Carmen E. Guerra, M.D., MSCE, FACP

Disclosure of Commercial Interest

It is the policy of the Prevent Cancer Foundation and the Nurse Practitioners in Women's Health that the education presented at CE-certified activities will be unbiased and based on scientific evidence. To help participants make judgments about the presence of bias, the Prevent Cancer Foundation provides information that faculty have disclosed about financial relationships they have with commercial entities that produce or market products or services related to the content of this educational activity.

There will not be any off-label and/or investigational use of products discussed within the content at any of the presentations at this conference.

Considerations about the Current Colorectal Cancer Screening Guidelines from the American Cancer Society

Dr. Carmen Guerra has indicated she has no relevant financial relationships within the past 12 months.

Considerations about the 2018 Colorectal Cancer Screening Guidelines from the American Cancer Society

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Dialogue for Action on Cancer Screening and Prevention
Crystal City, VA
April 26, 2019

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Disclosures

- No financial disclosures
- Volunteer as ACS, Inc. Board Scientific Officer, Chair of Mission Outcomes Committee, Member of the Guidelines Development Group

ACS 2018 Recommendations for CRC Screening

- The ACS recommends that adults aged 45 years and older with an average risk of colorectal cancer undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) exam, depending on patient preference and test availability.
- 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.

ACS 2018 Recommendations for CRC Screening

- **The ACS recommends that average-risk adults in good health with a life expectancy of greater than 10 years continue colorectal cancer screening through the age of 75 years. *(qualified recommendation)***
- **The ACS recommends that clinicians individualize colorectal cancer screening decisions for individuals aged 76 through 85 years, based on patient preferences, life expectancy, health status, and prior screening history. *(qualified recommendation)***
- **The ACS recommends that clinicians discourage individuals over age 85 years from continuing colorectal cancer screening. *(qualified recommendation)***

ACS 2018 Recommendations for CRC Screening

- **Options for CRC screening**
  - Stool-based tests:
    - Fecal immunochemical test (FIT) every year
    - High sensitivity guaiac-based fecal occult blood test (HS-gFOBT) every year
    - Multi-target stool DNA test (mt-sDNA) every 3 years
  - Structural (visual) exams:
    - Colonoscopy (CSY) every 10 years
    - CT Colonography (CTC) every 5 years
    - Flexible sigmoidoscopy (FS) every 5 years
- **As a part of the screening process, all positive results on non-colonoscopy screening tests should be followed up with timely colonoscopy.**

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

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 • mt-sDNA (aka FIT-DNA) 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)

What Informed the GDG Decisions? GRADE

- **Quality of evidence**
  - Evidence on the burden of disease by age and race
  - High-quality studies of test performance and effectiveness of screening
  - Modeling studies (Same models used by USPSTF)
- **Balance between desirable and undesirable effects – for each of the included screening modalities, benefits significantly exceed harms.**
- **Values and preferences –Since there is no single test that is consistently preferred by adults in the U.S., the GDG emphasized the importance of offering choice, rather than ranking tests based solely on quality of evidence for individual tests.**

The ACS relied on two reports commissioned for the 2016 USPSTF CRC recommendation update

Clinical Review & Education

US Preventive Services Task Force | EVIDENCE REPORT

Screening for Colorectal Cancer
Updated Evidence Report and Systematic Review
for the US Preventive Services Task Force

Jennifer S. Lin, MD; Margaret A. Piper, PhD; Leslie A. Perdue, MPH; Carolyn M. Rutter, PhD; Elizabeth M. Webber, MS; Elizabeth O'Connor, PhD; Ning Smith, PhD; Evelyn P. Whitlock, MD

IMPORTANCE Colorectal cancer (CRC) remains a significant cause of morbidity and mortality in the United States.

OBJECTIVE To systematically review the effectiveness, diagnostic accuracy, and harms of screening for CRC.

DATA SOURCES Searches of MEDLINE, PubMed, and the Cochrane Central Register of Controlled Trials for relevant studies published from January 1, 2008, through December 31, 2014, with surveillance through February 23, 2016.

STUDY SELECTION English-language studies conducted in asymptomatic populations at general risk of CRC.

DATA EXTRACTION AND SYNTHESIS Two reviewers independently appraised the articles and extracted relevant study data from fair- or good-quality studies. Random-effects meta-analyses were conducted.

MAIN OUTCOMES AND MEASURES Colorectal cancer incidence and mortality, test accuracy in detecting CRC or adenomas, and serious adverse events.

RESULTS Four pragmatic randomized clinical trials (RCTs) evaluating 1-time or 2-time flexible sigmoidoscopy (n = 458 002) were associated with decreased CRC-specific mortality compared with no screening (incidence rate ratio, 0.73; 95% CI, 0.66-0.82). Five RCTs with multiple rounds of biennial screening with guaiac-based fecal occult blood testing (n = 419 966) showed reduced CRC-specific mortality (relative risk [RR], 0.91; 95% CI, 0.84-0.98, at 19.5 years to RR, 0.78; 95% CI, 0.65-0.93, at 30 years). Seven studies of computed tomographic colonography (CTC) with bowel preparation demonstrated per-person sensitivity and specificity to detect adenomas 6 mm and larger comparable with colonoscopy (sensitivity from 73% [95% CI, 58%-84%] to 98% [95% CI, 91%-100%]; specificity from 89% [95% CI, 84%-93%] to 91% [95% CI, 88%-93%]); variability and imprecision may be due to differences in study designs or CTC protocols. Sensitivity of colonoscopy to detect adenomas 6 mm or larger ranged from 75% (95% CI, 63%-84%) to 93% (95% CI, 88%-96%). On the basis of a single stool specimen, the most commonly evaluated families of fecal immunochemical tests (FITs) demonstrated good sensitivity (range, 73%-88%) and specificity (range, 90%-96%). One study (n = 9989) found that FIT plus stool DNA test had better sensitivity in detecting CRC than FIT alone (92%) but lower specificity (84%). Serious adverse events from colonoscopy in asymptomatic persons included perforations (4/10 000 procedures, 95% CI, 2-5 in 10 000) and major bleeds (8/10 000 procedures, 95% CI, 5-14 in 10 000). Computed tomographic colonography may have harms resulting from low-dose ionizing radiation exposure or identification of extracolonic findings.

CONCLUSIONS AND RELEVANCE Colonoscopy, flexible sigmoidoscopy, CTC, and stool tests have differing levels of evidence to support their use, ability to detect cancer and precursor lesions, and risk of serious adverse events in average-risk adults. Although CRC screening has a large body of supporting evidence, additional research is still needed.

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2576

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Clinical Review & Education

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

IMPORTANCE The US Preventive Services Task Force (USPSTF) is updating its 2008 colorectal cancer (CRC) screening recommendations.

OBJECTIVE To inform the USPSTF by modeling the benefits, burden, and harms of CRC screening strategies; estimating the optimal ages to begin and end screening; and identifying a set of model-recommendable strategies that provide similar life-years gained (LYG) and a comparable balance between LYG and screening burden.

DESIGN, SETTING, AND PARTICIPANTS Comparative modeling with 3 microsimulation models of a hypothetical cohort of previously unscreened US 40-year-olds with no prior CRC diagnosis.

EXPOSURES Screening with sensitive guaiac-based fecal occult blood testing, fecal immunochemical testing (FIT), multitarget stool DNA testing, flexible sigmoidoscopy with or without stool testing, computed tomographic colonography (CTC), or colonoscopy starting at age 45, 50, or 55 years and ending at age 75, 80, or 85 years. Screening intervals varied by modality. Full adherence for all strategies was assumed.

MAIN OUTCOMES AND MEASURES Life-years gained compared with no screening (benefit), lifetime number of colonoscopies required (burden), lifetime number of colonoscopy complications (harms), and ratios of incremental burden and benefit (efficiency ratios) per 1000 40-year-olds.

RESULTS The screening strategies provided LYG in the range of 152 to 313 per 1000 40-year-olds. Lifetime colonoscopy burden per 1000 persons ranged from fewer than 900 (FIT every 3 years from ages 55-75 years) to more than 7500 (colonoscopy screening every 5 years from ages 45-85 years). Harm from screening was at most 23 complications per 1000 persons screened. Strategies with screening beginning at age 50 years generally provided more LYG as well as more additional LYG per additional colonoscopy than strategies with screening beginning at age 55 years. There were limited empirical data to support a start age of 45 years. For persons adequately screened up to age 75 years, additional screening yielded small increases in LYG relative to the increase in colonoscopy burden. With screening from ages 50 to 75 years, 4 strategies yielded a comparable balance of screening burden and similar LYG (median LYG per 1000 across the models): colonoscopy every 10 years (270 LYG); sigmoidoscopy every 10 years with annual FIT (256 LYG); CTC every 5 years (248 LYG); and annual FIT (244 LYG).

CONCLUSIONS AND RELEVANCE In this microsimulation modeling study of a previously unscreened population undergoing CRC screening that assumed 100% adherence, the strategies of colonoscopy every 10 years, annual FIT, sigmoidoscopy every 10 years with annual FIT, and CTC every 5 years performed from ages 50 through 75 years provided similar LYG and a comparable balance of benefit and screening burden.

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Related article page 2564
Supplemental content at jama.com

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JAMA. 2016;315(23):2595-2609. doi:10.1001/jama.2016.6828

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The ACS also:

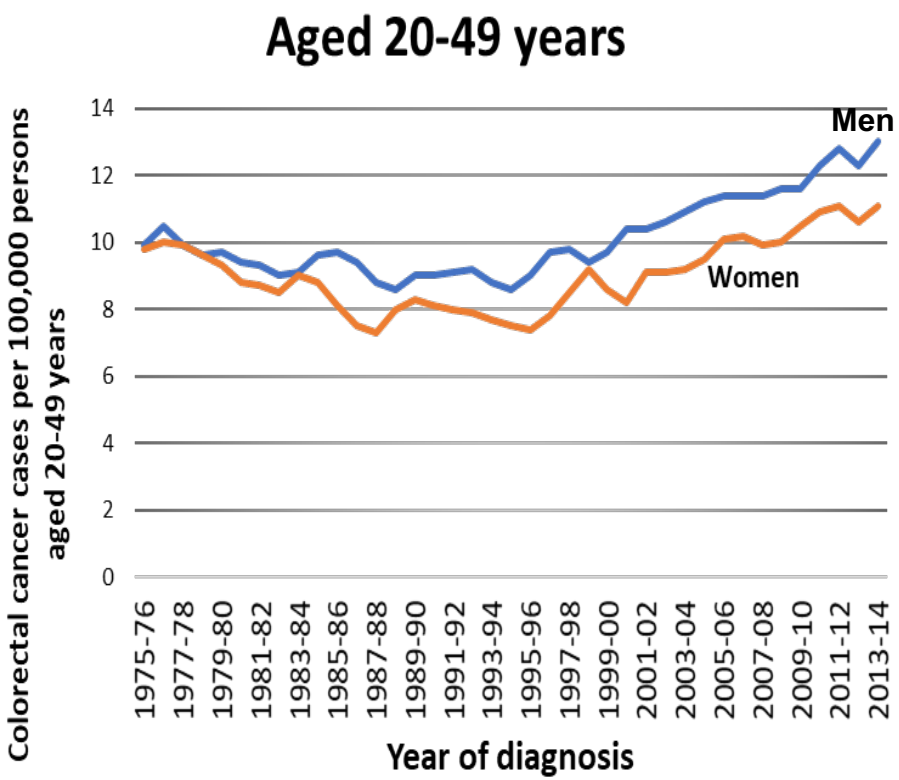
- Examined disease burden data & trends in incidence in <55yo
- Conducted supplemental literature reviews to identify:
  - New literature since the publication of the USPSTF systematic review
  - Literature on risk associated with age, gender, and racial and ethnic subgroups

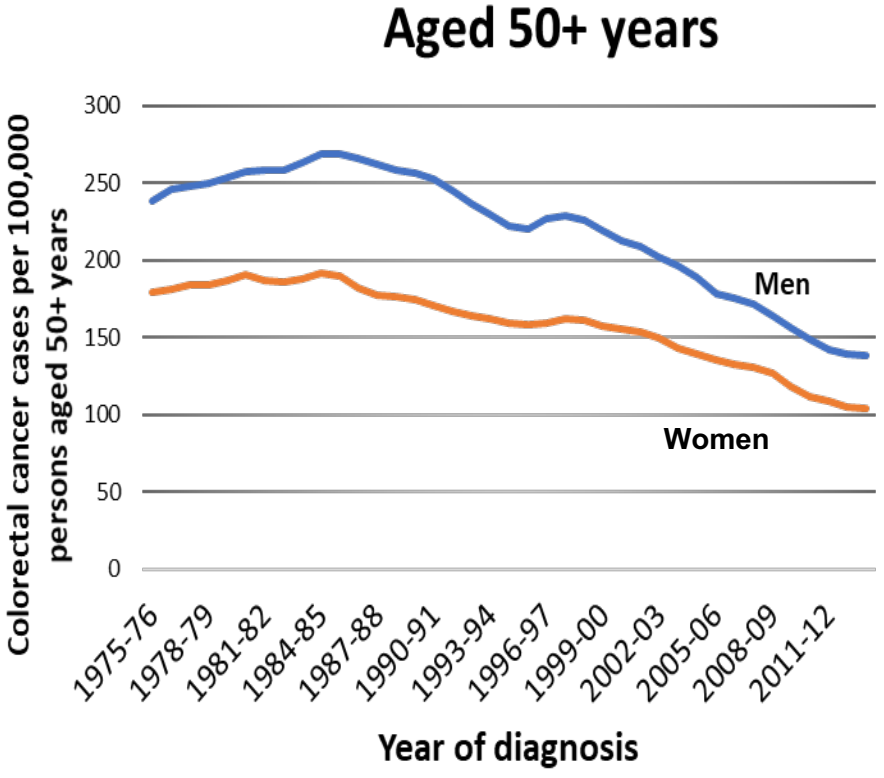
"For all modalities, strategies with screening beginning at age 45 years predominated on the efficient frontier; that is, these strategies generally provided additional LYGs at a lower number of additional colonoscopies than strategies with screening beginning at later ages." However, beginning screening at age 45 years while maintaining the10-year screening interval, resulted in an increase in the estimated lifetime number of colonoscopies. USPSTF judged the additional LYG as "modest"

Rationale – Disease Burden of CRC by Sex

Trends in Colorectal Cancer Incidence Rates by Age and Sex, 1975-2014

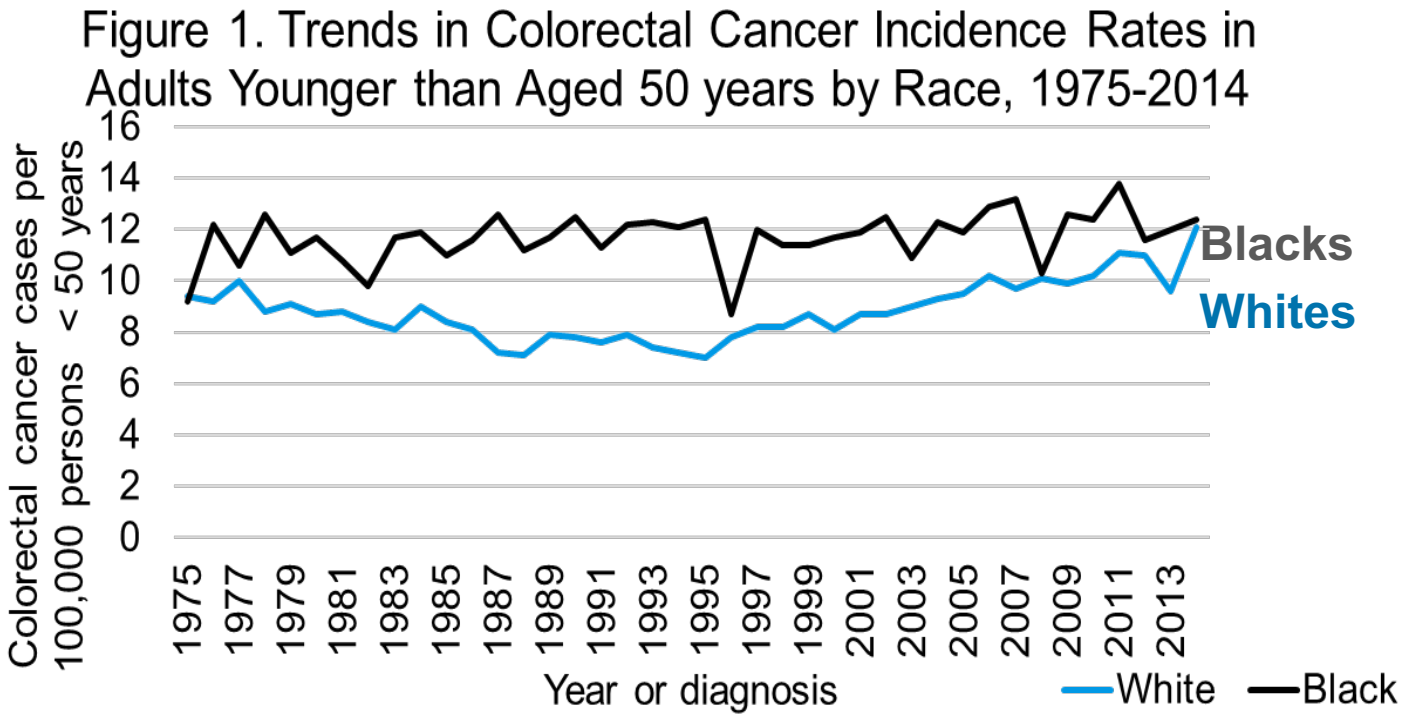
From 1994-2014 there is ~50% incidence in CRC in <50yo





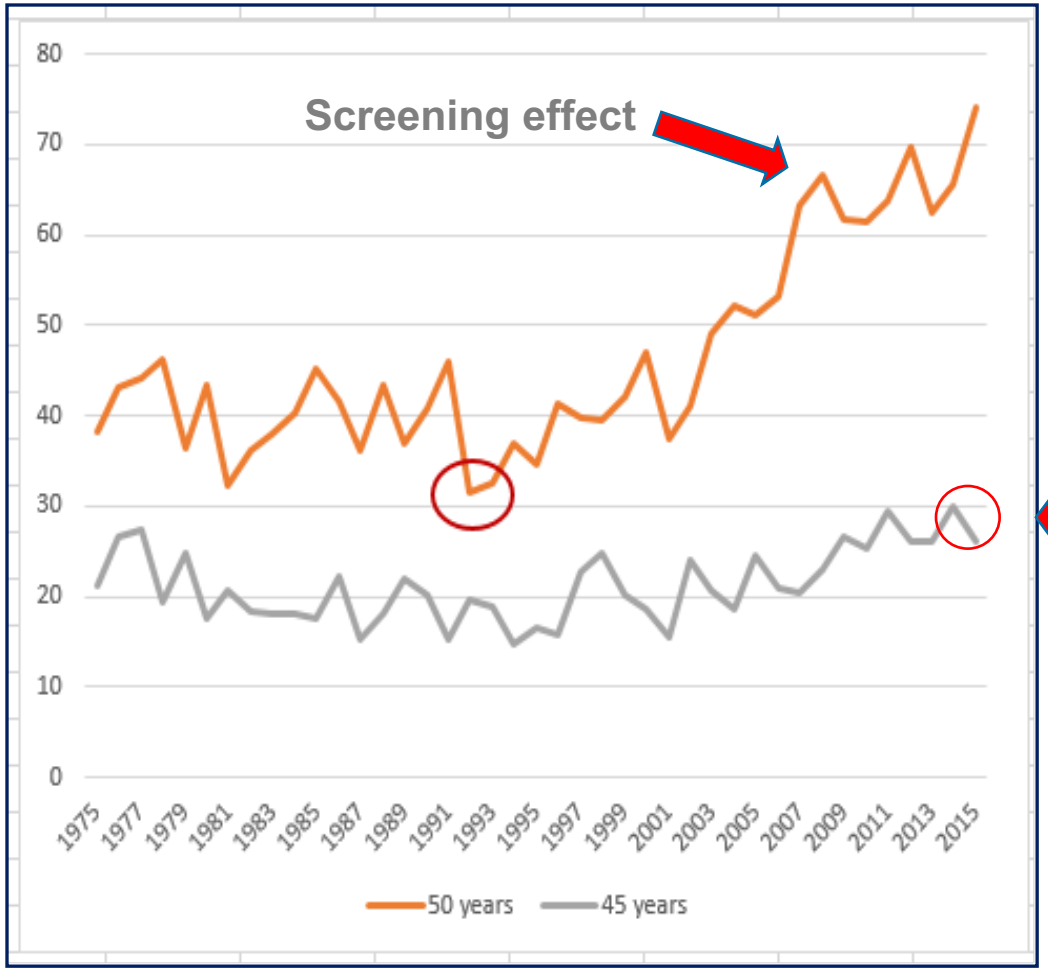
Source: Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. CA Cancer J Clin. 2018; 68: 000-000 [epub ahead of print]. URL to be: https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21457

Rationale – Disease Burden of CRC in <50 yo by Race



Source: Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. CA Cancer J Clin. 2018; 68: 000-000 [epub ahead of print]. URL to be: https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21457

CRC Incidence Among U.S. Adults Aged 45 & 50 Years, SEER, 1975-2015



Age 50

Age 45

Age-specific incidence is about the same for a 45 year old in 2015 as it was for a 50 year old in 1993, about 30 per 100,000

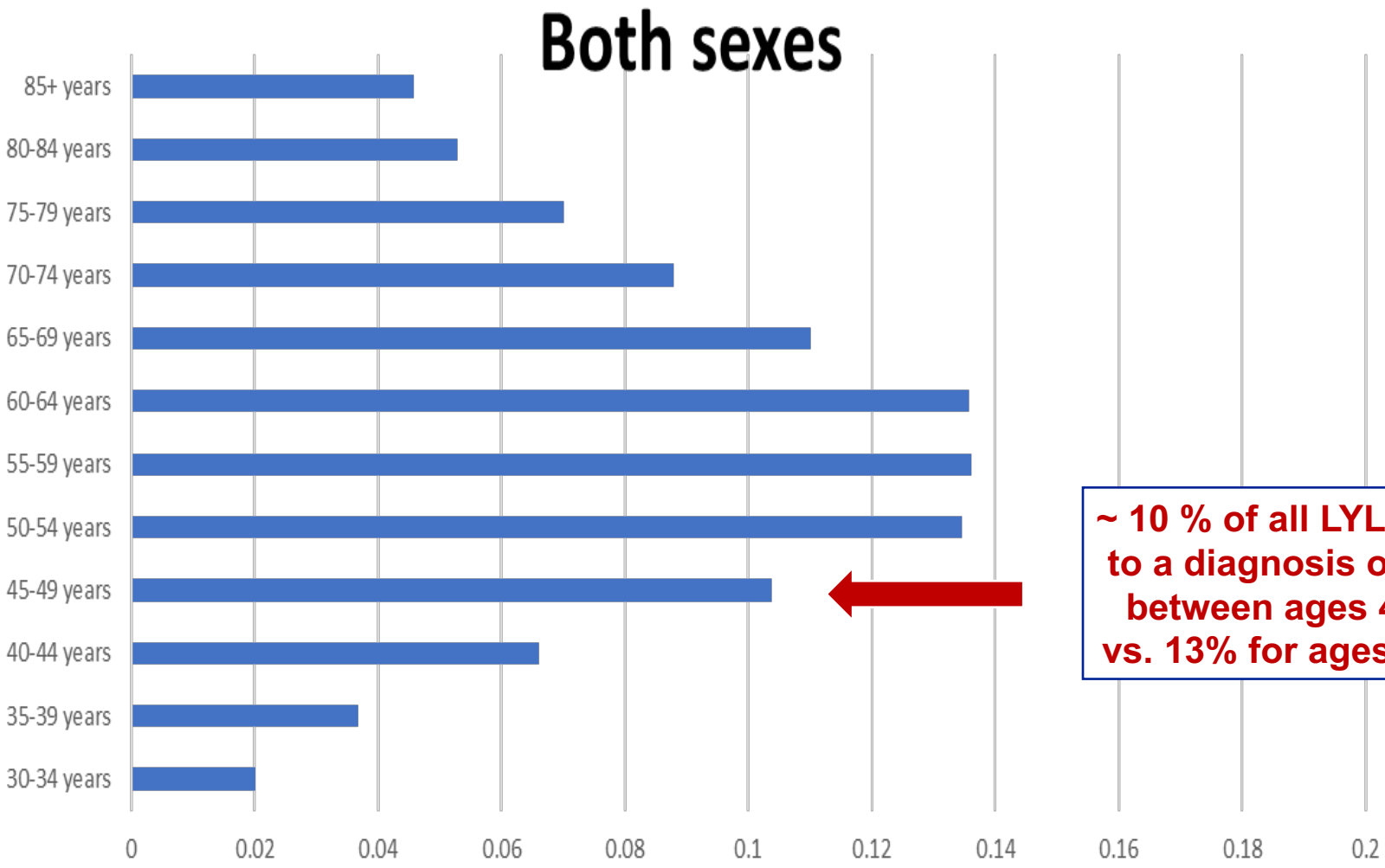
Some Observations about CRC in Adults aged 45-49

- **In 2018, an estimated 16,450 new CRC cases will be diagnosed in adults younger than 50**

- **In 2014, approximately 43% of CRC cases under age 50 were in ages 45-49**

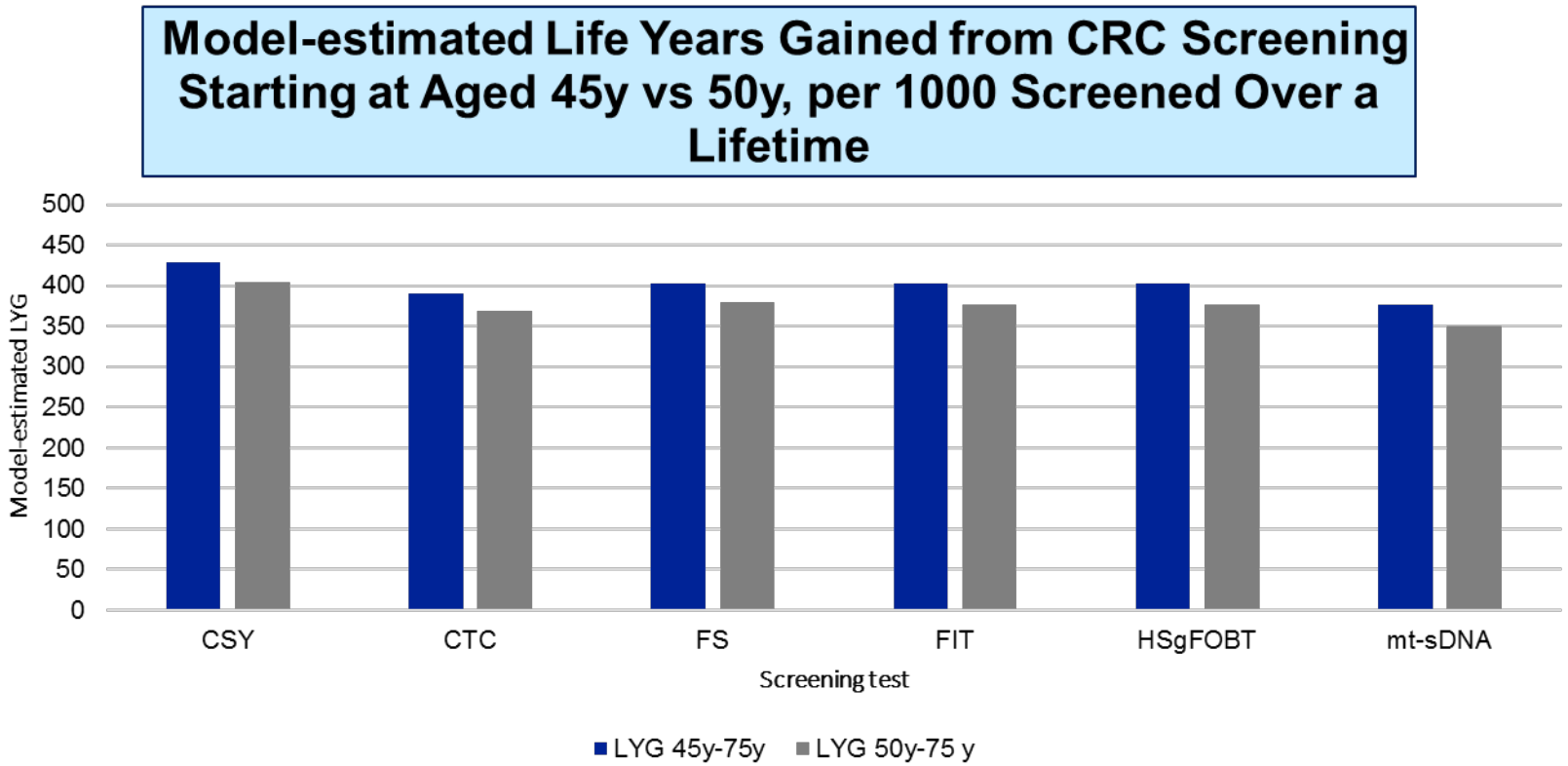
Source: Based on ACS estimated total cases in 2018 (140,250) and the proportion of cases < 50 in SEER 9 registries during 2014 (0.117253).

Percentage of Years of Potential Life Lost Due to Death from Colorectal Cancer by Age at Diagnosis *(incidence-based mortality 2010-14 with follow-up 20 years after diagnosis)*



~ 10 % of all LYL is due to a diagnosis of CRC between ages 45-49 vs. 13% for ages 50-54

Model-estimated Benefit CRC Screening by Starting Age



Among 9 efficient and 5 near-efficient colonoscopy strategies, the strategy recommended by the model under the increased-risk scenario was screening every 10 years from ages 45 to 75 years, which, compared with screening every 10 years from ages 50 to 75 years, had 6.2% more LYGs and 17% more colonoscopies per 1000 adults over a lifetime of screening

Source: Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. CA Cancer J Clin. 2018; 68: 000-000 [epub ahead of print]. URL to be: https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21457

Two CISNET Microsimulation Models (MISCAN & SimCRC) Were Used to Examine Outcomes by Age, Race/Ethnicity, and Sex Under Assumptions of Stable and Increasing Incidence

Original Article

The Impact of the Rising Colorectal Cancer Incidence in Young Adults on the Optimal Age to Start Screening: Microsimulation Analysis I to Inform the American Cancer Society Colorectal Cancer Screening Guideline

Elisabeth F.P. Peterse, MSc [1]; Reinier G.S. Meester, PhD [1,2]; Rebecca L. Siegel, MPH[3]; Jennifer C. Chen, MPH[4]; Andrea Dwyer, BS[5,6]; Dennis J. Ahnen, PhD[7]; Robert A. Smith, PhD [8]; Ann G. Zauber, PhD[4]; and Iris Lansdorp-Vogelaar, PhD[1]

Original Article

Optimizing Colorectal Cancer Screening by Race and Sex: Microsimulation Analysis II to Inform the American Cancer Society Colorectal Cancer Screening Guideline

Reinier G. S. Meester, PhD [1,2]; Elisabeth F. P. Peterse, MSc [1]; Amy B. Knudsen, PhD[3]; Anne C. de Weerdt, BS[1]; Jennifer C. Chen, MPH[4]; Anna P. Lietz, BA[3]; Andrea Dwyer, BS[5,6]; Dennis J. Ahnen, MD[5,7]; Rebecca L. Siegel, MPH[8]; Robert A. Smith, PhD [9]; Ann G. Zauber, PhD[4]; and Iris Lansdorp-Vogelaar, PhD[1]

Starting CRC Screening at Age 45: Conclusions

- **Modeling convincingly demonstrates that, due to the rising incidence of CRC in younger individuals, screening all average-risk persons between the ages of 45 and 75 reduces mortality from CRC with an acceptable risk (*as measured by number of colonoscopies per LYG*).**
- **The trend of increasing CRC incidence in successively younger birth cohorts suggests that the recommended starting age of 45 will continue to be appropriate.**
- **The benefit-burden balance strongly favors changing the starting age from 50 to 45.**

Screening for CRCS in <45 yo is cost-effective

- **Initiating screening colonoscopies at age 45 years averted four CRCs and two deaths due to CRC per 1,000 persons. It resulted in a gain of 14 quality-adjusted life years (QALYs) at a cost of $33,900 per QALY gained.**

- **Fecal immunochemical test (FIT), followed by colonoscopies for abnormal results, and found that initiating FIT at age 45 years instead of 50 years would cost $7,700 per QALY gained.**

- Ladabaum U. Cost-effectiveness and National Effects of Initiating Colorectal Cancer Screening for Average-risk Persons at Age 45 Years Instead of 50 Years. Gastroenterology 2019, in press.

Criticism of Reducing the Age to Begin CRCS

Annals of Internal Medicine

IDEAS AND OPINIONS

From Colorectal Cancer Screening Guidelines to Headlines: Beware!

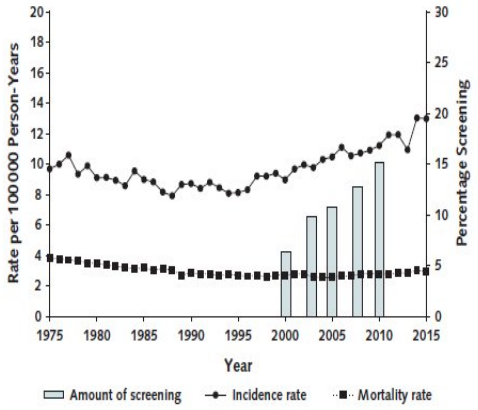
Michael Bretthauer, MD, PhD; Mette Kalager, MD, PhD; and David S. Weinberg, MD, MSc

On 30 May 2018, scores of media outlets ran headlines like "Cancer Group Calls for Colorectal Cancer Screening Starting at Age 45" in response to updated guidelines for colorectal cancer (CRC) screening from the American Cancer Society (ACS). Whereas nearly all previous guidelines recommended screening beginning at age 50 years, the ACS added the *qualified* recommendation that an additional 22 million Americans aged 45 to 49 years also participate in screening (1).

Screening for CRC starting at age 50 years can reduce CRC incidence and mortality (2, 3). The ACS advocates any of several screening tests, either fecal-based (guaiac, immunochemical, or DNA) or structural (colonoscopy, sigmoidoscopy, or computed tomography colonography) (1). Despite wide variation in effect size and evidence quality among tests, the ACS argues that screening participation may be enhanced when patients can choose a test that aligns with their preferences (1).

What new evidence prompted this age shift? Screening participation may partly explain why CRC incidence rates for persons aged 54 years or older have steadily decreased in the United States since the early 1990s (4). However, CRC incidence in younger persons has increased over the same time frame. The ACS cites

Figure. CRC incidence and mortality rates per 100 000 person-years and percentage of persons aged 20 to 49 years screened for CRC, United States, 1975 to 2015.



Rates are age-adjusted to the U.S. standard population from the year 2000. "Amount of screening" data from reference 9; "Incidence rate" and "Mortality rate" data from SEER 9 Regs Research Data, National Cancer Institute, Division of Cancer Control and Population Sciences. CRC = colorectal cancer; SEER = Surveillance, Epidemiology, and End Results.

Annals.org on 10 July 2018.

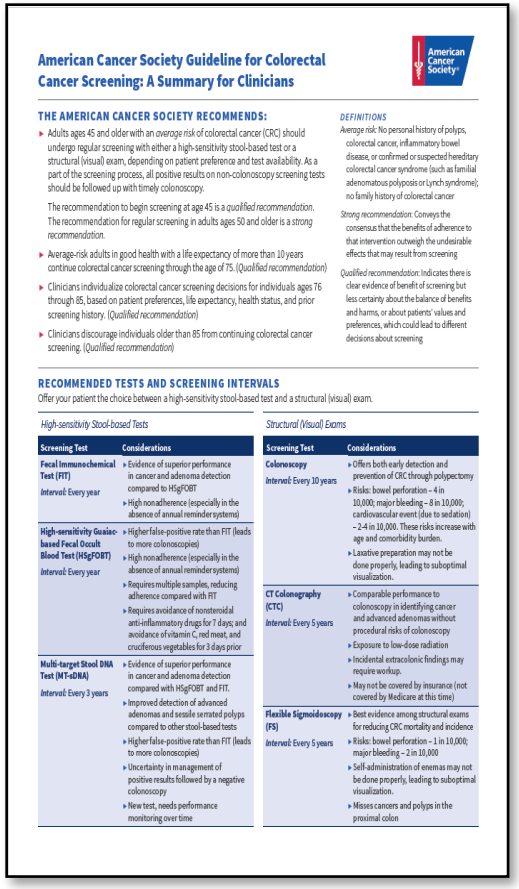
What concerns have been raised about the new guideline?

- **What concerns have been raised about the new guideline?**

- **CRC is a different disease in adults under 50**
- **Burden of disease is very small in this age group; high costs and many harms for a small benefit**
- **No empirical evidence; *recommendations based on modeling***
- **Important to concentrate further on adults 50+**
- **The new guideline will worsen existing disparities**
- **The new guideline will strain existing capacity**
- **Insurance coverage may not be available for adults 45-49**

New Decision Aids for CRC Screening

Summary for Clinicians



American Cancer Society Guideline for Colorectal Cancer Screening: A Summary for Clinicians

THE AMERICAN CANCER SOCIETY RECOMMENDS:

- Adults ages 45 and older with an *average risk* of colorectal cancer (CRC) should undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) exam, 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 is a *qualified recommendation*. The recommendation for regular screening in adults ages 50 and older is a *strong recommendation*.
- Average-risk adults in good health with a life expectancy of more than 10 years continue colorectal cancer screening through the age of 75. (*Qualified recommendation*)
- Clinicians individualize colorectal cancer screening decisions for individuals ages 76 through 85, based on patient preferences, life expectancy, health status, and prior screening history. (*Qualified recommendation*)
- Clinicians discourage individuals older than 85 from continuing colorectal cancer screening. (*Qualified recommendation*)

DEFINITIONS

Average risk: No personal history of polyps, colorectal cancer, inflammatory bowel disease, or confirmed or suspected hereditary colorectal cancer syndrome (such as familial adenomatous polyposis or Lynch syndrome); no family history of colorectal cancer

Strong recommendation: Conveys the consensus that the benefits of adherence to that intervention outweigh the undesirable effects that may result from screening

Qualified recommendation: Indicates there is clear evidence of benefit of screening but less certainty about the balance of benefits and harms, or about patients' values and preferences, which could lead to different decisions about screening

RECOMMENDED TESTS AND SCREENING INTERVALS

Offer your patient the choice between a high-sensitivity stool-based test and a structural (visual) exam.

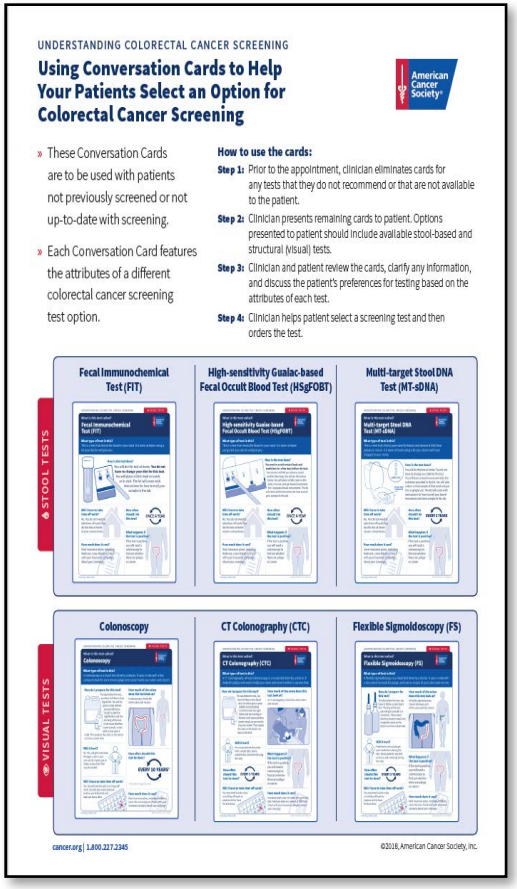
High-sensitivity Stool-based Tests

Screening Test	Considerations
Fecal Immunochemical Test (FIT) *Interval:* Every year	▸ Evidence of superior performance in cancer and adenoma detection compared to HSgFOBT ▸ High non-adherence (especially in the absence of annual reminder systems)
High-sensitivity Guaiac-based Fecal Occult Blood Test (HSgFOBT) *Interval:* Every year	▸ Higher false-positive rate than FIT (leads to more colonoscopies) ▸ High non-adherence (especially in the absence of annual reminder systems) ▸ Requires multiple samples, reducing adherence compared with FIT ▸ Requires avoidance of nonsteroidal anti-inflammatory drugs for 7 days; and avoidance of vitamin C, red meat, and cruciferous vegetables for 3 days prior
Multi-target Stool DNA Test (MT-sDNA) *Interval:* Every 3 years	▸ Evidence of superior performance in cancer and adenoma detection compared with HSgFOBT and FIT. ▸ Improved detection of advanced adenomas and sessile serrated polyps compared to other stool-based tests ▸ Higher false-positive rate than FIT (leads to more colonoscopies) ▸ Uncertainty in management of positive results followed by a negative colonoscopy ▸ New test, needs performance monitoring over time

Structural (Visual) Exams

Screening Test	Considerations
Colonoscopy *Interval:* Every 10 years	▸ Offers both early detection and prevention of CRC through polypectomy ▸ Risks: bowel perforation – 4 in 10,000; major bleeding – 8 in 10,000; cardiovascular event (due to sedation) – 2-4 in 10,000. These risks increase with age and comorbidity burden. ▸ Laxative preparation may not be done properly, leading to suboptimal visualization.
CT Colonography (CTC) *Interval:* Every 5 years	▸ Comparable performance to colonoscopy in identifying cancer and advanced adenomas without procedural risks of colonoscopy ▸ Exposure to low-dose radiation ▸ Incidental extracolonic findings may require workup. ▸ May not be covered by insurance (not covered by Medicare at this time)
Flexible Sigmoidoscopy (FS) *Interval:* Every 5 years	▸ Best evidence among structural exams for reducing CRC mortality and incidence ▸ Risks: bowel perforation – 1 in 10,000; major bleeding – 2 in 10,000 ▸ Self-administration of enemas may not be done properly, leading to suboptimal visualization. ▸ Misses cancers and polyps in the proximal colon

Conversation Cards



UNDERSTANDING COLORECTAL CANCER SCREENING

Using Conversation Cards to Help Your Patients Select an Option for Colorectal Cancer Screening

- These Conversation Cards are to be used with patients not previously screened or not up-to-date with screening.
- Each Conversation Card features the attributes of a different colorectal cancer screening test option.

How to use the cards:

Step 1: Prior to the appointment, clinician eliminates cards for any tests that they do not recommend or that are not available to the patient.

Step 2: Clinician presents remaining cards to patient. Options presented to patient should include available stool-based and structural (visual) tests.

Step 3: Clinician and patient review the cards, clarify any information, and discuss the patient's preferences for testing based on the attributes of each test.

Step 4: Clinician helps patient select a screening test and then orders the test.

STOOL TESTS

Fecal Immunochemical Test (FIT)

High-sensitivity Guaiac-based Fecal Occult Blood Test (HSgFOBT)

Multi-target Stool DNA Test (MT-sDNA)

VISUAL TESTS

Colonoscopy

CT Colonography (CTC)

Flexible Sigmoidoscopy (FS)

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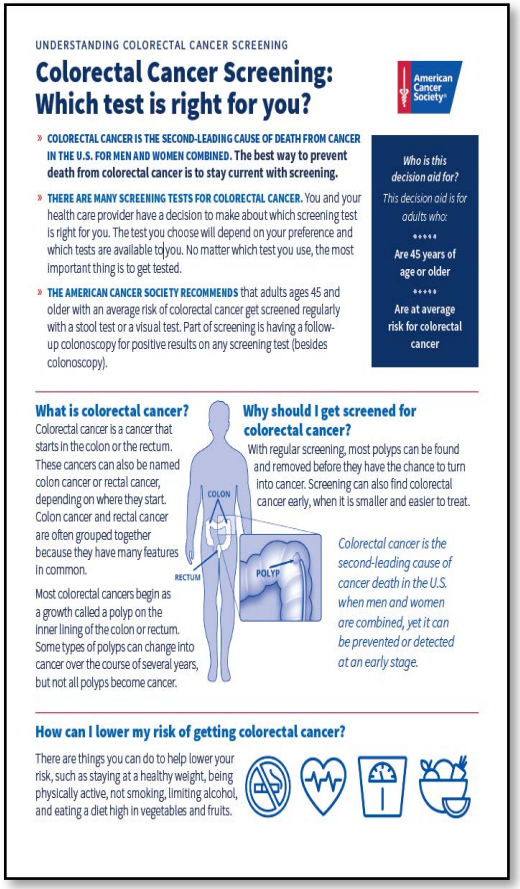
Patient Decision Aid



UNDERSTANDING COLORECTAL CANCER SCREENING

Colorectal Cancer Screening: Which test is right for you?

- **COLORECTAL CANCER IS THE SECOND-LEADING CAUSE OF DEATH FROM CANCER IN THE U.S. FOR MEN AND WOMEN COMBINED. The best way to prevent death from colorectal cancer is to stay current with screening.**
- **THERE ARE MANY SCREENING TESTS FOR COLORECTAL CANCER.** You and your health care provider have a decision to make about which screening test is right for you. The test you choose will depend on your preference and which tests are available to you. No matter which test you use, the most important thing is to get tested.
- **THE AMERICAN CANCER SOCIETY RECOMMENDS** that adults ages 45 and older with an average risk of colorectal cancer get screened regularly with a stool test or a visual test. Part of screening is having a follow-up colonoscopy for positive results on any screening test (besides colonoscopy).

Who is this decision aid for?

This decision aid is for adults who:

★★★★★

Are 45 years of age or older

★★★★★

Are at average risk for colorectal cancer

What is colorectal cancer?

Colorectal cancer is a cancer that starts in the colon or the rectum. These cancers can also be named colon cancer or rectal cancer, depending on where they start. Colon cancer and rectal cancer are often grouped together because they have many features in common.

Most colorectal cancers begin as a growth called a polyp on the inner lining of the colon or rectum. Some types of polyps can change into cancer over the course of several years, but not all polyps become cancer.

COLON

RECTUM

POLYP

Why should I get screened for colorectal cancer?

With regular screening, most polyps can be found and removed before they have the chance to turn into cancer. Screening can also find colorectal cancer early, when it is smaller and easier to treat.

Colorectal cancer is the second-leading cause of cancer death in the U.S. when men and women are combined, yet it can be prevented or detected at an early stage.

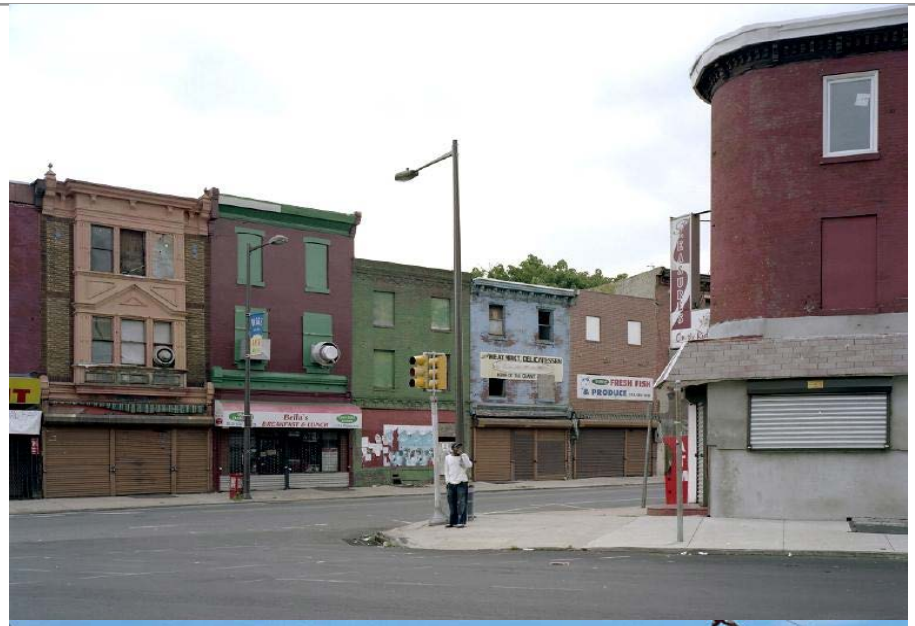
How can I lower my risk of getting colorectal cancer?

There are things you can do to help lower your risk, such as staying at a healthy weight, being physically active, not smoking, limiting alcohol, and eating a diet high in vegetables and fruits.

https://www.cancer.org/health-care-professionals/colon-md.html

University of Pennsylvania

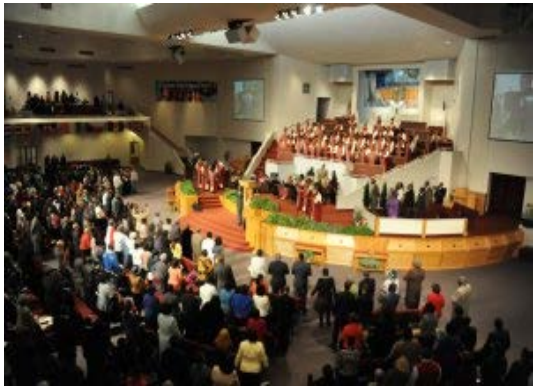
West Philadelphia



West Philadelphia CRCS Patient Navigation Program

- **Reduce disparities in CRCS by:**
  - **Hire/train a patient navigator**
    - **Harold Freeman Patient Navigation Institute, Bronx, NY**
  - **Foundation grants for resources for program and patient care expenses**
    - **cell phone and service, computer, printer, printing, stationary, software, etc.**
    - **free prep, Septa tokens**
    - **video colonoscopy instructions**
      - https://www.youtube.com/watch?v=M5t8lhZ-aoY
  - **Conduct studies to determine program feasibility, acceptability, effectiveness**

West Philadelphia Colorectal Cancer Screening Navigation Program



Program participation	N (%)
No. patients contact attempted	2440
Agreed to participate	980 (40.2%)
Declined participation	739 (30.3%)
Unable to contact after 3-6 calls	721 (29.5%)

Screening colonoscopy results	(n=763)
Normal/no pathology or hyperplastic polyp(s)	353 (46.3%)
At least one adenomatous polyp	327 (42.9%)
Adenocarcinoma	5 (0.7%)
Repeat	16 (2%)
Other	30 (4%)
Pending scheduling	32 (4%)

Demographics	N=690 (%)
Age (mean, s.d.)	60.2, 8.3
Female	427 (61.9)
African American	621 (90)
Marital Status	
Single	320 (46.4)
Married	178 (25.8)
Education	
<High School	125 (18.1)
High School	316 (45.8)
Annual Income	
<$10,000	240 (34.8)
10,000-29,999	242 (35.1)

CRC Stage	N
Stage I	1
Stage II	0
Stage III	3
Stage IV	1
Total	**5**

Colorectal Cancer Screening Navigation for the Underserved: Experience of an Urban Program

Alicia Lamanna, MHA, Heather Sheaffer, DSW, LCSW, Carmen Guerra, MD, MSCE, FACP, and Michael Kochman, MD, AGAF, FASGE

Using community outreach to explore health-related beliefs and improve surgeon-patient engagement

Rebecca L. Hoffman, MD, MSCE,[a,*] Brenda Bryant, BA,[b] Steve R. Allen, MD,[c] Major K. Lee, MD PhD,[d] Cary B. Aarons, MD,[e] and Rachel R. Kelz, MD MSCE[f]

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University of Pennsylvania

Financial Sustainability

	HUP	PPMC	UPHS Total
Volume	80	40	120
Outpatient Net Revenue	$84,401	$59,557	$143,958
Direct Expenses	$91,955	$45,114	$137,089
Contribution Margin	($7,555)	$14,444	$6,869
Indirect expenses	$30,251	$11,653	$41,904
Net gain (loss)	($37,806)	$2,791	($35,015)
Downstream Contribution Margin	$115,004	($947)	$114,057
Total Gain/Loss including Downstream	$77,198	$1,843	$79,042

Sustainability of cancer screening programs

Cost-Effectiveness Analysis of the First Year of a Colorectal Cancer (CRC) Screening Patient Navigation Program at an Academic Medical Center

Penn LDI Leonard Davis Institute of Health Economics

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Abstract

- **Introduction:** We evaluated the first year of the CRC Screening Patient Navigation Program at the University of Pennsylvania Health System (UPHS), analyzing the costs of the program and cost per patient who successfully completed a screening colonoscopy (SC)
- **Methods:** This is a retrospective cost-effectiveness analysis of data gathered during the first full year (2012) of the navigation program. For this analysis, the outcome of interest was SC completion within 3 months of program enrollment. To perform the cost-effectiveness analysis, the total costs of the navigation program inputs were recorded, and the costs were divided by the number of patients enrolled, scheduled, and screened (both unadjusted and adjusting for an estimate of those who would have completed SC without navigation)
- **Results:** The cost per patient enrolled was $453.76 and the cost per patient screened was $703.54. However, after adjusting for completion without navigation, the cost was $874.50 per additional patient screened. Labor comprised over 84% of the cost per successfully screened patient
- **Conclusions:** Although the navigation program significantly increased the percentage of completed CRCS for this previously non-adherent and underserved cohort, there is a significant cost to this navigation program, driven largely by labor costs. However, such cost-intensive interventions may be beneficial in high-risk populations

Background

- Patient navigation programs have been shown to be effective in increasing colorectal cancer (CRC) screening rates, particularly for underserved populations
- However, the costs required to institute a successful program and the cost-effectiveness of such programs remains less clear

Figure 1: Navigation Program Process

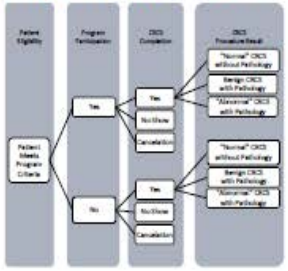
1. Common barriers include poor awareness, negative attitudes, inability to afford the out-of-pocket costs of the prep and lack of transportation
2. Navigation often includes helping patients identify an escort, planning transportation, and providing emotional support
3. Phone reminders, especially the colonoscopy prep procedure review call, are crucial to maximizing the likelihood of successful CRC screening in populations with historically low SC completion rates

Objectives

1. To determine the cost effectiveness of the first year of a CRC Screening Patient Navigation Program instituted at UPHS

Methods

Figure 2: Cost-Effectiveness Analysis Decision Tree



- The outcome of interest was SC completion within 3 months of program enrollment
- Both program participants and those who declined navigation were followed and the number of cancelled, missed, and completed SC appointments was recorded
- To perform the cost-effectiveness analysis, the total costs of the navigation program inputs were recorded, including the navigator's total compensation and training, office supplies, and patient supplies (free prep materials and public transit tokens)
- The costs were divided by the number of patients enrolled, scheduled, and screened (both unadjusted and adjusting for an estimate of those who would have completed SC without navigation)

Figure 3: Target Population – West Philadelphia

Results

Table 1: Demographics

	Navigated Patients (n=138)	Non-participants (n=133)
Female	66%	67%
Average Age	58.5	59.2
Black or African American	93%	86%
White	4%	12%
Hispanic/Latino	1%	2%
Insurance:		
Medicaid	33%	27%
Medicare	43%	26%
Private	21%	43%

- Patients at UPHS from West Philadelphia (representing prespecified zip codes that historically had low SC completion rates) were targeted for the navigation intervention
- Patients had to be between 50 and 75 years old, live in West Philadelphia, have insurance, have a primary care provider (PCP) in a participating UPHS clinic (3), and have an open SC order
- "Navigated Patients" agreed to participate in the program; "Non-participants" are defined as individuals who declined to participate after being contacted by the navigation program to enroll

Table 2: Clinical Effectiveness Analysis

	Navigated Patients	Non-participants
Total Sample, N	169	319
Average Number of Prior Orders (Range)	1.68 (1-5)	1.30 (1-4)
Patients who Scheduled SC (n)	81.7% (138)	41.7% (133)
Patients who Cancelled Appointments	23.9%	44.4%
Patients who Missed Appointments	11.6%	42.9%
Outcomes, n	138	133
Patients who Completed SC within 3 Months (n)	79.0% (109)	19.6% (26)
Adenoma Detection Rate	40.4%	30.8%

- "Total Sample" refers to the total number of patients contacted who enrolled in or declined navigation. All patients in the total sample fulfill the program criteria outlined above
- "Outcomes" were calculated only for the patients who scheduled SC in each group

Table 3: Cost-Effectiveness Analysis

Inputs (2012 Dollars)	CY 2012 Costs
Labor	$64,531
Training	$1,800
Office Supplies	$5,095
Patient Supplies	$5,260
Total Cost (TC)	$76,686
TC, Excluding Start-Up Costs	$73,329
Variable Cost	$3,838

Outputs (2012 Dollars)	Average Total Cost	Average Labor Cost
Per Patient Enrolled in Navigation Program (n=169)	$453.76	$381.84
Per Navigated Patient Scheduled (n=138)	$555.70	$467.62
Per Completed SC (n=109)	$703.54	$592.03
Per Completed SC, Adjusted (n=88)	$874.50	$736.88

- To calculated the adjusted costs, it was assumed that 19.6% of the navigation group's successful screenings would have completed SC without the program and were removed, as 19.6% of the non-participating patients were successfully screened

Conclusions

- Although the navigation program significantly increased the percentage of completed CRCS for this previously non-adherent and underserved cohort, there is a significant cost to this navigation program, driven largely by labor costs
- However, such cost-intensive interventions may be beneficial in high-risk populations like West Philadelphia patients, given the above-average adenoma detection rate of 40%
- Future efforts may wish to analyze not only the true downstream impact of screening on this population, but also less labor-intensive ways to engage this population.

Limitations

- Since we were only able to recruit about 30% of the contacted patients for the program, our results may be subject to participation bias

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