FluFIT:

An Evidence-Based Intervention to Improve CRC Screening

Mountain-Pacific Quality Health Foundation

June 20, 2017

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Objectives

- Importance of CRC screening
- CRC screening patterns
- Current evidence for stool-based CRC screening tests
- Overview of FluFIT program

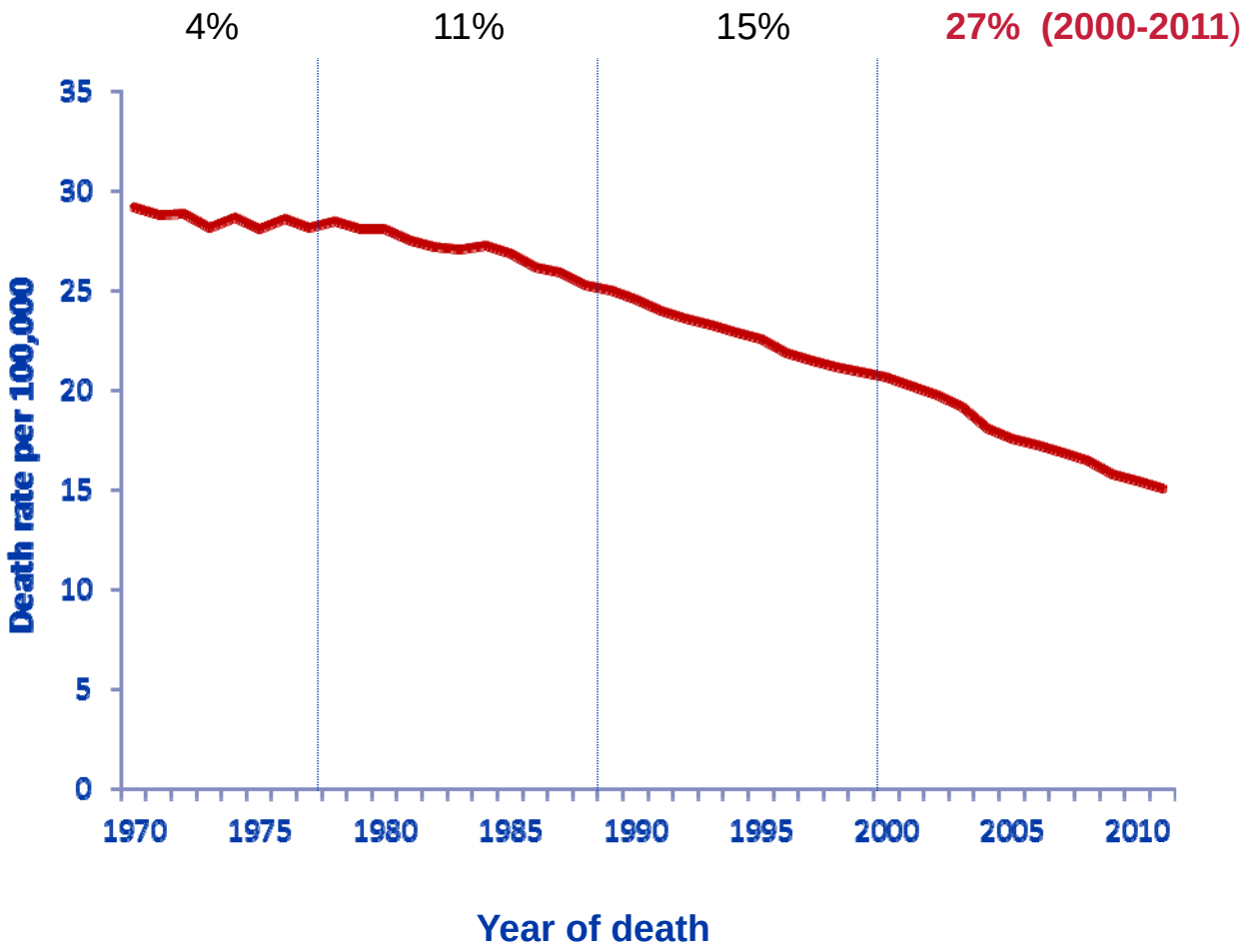
Colorectal Cancer (CRC)

- Incidence and Mortality (US, 2017)
  - 135,430 new cases expected
  - 50,260 deaths
- 1.4 million Americans living with CRC
- Incidence and death rates have fallen steadily past 30 years

Cancer Facts and Figures 2017

Overall CRC death rate decline in the US

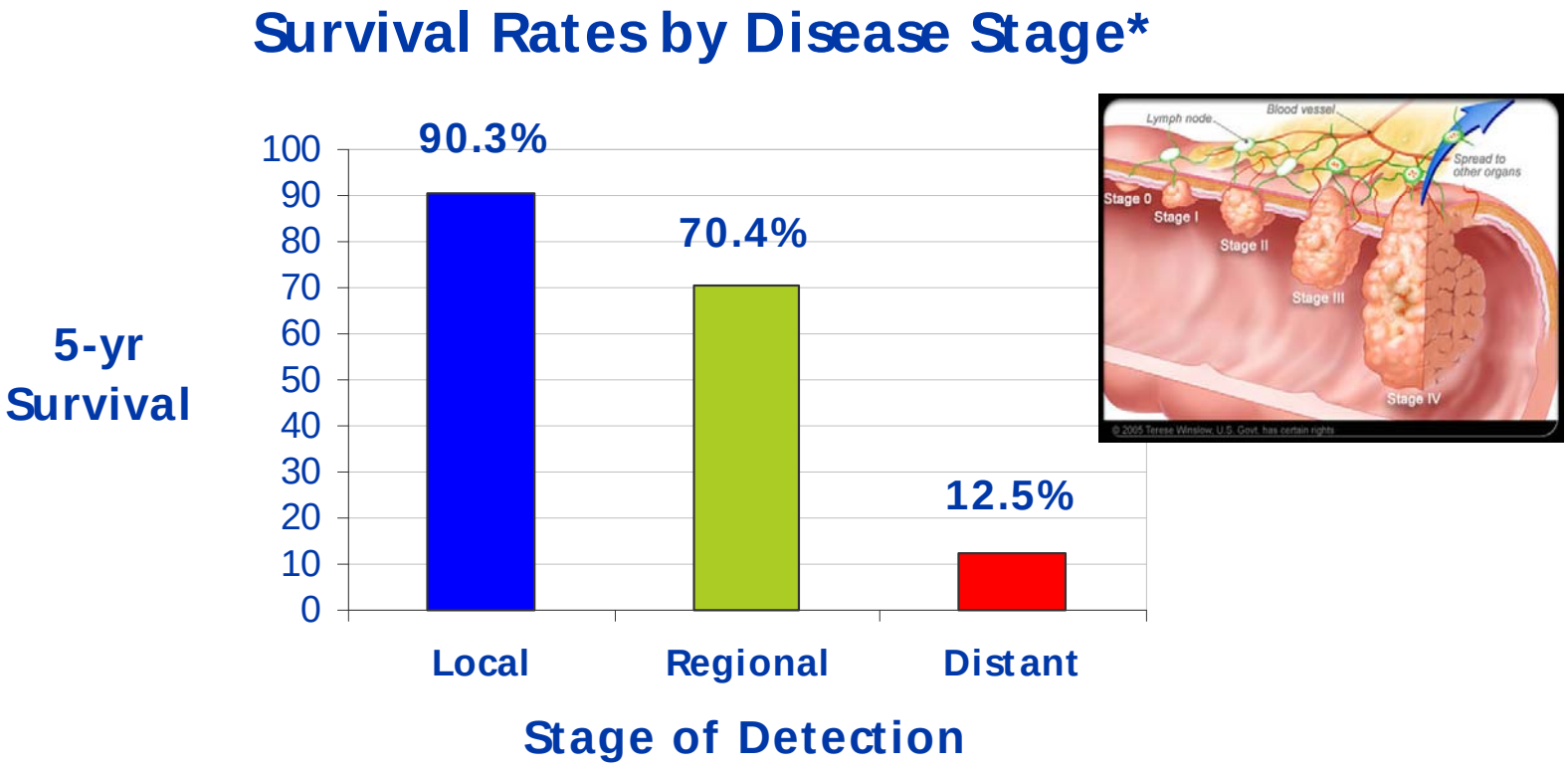
CRC mortality decline per decade:



Siegel et al, CEBP 2015

Decline in CRC Incidence and Mortality

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



Decline in CRC **Incidence**

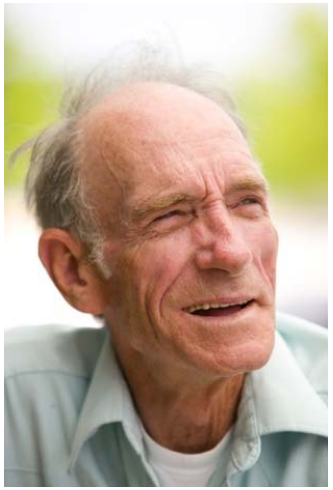
- Decline due to:
  - **Screening** → polyp removal → prevention
- Estimated that screening may have prevented **550,000** cases of colorectal cancer in the US over the past three decades

Yang, Cancer 2014

CRC Screening Rates

In 2014, **66.3%** of eligible US adults were up to date with CRC screening

- Lower rates in Hispanics, Asian Americans, Native Americans
- Lowest rates among low income, low education level and uninsured populations

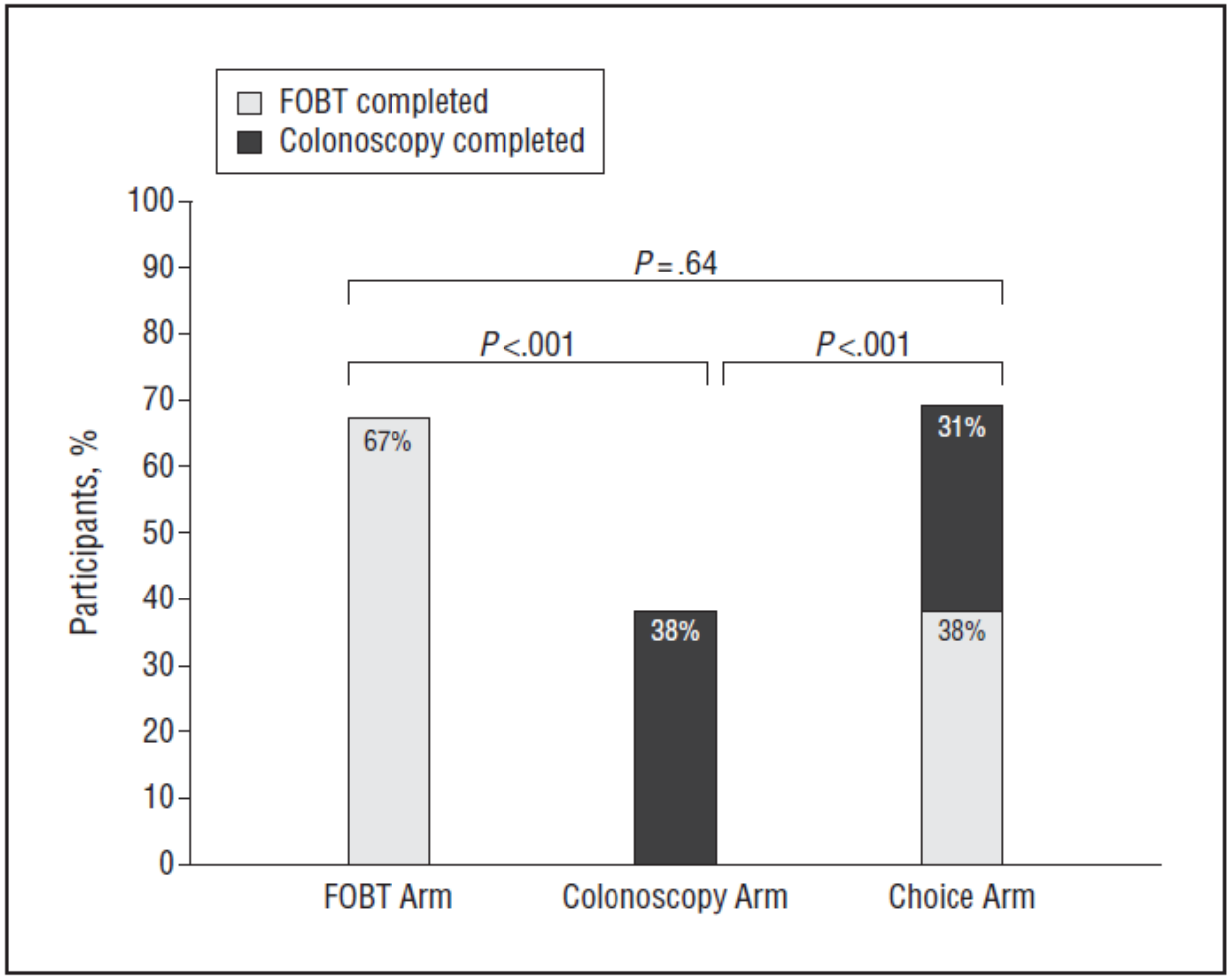


Source: CDC BRFSS 2014

PCP Beliefs and Preferences

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

Patient Preferences



Inadomi, Arch Intern Med 2012

Patient Preferences

- Diverse sample of 323 adults given detailed side-by-side description of FOBT and colonoscopy (DeBourcy et al. 2007)
  - 53% preferred FOBT
  - Almost half felt very strongly about their preference
- 212 patients at 4 health centers rated different screening options with different attributes (Hawley et al. 2008)
  - 37% preferred colonoscopy
  - 31% preferred FOBT
- Nationally representative sample of 2068 VA patients given brief descriptions of each screening mode (Powell et al. 2009)
  - 37% preferred colonoscopy
  - 29% preferred FOBT

Fecal Immunochemical Tests (FIT)

- Detect blood by immunoassay
- An antibody specifically recognizes the globin component of human hemoglobin
- Globin is prone to degradation from upper gastrointestinal tract proteases thus FIT are less likely to present false positive results from UGI bleeding
  - High specificity for human blood and for lower GI bleeding
- Some types require only 1 or 2 stool specimens
- Higher sensitivity than guaiac FOBT

FOBT/FIT: Accuracy

Annals of Internal Medicine | REVIEW

Accuracy of Fecal Immunochemical Tests for Colorectal Cancer

Systematic Review and Meta-analysis

Jeffrey K. Lee, MD, MAS; Elizabeth G. Liles, MD, MCR; Stephen Bent, MD; Theodore R. Levin, MD; and Douglas A. Corley, MD, PhD

Background: Performance characteristics of fecal immunochemical tests (FITs) to screen for colorectal cancer (CRC) have been inconsistent.

Purpose: To synthesize data about the diagnostic accuracy of FITs for CRC and identify factors affecting its performance characteristics.

Data Sources: Online databases, including MEDLINE and EMBASE, and bibliographies of included studies from 1996 to 2013.

Study Selection: All studies evaluating the diagnostic accuracy of FITs for CRC in asymptomatic, average-risk adults.

Data Extraction: Two reviewers independently extracted data and critiqued study quality.

Data Synthesis: Nineteen eligible studies were included and meta-analyzed. The pooled sensitivity, specificity, positive likelihood ratio, and negative likelihood ratio of FITs for CRC were 0.79 (95% CI, 0.69 to 0.86), 0.94 (CI, 0.92 to 0.95), 13.10 (CI, 10.49 to 16.35), 0.23 (CI, 0.15 to 0.33), respectively, with an overall diagnostic accuracy of 95% (CI, 93% to 97%). There was substantial heterogeneity between studies in both the pooled sensitivity and specificity estimates. Stratifying by cutoff value for a positive test result or removal of discontinued FIT brands resulted in homogeneous sensitivity estimates. Sensitivity for CRC improved with lower assay cutoff values for a positive test result (for example, 0.89 [CI, 0.80 to 0.95] at a cutoff value less than 20 $\mu g/g$ vs. 0.70 [CI, 0.55 to 0.81] at cutoff values of 20 to 50 $\mu g/g$) but with a corresponding decrease in specificity. A single-sample FIT had similar sensitivity and specificity as several samples, independent of FIT brand.

Limitations: Only English-language articles were included. Lack of data prevented complete subgroup analyses by FIT brand.

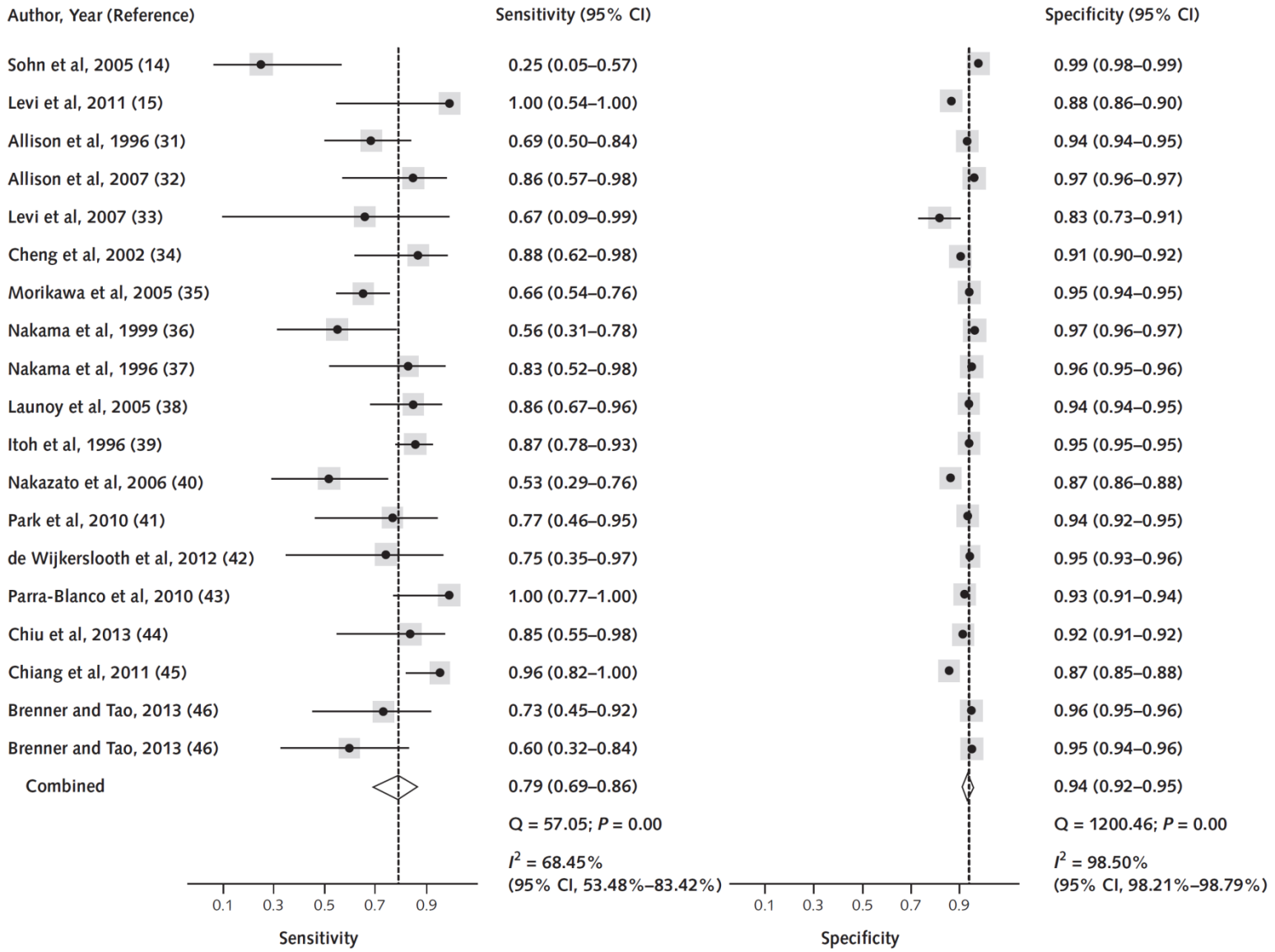
Conclusion: Fecal immunochemical tests are moderately sensitive, are highly specific, and have high overall diagnostic accuracy for detecting CRC. Diagnostic performance of FITs depends on the cutoff value for a positive test result.

Primary Funding Source: National Institute of Diabetes and Digestive and Kidney Diseases and National Cancer Institute.

Ann Intern Med. 2014;160:171-181. www.annals.org

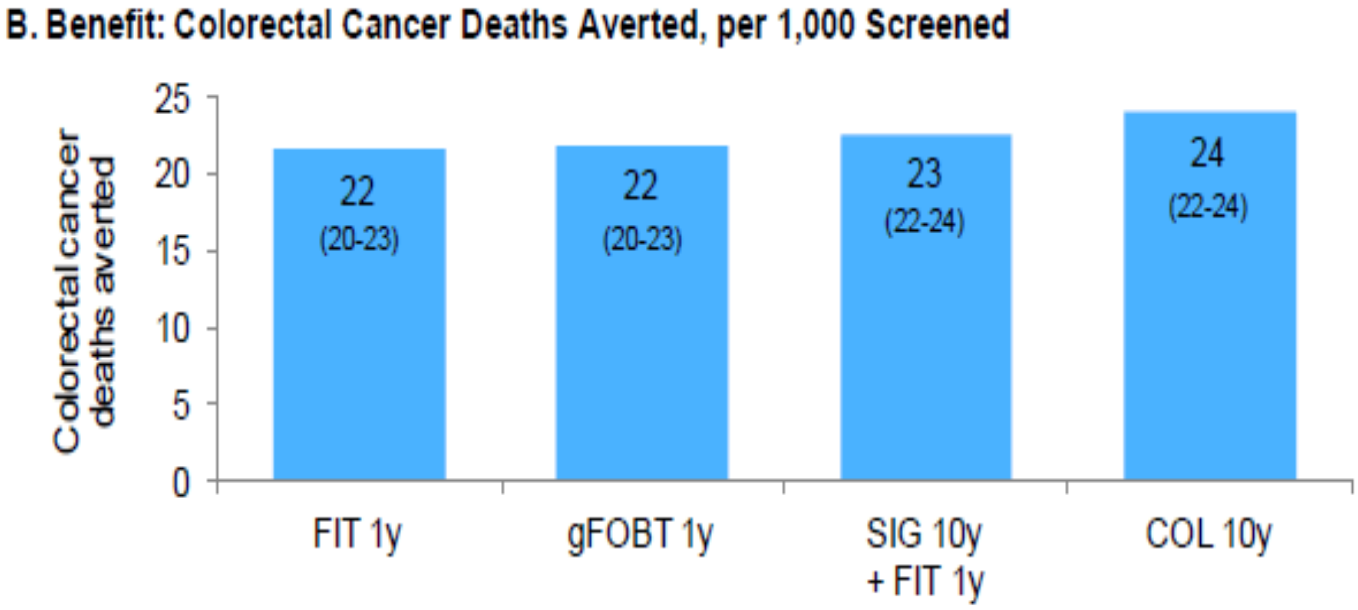
For author affiliations, see end of text.

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



FOBT/FIT Efficacy (USPSTF 2015)

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

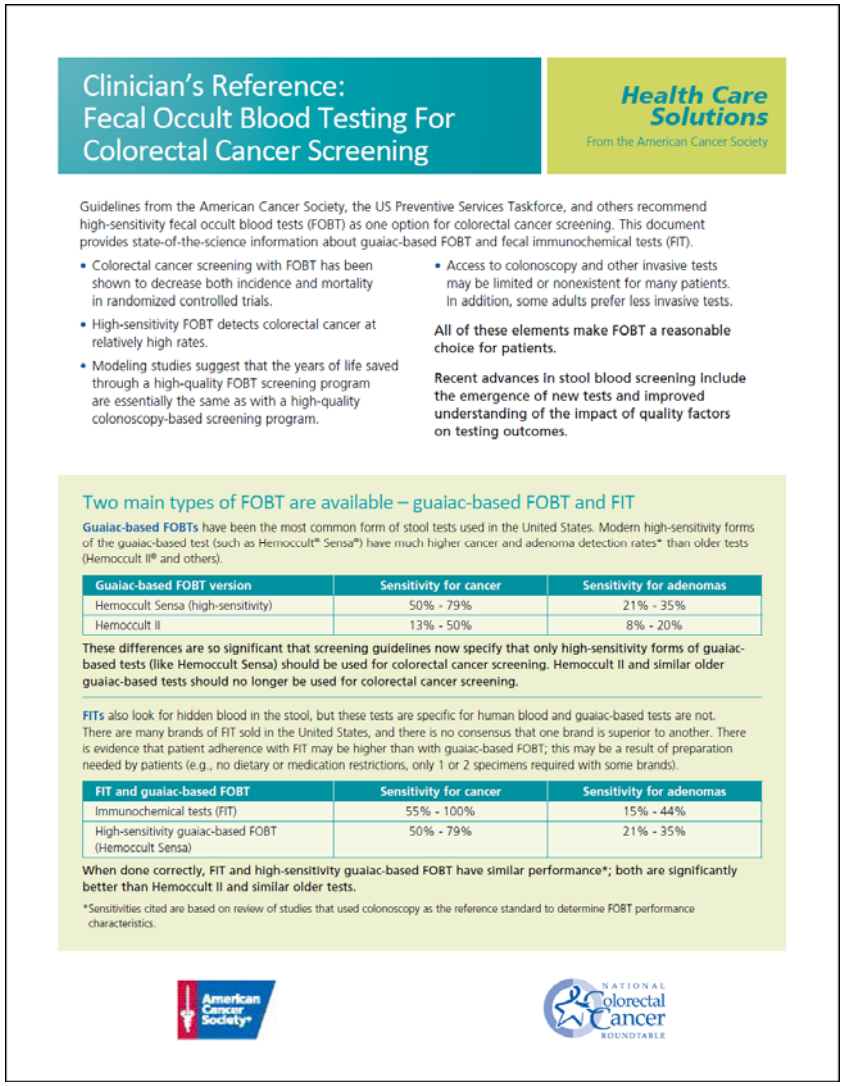


http://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement38/colorectal-cancer-screening2

Stool Test Quality Issues

- Stool tests are appropriate only for *average risk* (no family history, no history of adenomas,…)
- Use only high sensitivity guaiac or FIT
  - Hemoccult II and other less sensitive guaiac tests should not be used for screening
- Digital Rectal Exam specimens are not evidence based and should not be used for CRC screening
  - Missed 19 of 21 cancers in largest study
- All positive tests must be followed up with colonoscopy
  - Follow up often lacking (<75% adherence in many settings)
  - Patient should be aware of potential cost sharing if stool test is used for initial screen

High Quality Stool Testing



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

Health Care Solutions
From the American Cancer Society

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

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

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

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

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

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

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

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

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

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

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

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

American Cancer Society

National Colorectal Cancer Roundtable

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

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

Available at
www.cancer.org/colonmd

FluFIT

What is a FluFIT program?

- Annual flu shot visits are an opportunity to reach many people who also need CRC screening
- Health center staff recommend CRC screening and provide FIT/FOBT kits to average risk, eligible patients when they get their annual flu shot
  - Either a high sensitivity FOBT or a FIT can be used for the program
- Patient completes FIT/FOBT **at home** and returns kit to doctor's office or mails kit to the lab for processing
- FluFIT programs are well accepted by patients
- Studies show FluFIT lead to higher CRC screening rates in a variety of clinical environments

FluFOBT – San Francisco General Hospital Trial

	Flu shot + FOBT kit (268 patients)	**Flu shot only (246 patients)**
Up-to-date CRC screening *before* flu shot season	54.5%	52.9%
Up-to-date CRC screening *after* flu shot season	84.3%	57.3%
Change: (p<0.001)	+29.8 percentage points	+4.4 percentage points

Ann Fam Med, 2009

FluFOBT – Kaiser Trial

TABLE 2—Proportion of Participants Completing Colorectal Cancer Screening Within 90 Days of Receiving Influenza Vaccination: FLU-FIT Program, Kaiser Permanente Northern California, 2009–2010

Test	Intervention (n = 3351), No. (%)	Control (n = 2884), No. (%)	*P*
FIT	900 (26.9)	336 (11.7)	≤ .001
Sigmoidoscopy	62 (1.9)	68 (2.4)	.16
Colonoscopy	86 (2.6)	61 (2.1)	.24
FIT, sigmoidoscopy, or colonoscopy	996 (29.7)	438 (15.2)	≤ .001

Note. FIT = fecal immunochemical test.

Am J Public Health, 2013

Why try FluFIT?

- Many sites use FluFIT to begin the process of incorporating CRC screening into routine practice outside of Flu season
- Same Guidelines Apply
  - Like flu shots, CRC screening with stool test is repeated every year
  - Annual testing is needed to be effective and evidence-based

How To Set Up Your FluFIT Program

- Put your team together
  - Select a champion to coordinate your efforts
  - Select team members and staffing levels
- Train your team
    - Importance of flu shots and CRC screening
    - How to organize your workflow
    - Assessing patient eligibility
    - Patient education about FIT/gFOBT and how to complete the test
    - Test tracking and follow up

Program Set Up (continued)

- Choose times and locations for your program and advertise the fact that FIT/FOBT will be offered with flu shots this year. Decide:
  - When to start
  - Where to hold the program
  - How to advertise
- Design a patient flow and management plan
  - Assess patient eligibility
  - Offer FIT/FOBT BEFORE giving the flu shot

CRC Screening Eligibility & FluFIT

- When should a patient be offered a FIT/FOBT kit during the program?
- Patient –
  - Is 50 years or older…
  - Has not had a colonoscopy in the last 10 years…
  - Has not had an FIT/FOBT test in the past year…
  - Is NOT at increased risk for colon cancer

CRC Screening Eligibility & FluFIT

- When should a patient **NOT** be offered an FIT/FOBT kit?
  - Less than age 50
  - Had a colonoscopy in the last 10 years
  - Had an FIT/FOBT test in the past year
  - Has a personal history of Crohn's Disease or Ulcerative Colitis*
  - Has a personal history of polyps or cancer*
  - Has a family history of polyps or cancer in a family member younger than age 60*
  - Rectal bleeding, blood in stool or other symptoms

**Patients with these risk factors should be directed to a clinician for appropriate screening recommendations*

Program Set Up (continued)

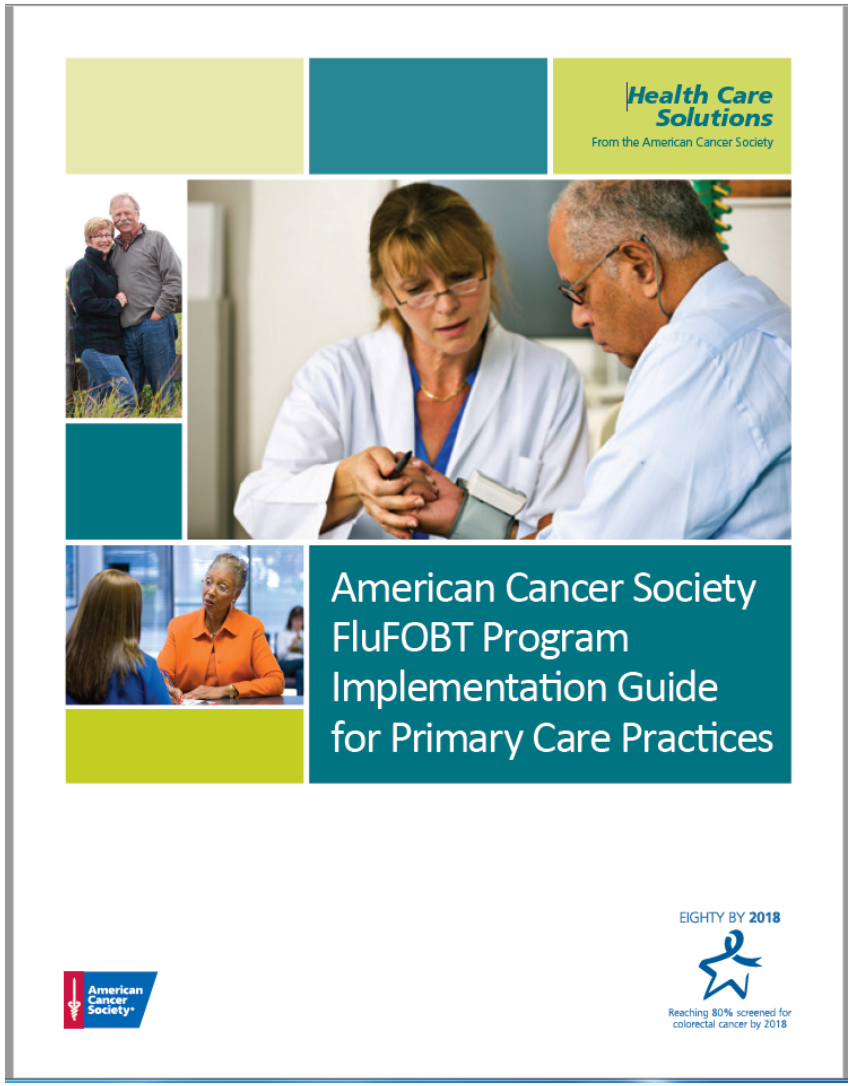
- Develop systems to support follow up for patients who receive FIT/FOBT kits
  - Provide patients with clear instructions
  - Provide a return envelope for kits
  - Reminder phone calls and/or postcards
  - Follow up care (remember: all patients with a positive stool test must have colonoscopy follow up)
- Get started, implement your FluFIT program

Talking with Patients about CRC

- It is important to educate your patients about the importance of colorectal cancer screening and the option of FIT/FOBT
- It is very important to remind patients to complete and return the FIT/FOBT kit at the time the kits are distributed
- Telephone or post card reminders are imperative if the patient has not returned the kit within 14 days.

Studies show that reminders can double return rates!

ACS FluFOBT Implementation Guide and Materials



https://www.cancer.org/content/dam/cancer-org/cancer-control/en/reports/american-cancer-society-flufobt-program-implementation-guide-for-primary-care-practices.pdf

What's in the ACS FluFOBT Program Implementation Guide?

- Background information on Colorectal Cancer and FluFIT/FluFOBT
- Patient eligibility criteria
- Colorectal cancer screening recommendations
- Patient education
- Guidance on setting up your program
- Implementation recommendations and resources
- Example advertising and tracking tools

Additional Resources: UCSF FluFIT/FluFOBT Program

http://flufit.org/

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