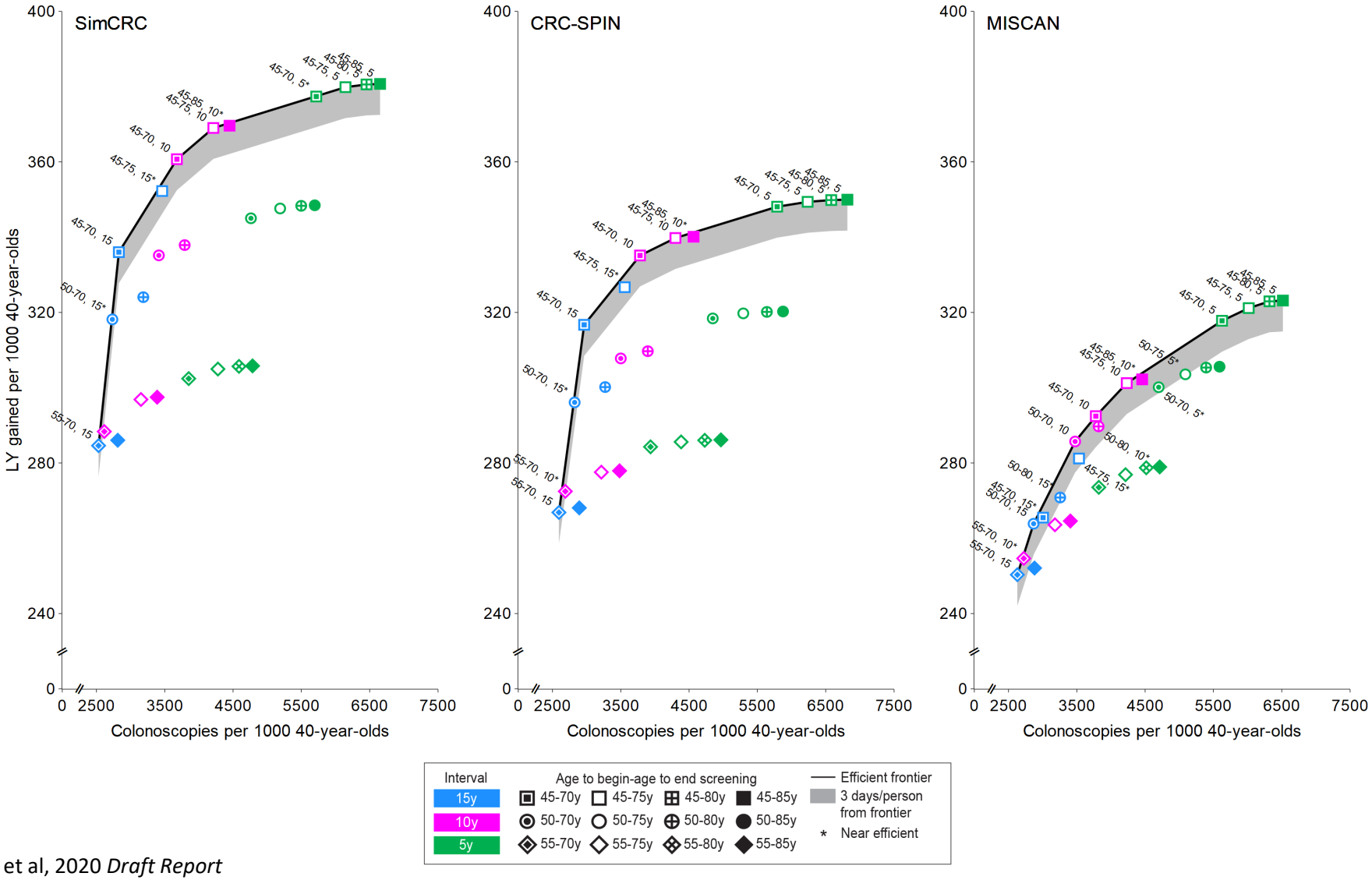
LYG and Number of Colonoscopies



Colonoscopy Strategies 2020: Base Case IRR=1.19

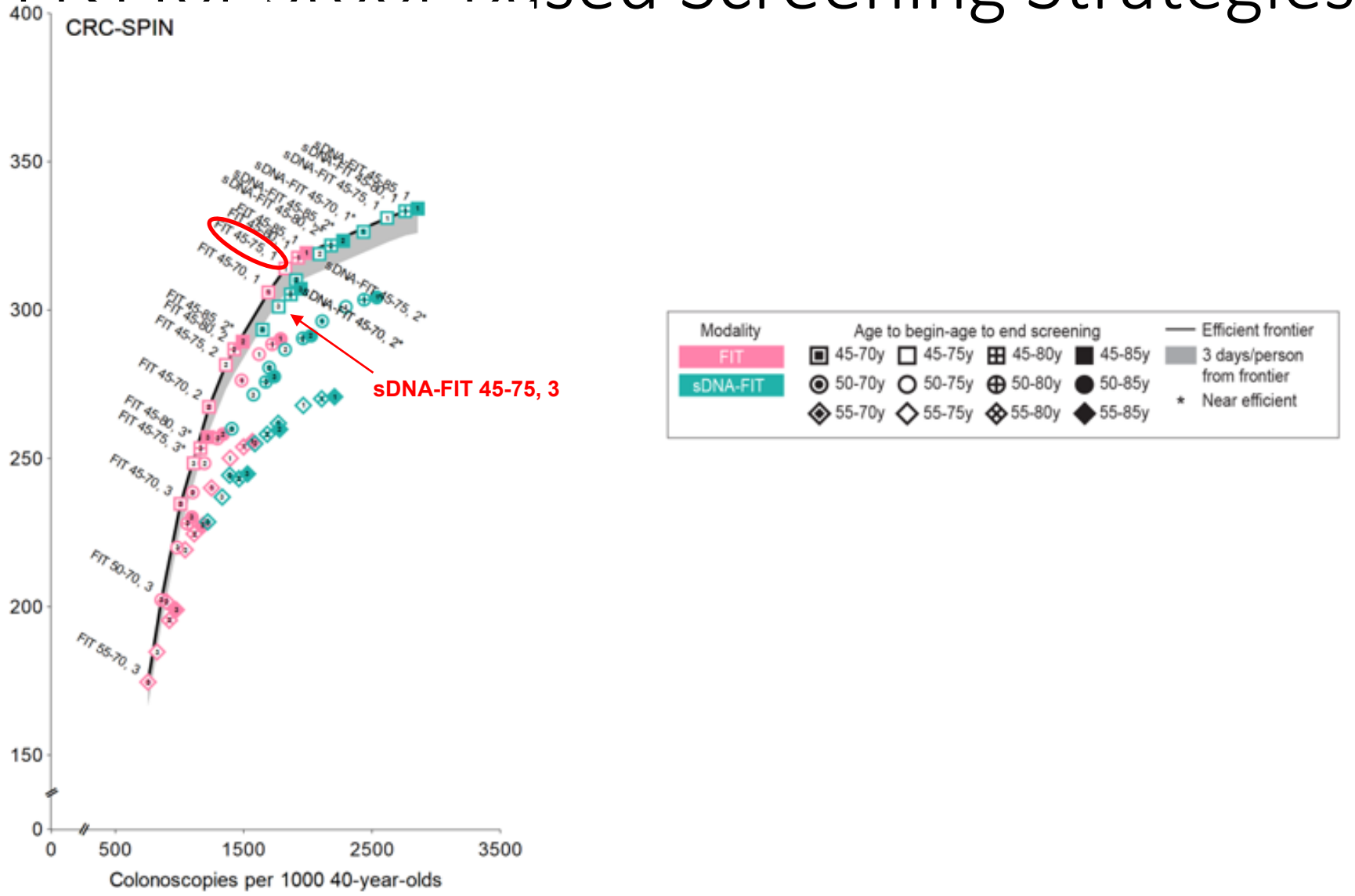
Knudsen et al, 2020 *Draft Report*

Life Years Gained and Lifetime Number of Colonoscopies:



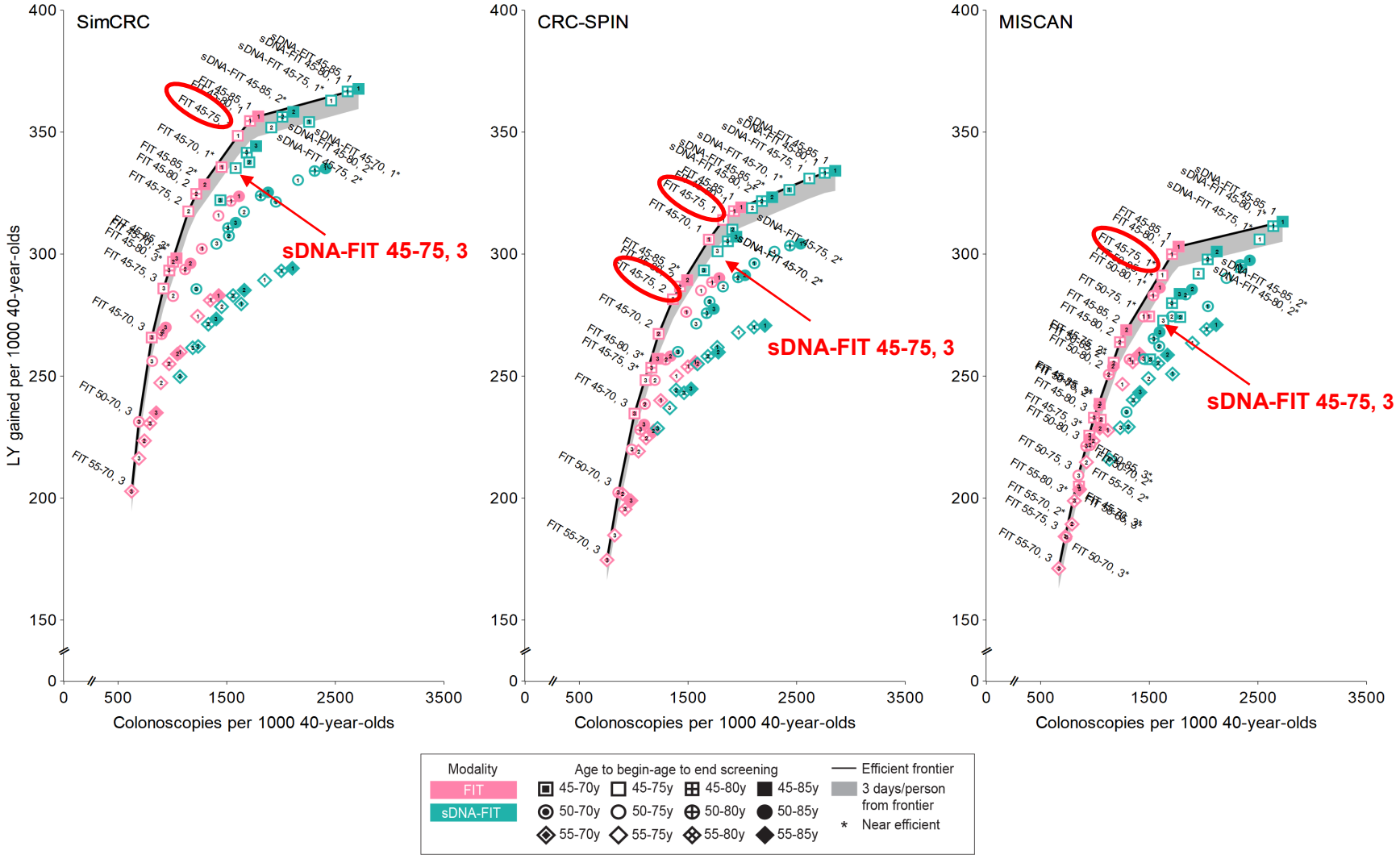
Knudsen et al, 2020 *Draft Report*

Lifetime Number of Colonoscopies and LYG for Stool-Based Screening Strategies



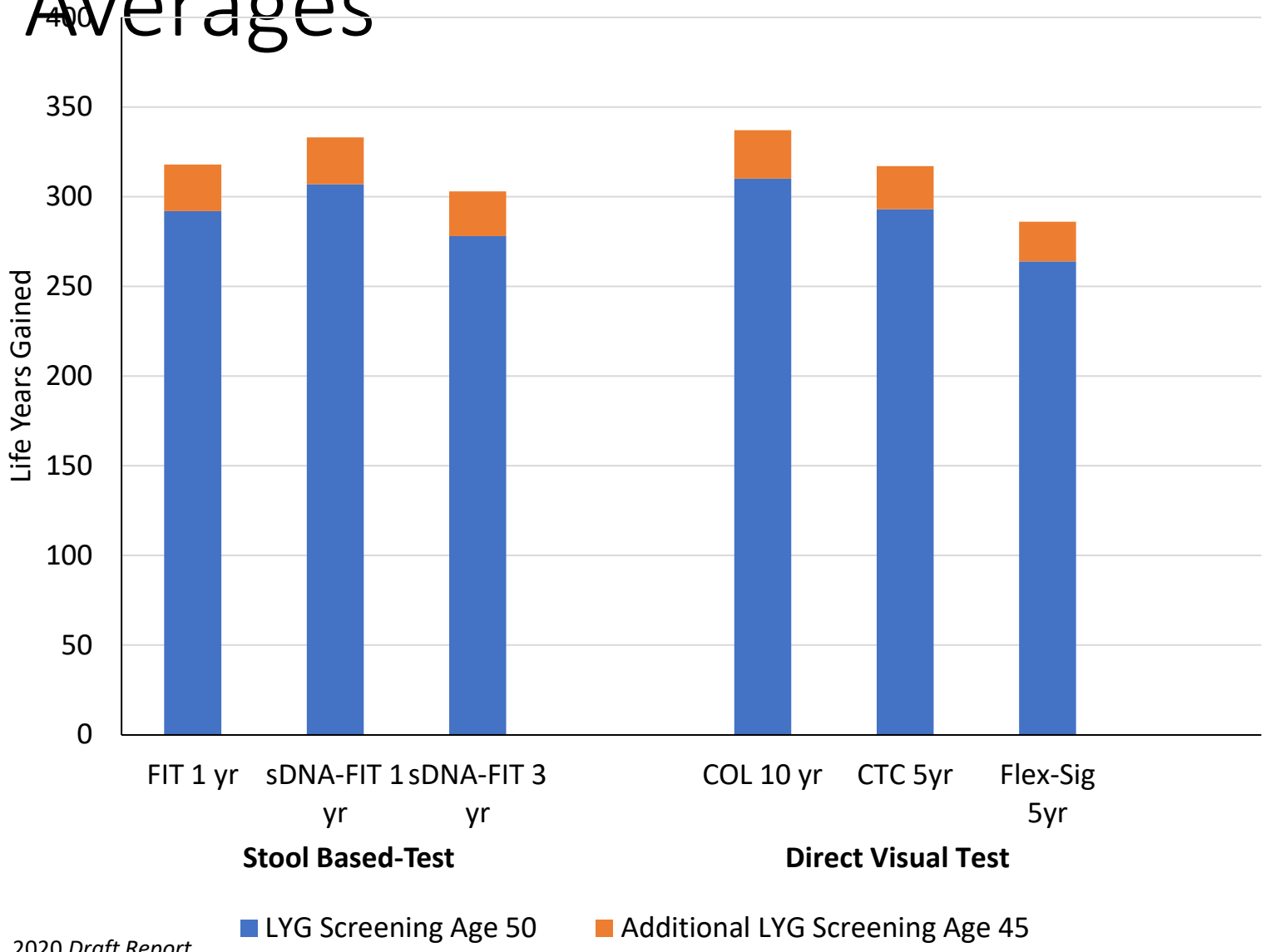
Knudsen et al, 2020 *Draft Report*

FIT and sDNA FIT Screening Modalities:



Knudsen et al, 2020 *Draft Report*

Life Years Gained By Age to Begin Screening, Model Averages



Knudsen et al, 2020 *Draft Report*

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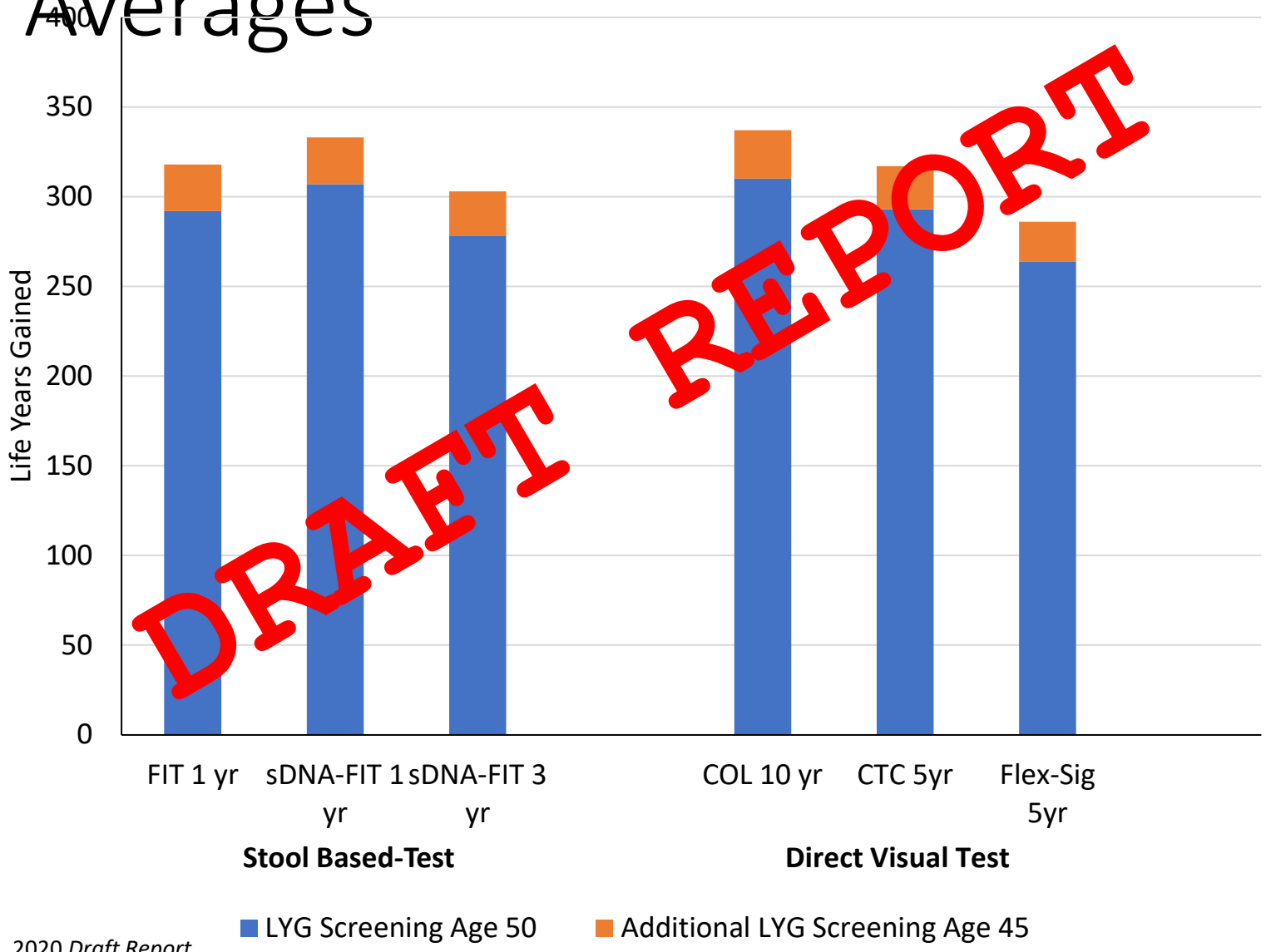


Knudsen et al, 2020 *Draft Report*

Summary

- The increase of early-onset CRC appears to be a birth cohort effect
- Current guidelines are in favor of an earlier age to screen, although with debate
- Stool based exams may ***offer a less invasive method*** to screen for CRC
- Adherence, along with the diagnostic accuracy of all screening exams are crucial to detect CRC

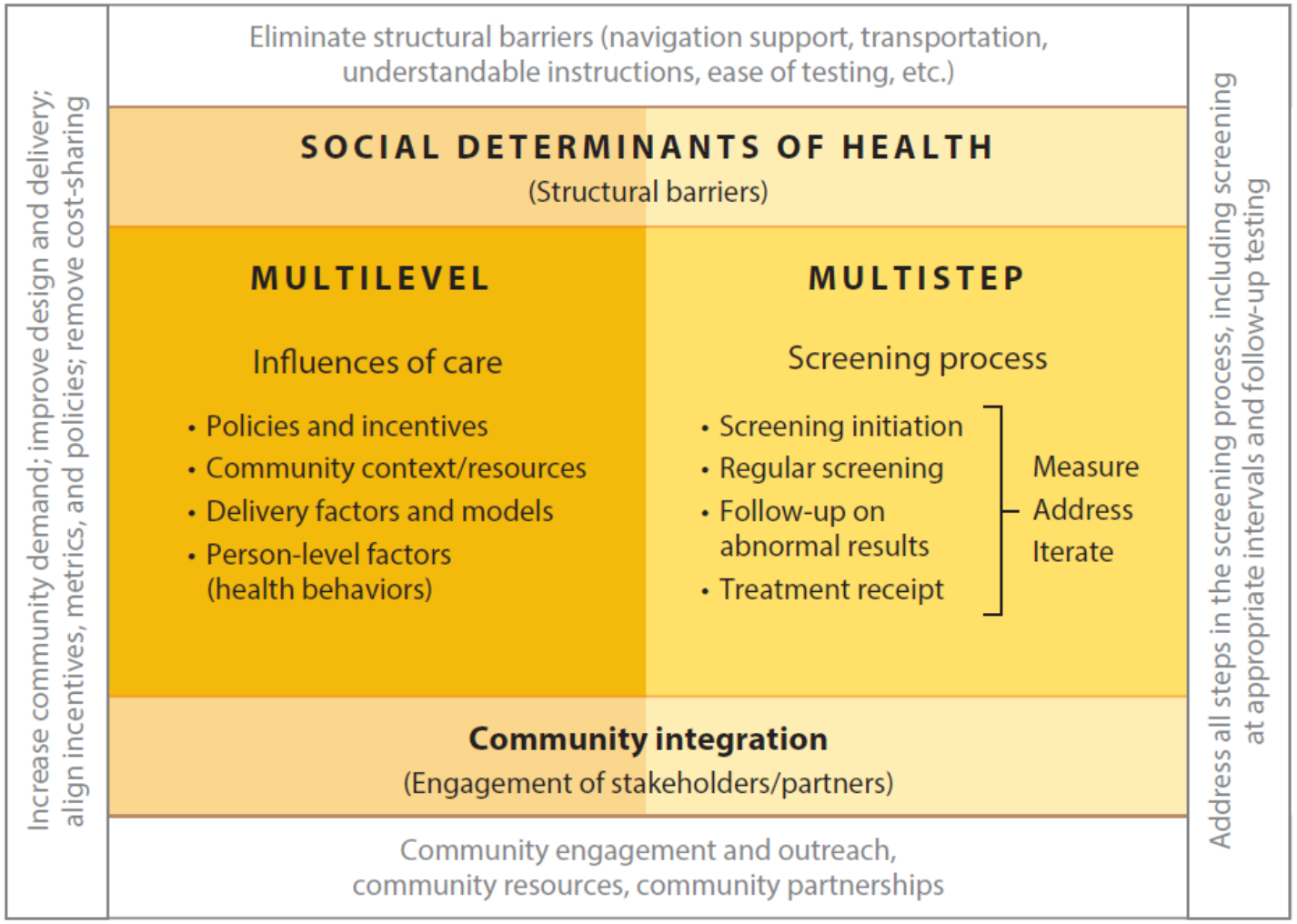
The Need for Health Equity

MAJOR STRATIFICATIONS OF DISPARITIES IN COLORECTAL CANCER SCREENING OUTCOMES

1. Race/ethnicity
2. English proficiency/language
3. Immigrant status
4. Educational level
5. Income
6. Insurance coverage
7. Occupation
8. Age
9. Sex/gender
10. Geography (neighborhoods, county, state, rural versus urban, etc.)
11. Behavioral risk factors (e.g., obesity)

Doubeni et al, Annual Reviews 2021

The Need for Health Equity



Doubeni et al, Annual Reviews 2021

Summary

"The best test is the one that gets done, and done well."

-Dr. Sidney Winawer

- Willingness to do testing
- Ease of testing
- Reliable diagnostic accuracy
- Burden of intervals
- Follow-up of colonoscopy with positive stool test
- Adherence to a program with repeat testing
- CRC Screening can reduce colorectal incidence and colorectal cancer mortality

Thank You!

The Kaiser Permanente Northern California Colorectal Cancer Screening Program: Lessons for the Pandemic and Beyond

- T. R. Levin, MD
- TPMG Clinical Lead for CRC Screening
- TPMG Assistant Chair of Gastroenterology
- Research Scientist, DOR

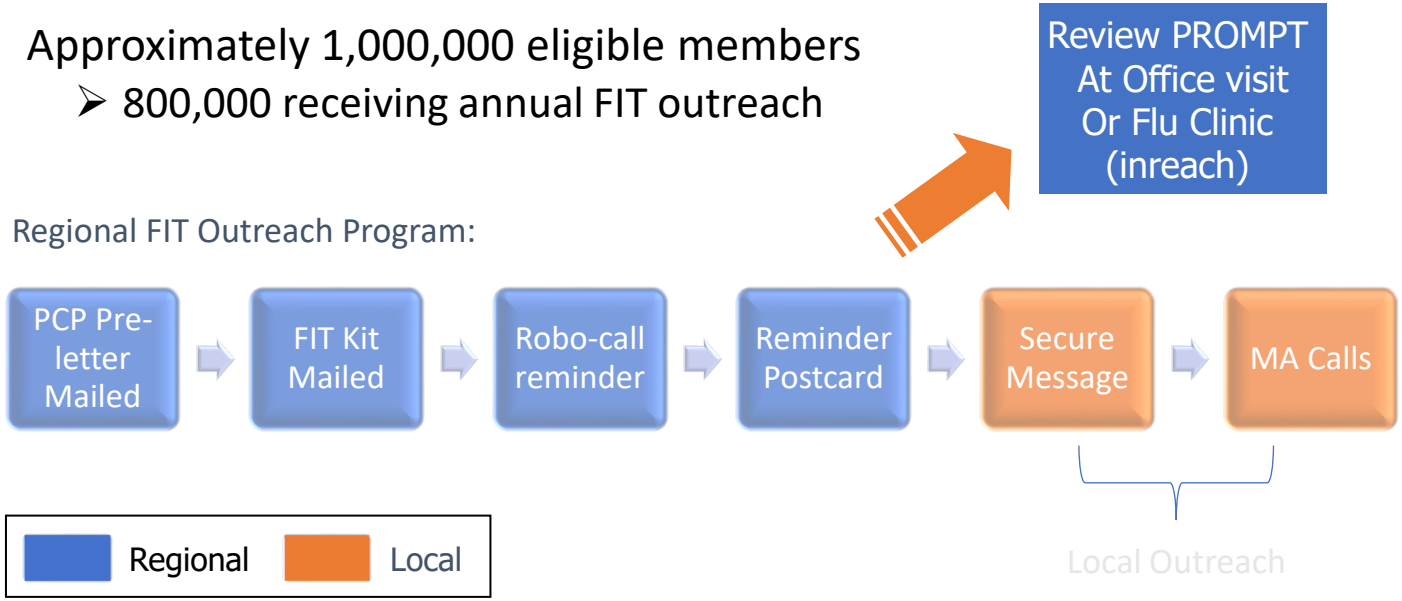
KAISER PERMANENTE®

KPNC CRC Screening Program

PERMANENTE MEDICINE
The Permanente Medical Group

Overview: KPNC CRC screening program

- All members 51-75
- Approximately 1,000,000 eligible members
  - ➢ 800,000 receiving annual FIT outreach



Colonoscopy by referral: high risk, or by referral, particularly 65-75 year olds

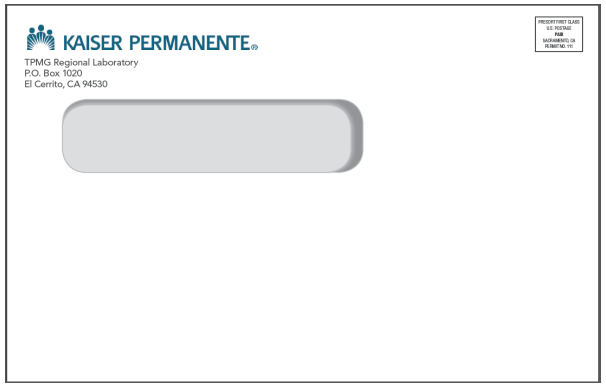
Regional FIT Kit Outreach

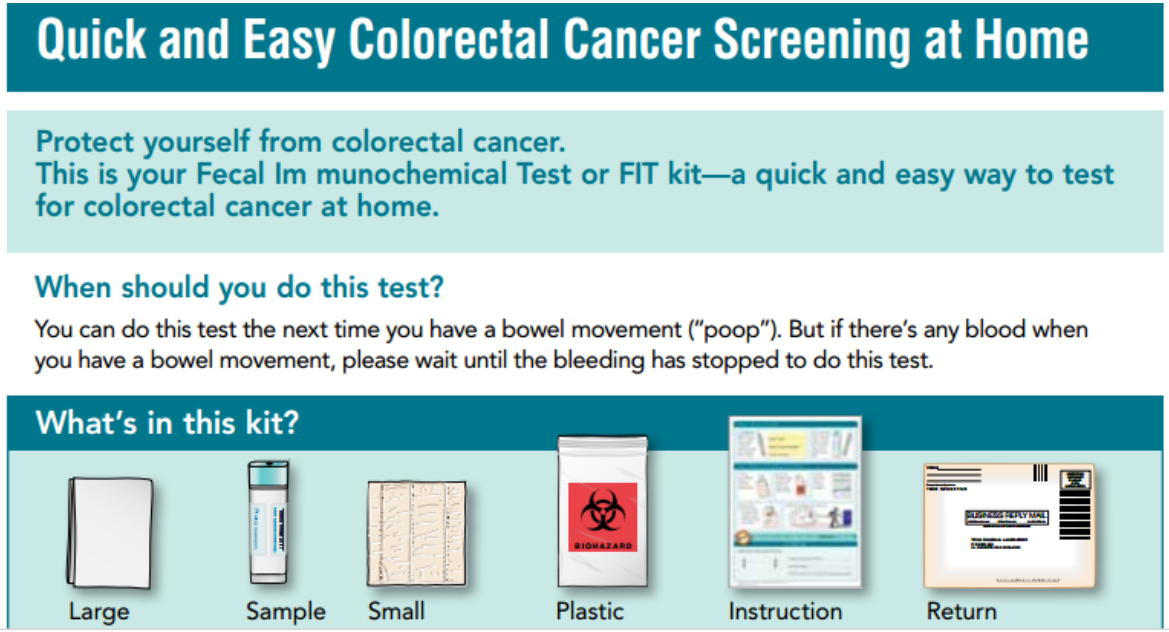
- All average risk members, due for CRC screening, ages 50-75 receive annual FIT kit outreach. Average risk African American members age 45-49 also receive outreach

Pre-eLetter or print letter mailed → **FIT Kit mailed** → **Robo-call reminder** → **Reminder eLetter or print letter**

FIT Kit (Touch 2)

- Mailed to member, labeled with MRN, PCP
- Includes instructions on how to complete test
- Includes postage-paid return envelope
- Member must write in collection date and mail within 2 days of taking sample





Quick and Easy Colorectal Cancer Screening at Home

Protect yourself from colorectal cancer.
This is your Fecal Im munochemical Test or FIT kit—a quick and easy way to test for colorectal cancer at home.

When should you do this test?

You can do this test the next time you have a bowel movement ("poop"). But if there's any blood when you have a bowel movement, please wait until the bleeding has stopped to do this test.

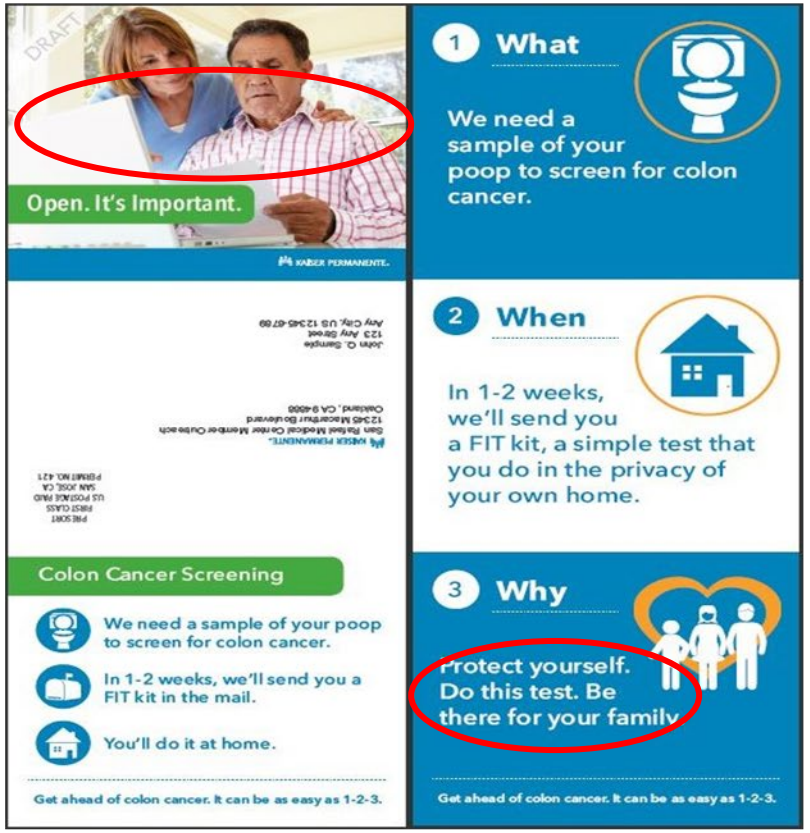
What's in this kit?

Targeted Outreach to Address Screening Disparities

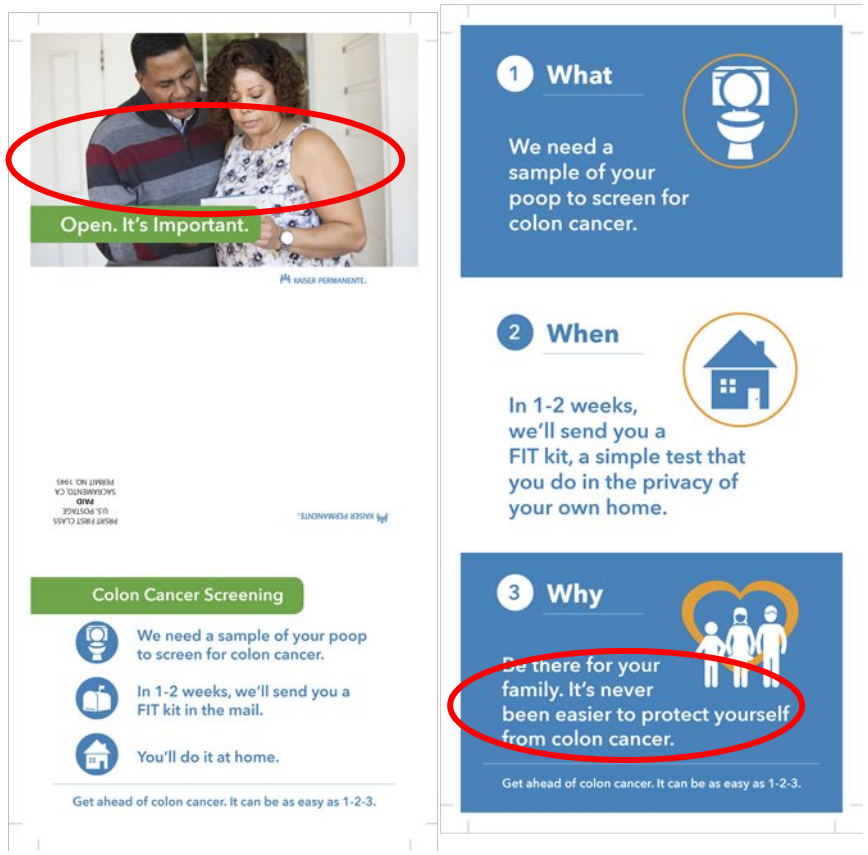
- Lower screening rates among Latinx and African American population
- Created targeted outreach
  - Use of existing outreach system (from standard outreach)
  - Focus groups co-designed content
  - Piloted new materials before regionalizing

Subtle Changes Across Cultural Groups

Latinx Outreach



African American Outreach



Provider facing information about where patients are in the CRC screening program

APM	Value		Actions
- CRC	due	remind or give FIT Last: Due: 12/19/2018	Rooming ▼ Outreach ▼

Colorectal Cancer Screening & Surveillance (PROMPT)

Colorectal cancer screening for members 50-75 years is done using one of three tests, depending on member risk.

FIT Testing is an annual stool sample test for average risk members. It can be completed at home.
Colonoscopy is an endoscopic procedure that requires prep and a referral to GI. This procedure is done every 10 years, or as recommended by a gastroenterologist.
Cologuard is an alternative at-home stool sample test for appropriate average risk candidates. Cologuard requires a referral to GI.

Screening History

Last Colonoscopy: N/A
Last Sigmoidoscopy: N/A
Last FIT: N/A
Last Cologuard: N/A
Last Plan: N/A

History

02/14/2019	regional letter sent
02/11/2019	eLetter sent
01/03/2019	regional FIT sent
12/24/2018	regional letter sent
12/19/2018	eLetter sent

+ Hold History

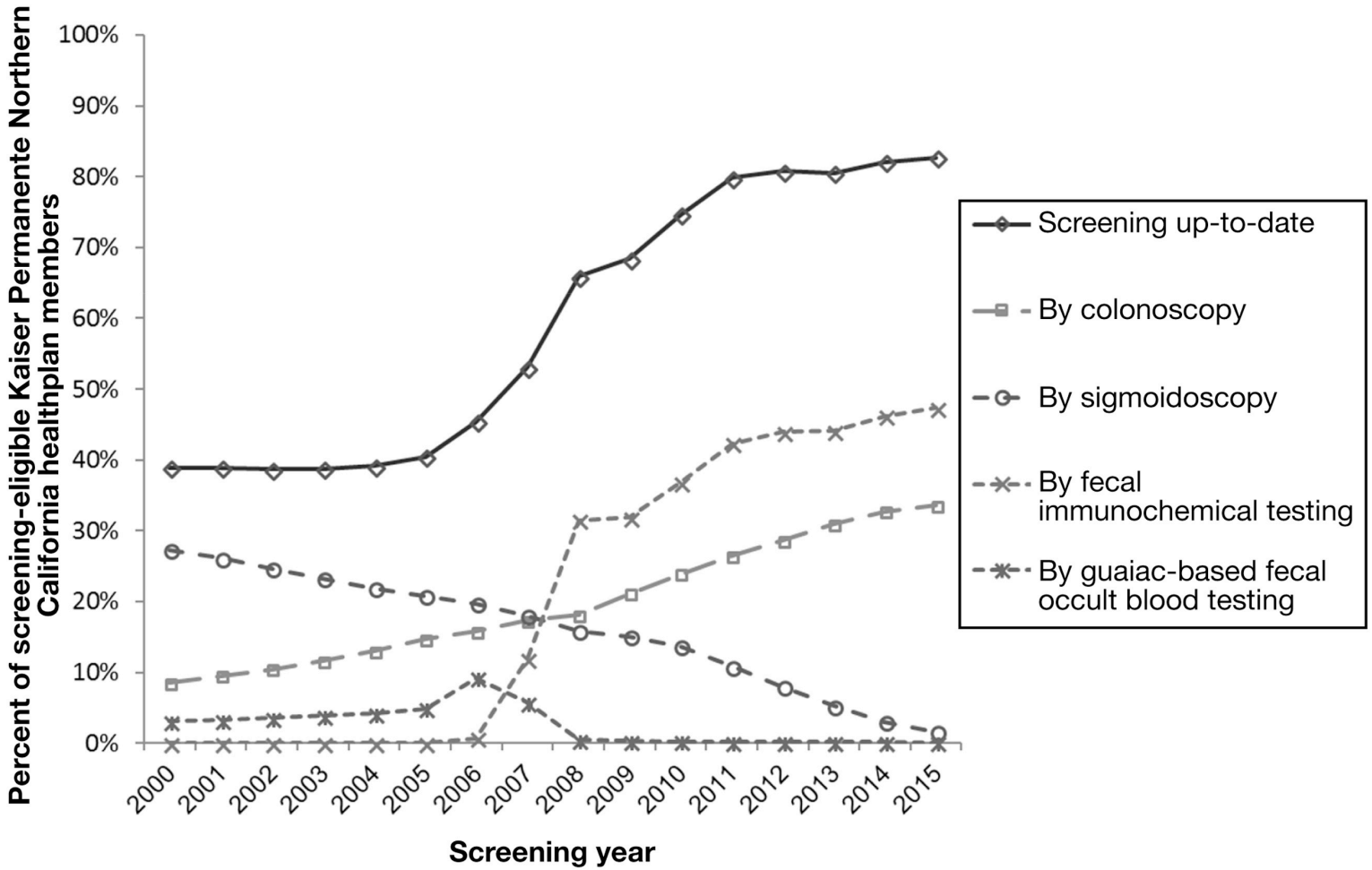
+ Plan History

The PROMPT drawer tells you the latest outreach the member received.

Outcomes of the CRC Screening Program

PERMANENTE MEDICINE
The Permanente Medical Group

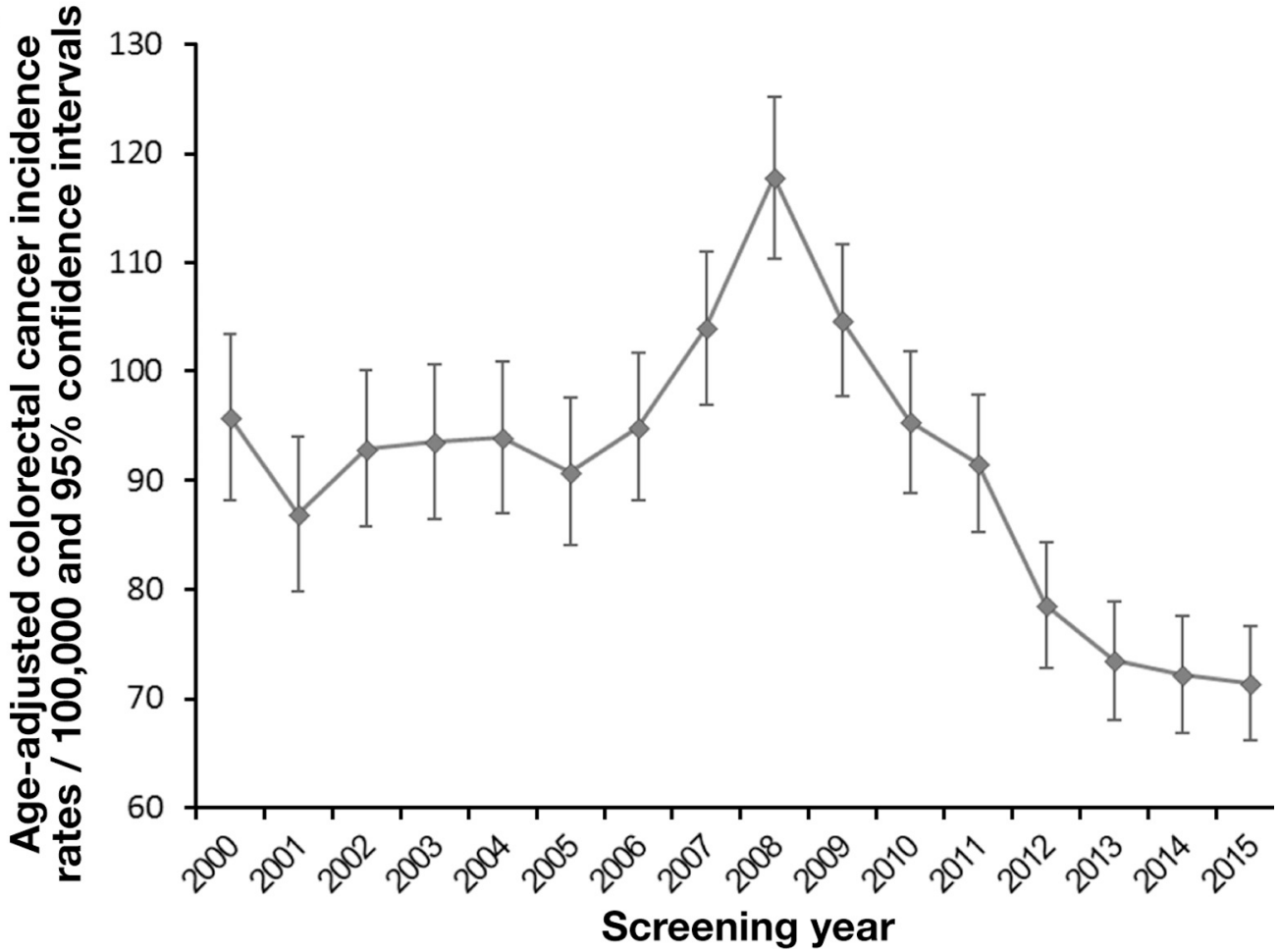
Impact on Test Use and CRC Screening Rates



Levin TR, Corley DA. Gastroenterology 2018;155:1383–1391

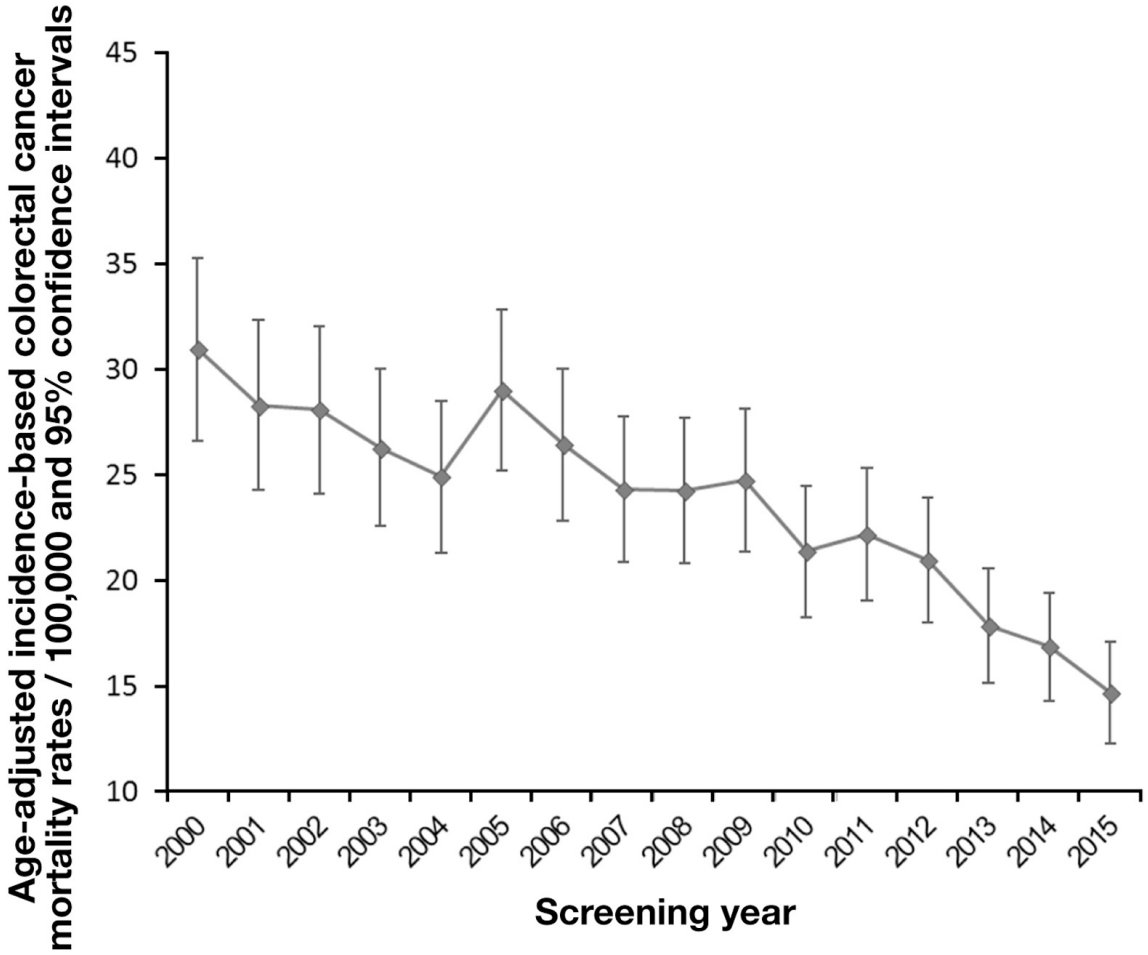
https://doi.org/10.1053/j.gastro.2018.07.017

Impact on Colorectal Cancer Incidence



Levin TR, Corley DA. Gastroenterology 2018;155:1383–1391

Impact on Colorectal Cancer Mortality



Levin TR, Corley DA. Gastroenterology 2018;155:1383–1391

Early Screening of African Americans (45–50 Years Old) in a Fecal Immunochemical Test–Based Colorectal Cancer Screening Program

Levin, Jensen, et al.
Gastroenterology 2020;159:1695–1704

Funded by TPMG Delivery Science Research Program

Multi-Society Task Force: 2017 Guideline

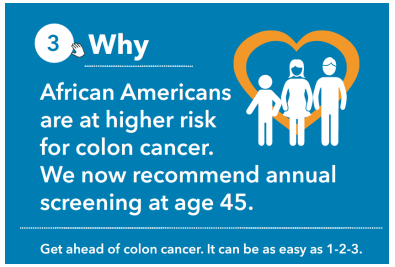
Tier 1
Colonoscopy every 10 years
Annual fecal immunochemical test
Tier 2
CT colonography every 5 years
FIT-fecal DNA every 3 years
Flexible sigmoidoscopy every 10 years (or every 5 years)
Tier 3
Capsule colonoscopy every 5 years
Available tests not currently recommended
Septin 9

Start at age 50, except African Americans start at 45

Rex, et al. *Am J Gastroenterol* 2017; 112:1016–1030

Regional African American tailored outreach, age 45-49

Pre-postcard → FIT Kit → Robocall → Reminder Postcard → Local Outreach



1 week before kit

1 week after pre-postcard

4 weeks after kit

6 weeks after kit

Comparisons to 51-56 with no prior screening

Characteristic	African American 51-56	African American 51-56	White 51-56	Hispanic 51-56	Asian Pacific Islander 51-56
Total, n	10,232	3603	22,832	10,930	8893
Complete FIT, n (%)	3390 (33.1)	805 (22.3)	6772 (29.7)	2905 (26.6)	2960 (33.3)
FIT+, n (%)	136 (4.0)	37 (4.6)	309 (4.6)	116 (4.0)	113 (3.8)
FIT+ colo, n (%)	116 (85.3)	30 (81.1)	245 (79.3)	92 (79.3)	84 (74.3)
Adv Adnoma n (%)	39 (33.6)	6 (20.0)	70 (28.6)	24 (26.1)	19 (22.6)
CRC, n (%)	3 (2.6)	1 (3.3)	10 (4.1)	0 (0.0)	6 (7.1)
Symptoms 1 year prior	336 (3.3)	77 (2.1)	202 (0.9)	128 (1.2)	118 (1.3)

Levin, Jensen, et al. Gastroenterology 2020;159:1695–1704

Comparison to 51-56 with and without prior screening

Characteristic	African American 51-56	African American 51-56	White 51-56	Hispanic 51-56	Asian Pacific Islander 51-56
Total, n	10,232	12,621	80,753	34,915	36,947
Complete FIT, n (%)	3390 (33.1)	7447 (59.0)	52,996 (65.6)	20,860 (26.6)	26,095 (70.6)
FIT+, n (%)	136 (4.0)	201 (2.7)	1610 (3.0)	584 (2.8)	744 (2.9)
FIT+ colo, n (%)	116 (85.3)	170 (84.6)	1371 (85.2)	507 (86.8)	632 (84.9)
Adv Adnoma, n (%)	39 (33.6)	35 (20.6)	256 (18.76)	75 (14.8)	82 (13.0)
CRC, n (%)	3 (2.6)	3 (1.8)	20 (1.5)	4 (0.8)	12 (1.9)

Levin, Jensen, et al. Gastroenterology 2020;159:1695–1704

American Cancer Society Guideline

The ACS recommends that people at average risk of colorectal cancer **start regular screening at age 45 (qualified recommendation)**. This can be done either with a sensitive test that looks for signs of cancer in a person's stool (a stool-based test), or with an exam that looks at the colon and rectum (a visual exam).

Wolff CA CANCER J CLIN 2018;68:250–281

Alternative View

Gastroenterology 2019;157:137–148

Cost-Effectiveness and National Effects of Initiating Colorectal Cancer Screening for Average-Risk Persons at Age 45 Years Instead of 50 Years

Uri Ladabaum,[1] Ajitha Mannalithara,[1] Reinier G. S. Meester,[1] Samir Gupta,[2] and Robert E. Schoen[3]

CONCLUSIONS: In a Markov model analysis, we found that starting CRC screening at age 45 years is likely to be cost effective. However, greater benefit, at lower cost, could be achieved by increasing participation rates for unscreened older and higher-risk persons.

USPSTF Guideline (Draft)

Recommendation Summary

Population	Recommendation	Grade
Adults ages 50 to 75 years	The USPSTF recommends screening for colorectal cancer in all adults ages 50 to 75 years. See the "Practice Considerations" section and Table 1 for details about screening strategies.	A
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A = high certainty, substantial benefit; B = moderate certainty, moderate benefit;
C = moderate certainty, small net benefit

www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening

New ACG Guideline

	Summary	Recommendation strength	GRADE quality of evidence
1	We recommend colorectal cancer (CRC) screening in average-risk individuals between ages 50 and 75 yr to reduce incidence of advanced adenoma, CRC, and mortality from CRC	Strong	Moderate
2	We suggest CRC screening in average-risk individuals between ages 45 and 49 yr to reduce incidence of advanced adenoma, CRC, and mortality from CRC	Conditional	Very low
4	We recommend colonoscopy and fecal immunochemical testing (FIT) as the primary screening modalities for CRC screening	Strong	Low

ACG Clinical Guidelines: Colorectal Cancer Screening 2021

Shaukat, A; Kahi, CJ; Burke, CA; Rabeneck, L; Sauer, BG.; Rex, DK.

ACG116(3):458-479, March 2021. doi: 10.14309/ajg.0000000000001122

Conclusions

- It may be reasonable to start screening at 45 for African Americans or for people of all races, but the overall incidence remains very low
- FIT represents an excellent way to efficiently select patients for colonoscopy only to those most likely to benefit from it.

Impact of the COVID-19 Pandemic on Colorectal Cancer Screening and Surveillance Outcomes (PICASO)

Funded by the Garfield Memorial Fund
Of The Permanente Federation

PERMANENTE MEDICINE
The Permanente Medical Group

COVID 19 Disruption in CRC screening

- March 2020: elective colonoscopies were halted nearly everywhere
- Pause in care delivery has affected millions across the US
- Patients continue to delay needed diagnostic and follow-up colonoscopies due to fear of infection
- Scheduling is more complex now due to need to also schedule Sars-CoV-2 testing
- Disruptions worldwide
  - NCI estimates approximately 10,000 excess deaths in the US alone from breast cancer and CRC (based on CISNET models)
  - IQVIA modeling study: 18,800 Americans may experience delays in CRC diagnosis this year.

Sharpless NE. COVID-19 and cancer. *Science* 2020;368:1290
Aitken M, Kleinrock M. Shifts in healthcare demand, delivery, and care during the COVID-19 era: Tracking the impact in the United States. IQVIA Institute for Human Data Science 2020
Dekker E, Gastroenterology 2020 ePub https://doi.org/10.1053/j.gastro.2020.09.018

Strategies for Shaping a COVID-19–Adapted Future for CRC Screening and Prevention

Remind patients and providers that CRC screening saves lives.
Ensure participation by offering patients multiple options for screening.
Expand the pool of patients participating in screening.
For individuals with greater than average CRC risk base on an abnormal screening test, family history of CRC, or prior history of adenoma or CRC, prioritize and emphasize importance of colonoscopy follow-up.
Make endoscopy as safe as possible.
Prepare for a future in which the role of colonoscopy in screening will shift increasingly toward diagnosis, therapy, and surveillance, and away from asymptomatic screening.

COVID, coronavirus disease-19; CRC, colorectal cancer.

Gupta and Lieberman. Gastroenterology 2020;159:1205–1208
https://doi.org/10.1053/j.gastro.2020.06.091

Pandemic Impact on CRC Screening

AIM:

Evaluate the impact of the pandemic on CRC screening at KPNC.

METHODS:

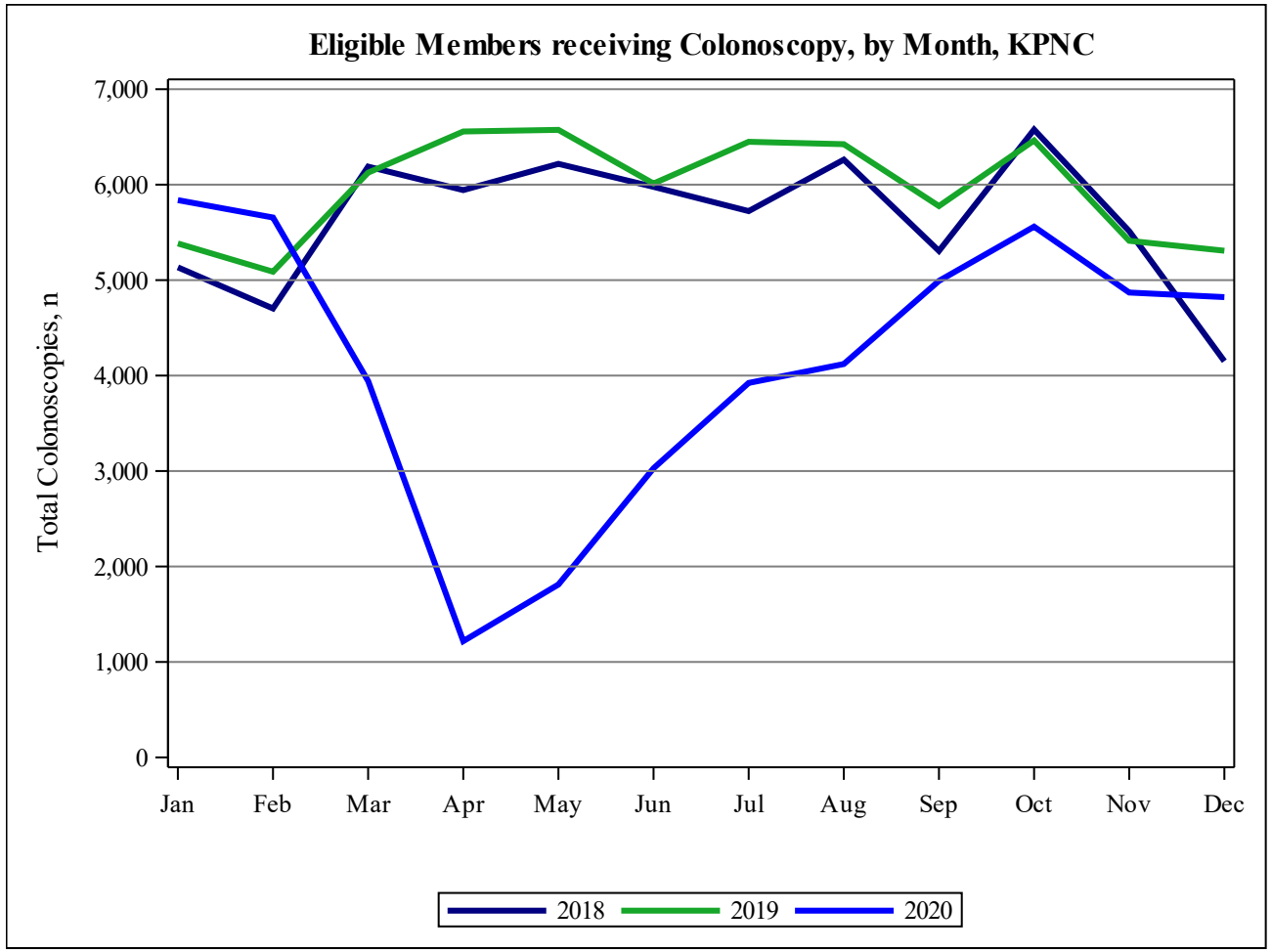
Compare January-December 2019 and January-October 2020

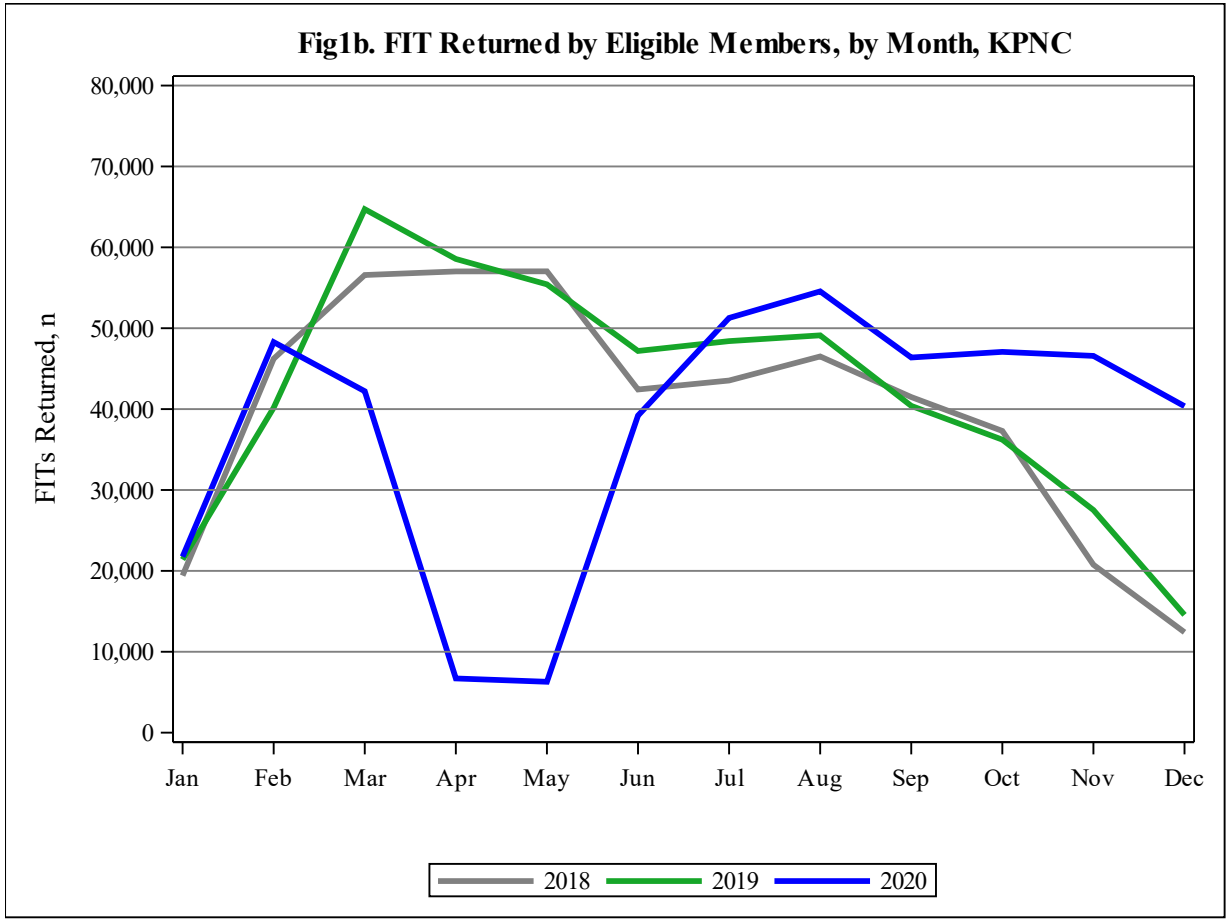
Evaluating:

- KPNC screening-eligible population aged 50-75;
- Those up to date with screening due to colonoscopy;
- Eligible for a FIT;
- Mailed a FIT kit;
- Completed a FIT;
- Completed a follow-up colonoscopy after a positive FIT;
- Completed a colonoscopy unrelated to a positive FIT;
- Up to date with screening by end of follow-up
  (i.e., 2019 and end of October 2020, respectively).

Results

Parameter	2019	2020 (up to end of October)
Eligible For CRC Screening	913,873	941,763
Up To Date from Prior Colo	151,252	150,407
Eligible for FIT	762,621	791,356
FIT returned completed, n (%)	504,152 (66.1)	365,972 (46.2)
Positive FIT, n (%)	15,402 (3.1)	10,922 (2.9)
Colonoscopy follow-up of positive FIT by year-end, n (%)	11,119 (72.2)	6,856 (62.8)
Colonoscopy Unrelated to FIT	14,420	9,902
Up To Date with CRC Screening, n (%)	665,541 (72.8)	522,215 (55.5)





Conclusions

- The COVID-19 pandemic resulted in temporary delays in the mailing and return of FITs, but the organized program allowed rapid resumption of screening as soon as it was feasible

- There was a reduction in colonoscopies performed, due, in part, to patient reluctance to complete follow-up colonoscopy during the pandemic

- Thank you!

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Discussion

EAO Workgroup: Upcoming Opportunities

01 Research Learning Series – Session #5

May 4, 2021 – 12-2 pm EST
Pt. 2: Equitable access to screening among 45-49
Registration coming soon!

02 2021 EAO CRC International Symposium

June 24 & 25, 2021. 11:30-3:30 EST
The 2021 symposium will include action-based dialogue between patients, advocates, clinicians, and researchers, and collaborative discussion of the successes and gaps in EAO CRC research and clinical care.

Registration and abstract submissions opening March 31, 2021


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