

Increasing CRC Screening Rates in NYS Is FIT the Answer?



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Pop Quiz

True or False?

Menu of recommended screening tests

- **Tests that find polyps and cancer**
 - ◆ Flexible sigmoidoscopy every 5 years
 - ◆ Colonoscopy every 10 years
 - ◆ Double-contrast barium enema every 5 years
 - ◆ CT colonography (virtual colonoscopy) every 5 years
- **Tests that primarily find cancer**
 - ◆ Yearly guaiac-based fecal occult blood test (gFOBT)
 - ◆ Yearly fecal immunochemical test (FIT)
 - ◆ Stool DNA test (sDNA), every 3 years

Lecture Outline

- The history of screening for CRC from 2000 - 2012
 - ◆ The CRC problem and screening as one solution
 - ◆ The elephant in the screening test room and how it got there
 - ◆ What are “precancerous” polyps and how often are they fatal?
 - ◆ Is there evidence that colonoscopy is the best/preferred CRC screening test?
 - ◆ The messages 2000 – 2012
- The current CRC Screening Guidelines (ACS/MSTF, USPSTF, ACG)
 - ◆ The recommended tests
- The messages 2012 – 2017 and beyond
- The PCP – how you can help increase CRC screening rates?
- Conclusions
- References

The Problem: Colorectal Cancer

- High prevalence in patients ≥ 50 years
 - In 2017 it is estimated that there will be 135,000 new cases and 50,000 deaths in U.S.
 - Represents 9% of all cancer deaths in the U.S
 - Third in incidence and cause of cancer death in both women and men
 - *67,000 cases and 28,600 (40%) deaths in women in the U.S. yearly*

Cancer statistics, 2012. CA Cancer J Clin. 2012;1:10-29.

2017, American Cancer Society, Inc., Surveillance Research

Colorectal Cancer: The Risk

- *The lifetime risk of CR cancer in the U.S. approaches 6% for both men and women*
- *Almost 50% of those affected will die of the disease*
- *A person at age 50 has a 5% lifetime risk of being diagnosed with CR cancer and a 2.5% chance of dying from it*

*Burt RW. Gastroenterology. 2000;119:837-853.
USPSTF. Ann Intern Med. 2002;137:129-131.*

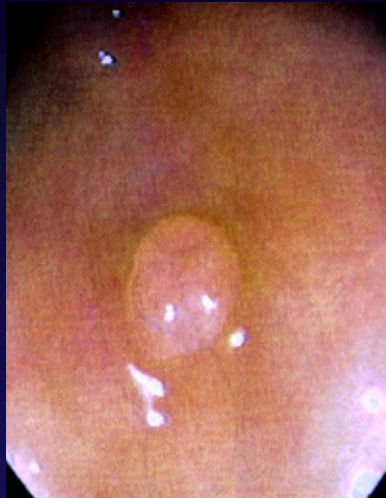
Colorectal Cancer Screening

Arguments for screening:

- *In most cases colorectal cancer develops slowly from an adenomatous polyp, a process which can take up to 10 years*
- *The polyps most likely to become cancers can be identified and removed thus preventing cancer*
- *Detection of early stage cancers allows for CRC mortality reduction*

Pathway to Colorectal Cancer

10 - 15 years



Normal

Adenoma

Carcinoma

*The prevalence of adenomas in average risk screening populations ranges from 22-58%
25% of U.S. population have polyps by age 50.*

Up to 50 percent of individuals will develop a colorectal adenoma (polyp) in their lifetime.

What are colonic polyps, adenomas, advanced neoplasms?

Polyp	Benign tumor that protrudes into the lumen of the colon
Adenoma	Benign polyp derived from the lining of the colon
Advanced adenoma	Refers to polyps 1 cm or greater or with villous features or high grade dysplasia Not cancers and natural history is unknown
Colonic neoplasm	Described in the gastroenterology literature as “advanced;” predominately advanced adenomas and very few Stage 4 cancers

How likely are they to kill you?

- *Most polyps, even the “advanced” ones, do not directly lead to death from colon cancer*
 - ◆ *Only 6% of these lesions will later develop into CRC*
 - ◆ *Only about 2.5/1000 polyps per year progress to cancer*
 - ◆ *Large polyps (>1cm) become colorectal cancers at a rate of roughly 1% per year*
 - ◆ *A large polyp, left in situ, has a cumulative risk of malignancy at 20 years of only 24%*
 - ◆ *The development of invasive cancer from a small (<10mm) adenoma is extremely unlikely in less than five years*

Ransohoff DF Editorial. The Lancet 2002; 359:1266-7.

Stryker S, Wolff B, Culp C, et al. Gastroenterology 1987; 93:1009-13.

Eide T. Int J Cancer 1986; 38:173-6.

Ahlquist DA.. Gastroenterology 2010(6):2127-39.

The New England Journal of Medicine

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USE OF COLONOSCOPY TO SCREEN ASYMPTOMATIC ADULTS FOR COLORECTAL CANCER

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HARINDER GAREWAL, M.D., PH.D., AND GREGORIO CHEJFEC, M.D., FOR VETERANS AFFAIRS COOPERATIVE STUDY GROUP 380*

2000-2009

American College of Gastroenterology CRC Screening Guidelines

- *“Colonoscopy every 10 years, beginning at age 50, remains the preferred CRC screening strategy”*
- *“It is impractical for a PCP to discuss 6 different options for CRC screening with each patient. Recommending one preferred strategy simplifies the discussion. Colonoscopy is the preferred strategy because it is the best test”*

Rex D, Johnson DA, Anderson JC et al Am J Gastroenterol. 2009;104:739-750

Rex D Medscape Medical News March 10,2009

The Media and Opinion Leaders Speak: The Aftermath

- *Congress bypassed CMS evaluation and added colonoscopy to the covered colon cancer screening tests for Medicare patients by mandate*
- *Since Medicare's decision to reimburse for screening colonoscopy, some gastroenterologists are spending up to 50% of their practice time simply performing colonoscopy*
- *Some commercial insurance plans are spending more every year on colonoscopies than on cardiac bypass, hip and knee surgeries, combined **

**Health Care Incentives Improvement Institute, Inc.*

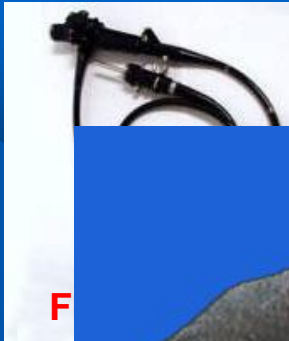
The Media Speaks

The Katie Couric Effect



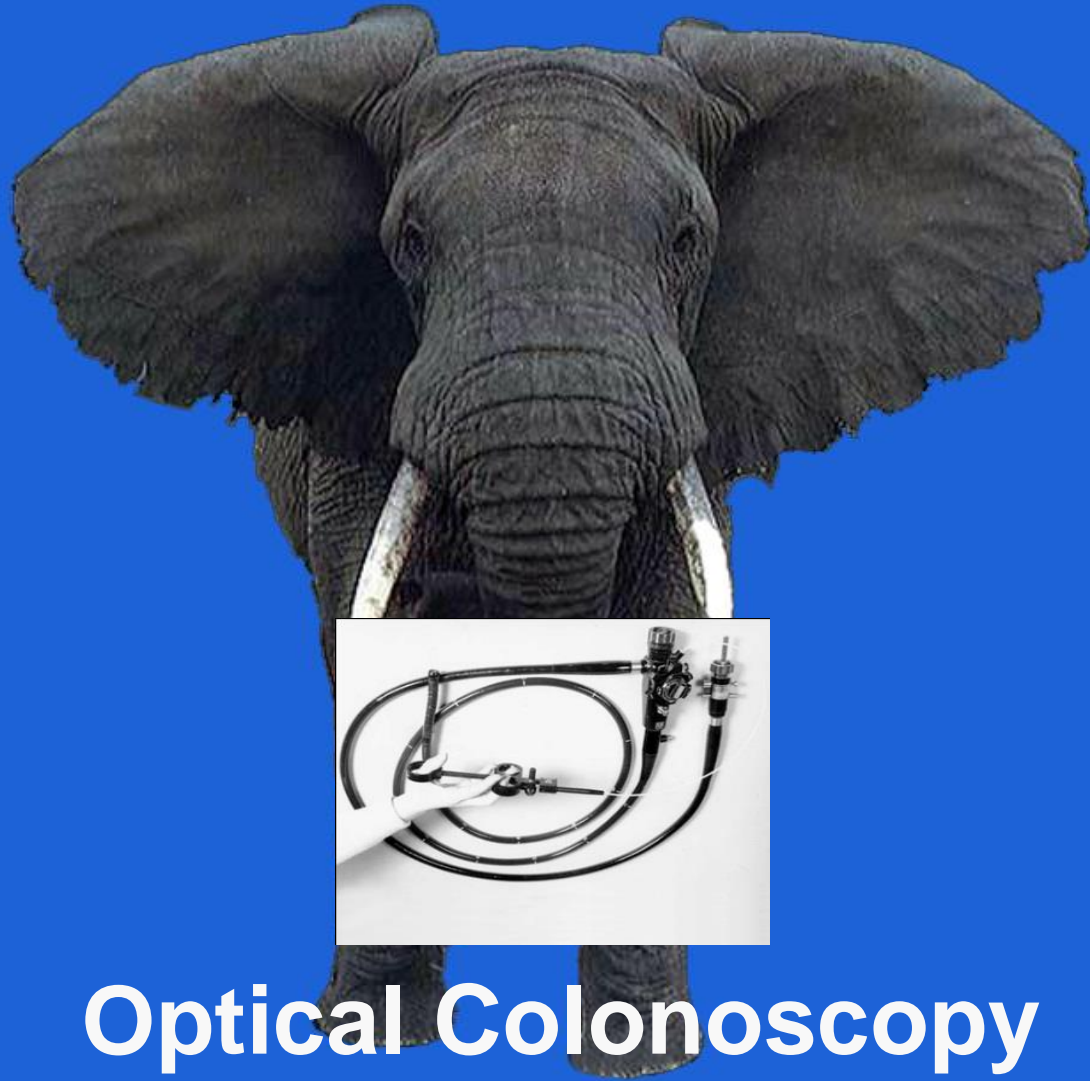
It's considered the most effective test for detecting colon cancer, and as Katie Couric says in her special report, "It really didn't hurt." Katie's first colonoscopy

Cram P, Fendrick MA, Inadomi J, et al. Arch Intern Med 2003;1601-1605.



F

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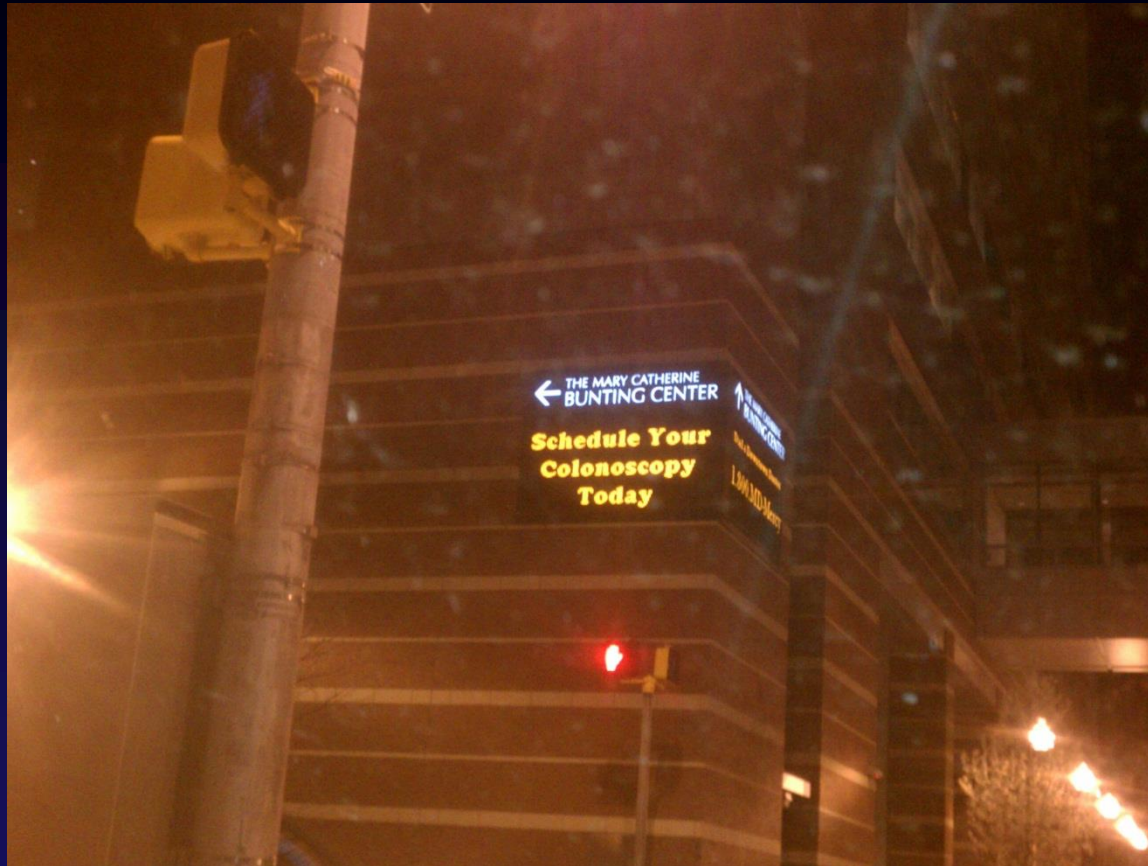


Optical Colonoscopy

2008 ACS/USMSTF CRC Guidelines

Precautions Re Menu of Options

- If fecal tests are used the “opportunity for prevention is both limited and incidental and not the primary goal of CRC screening with these tests”
- “It is the strong opinion of this expert panel that colon cancer prevention should be the primary goal of CRC screening and that providers and patients should understand that noninvasive tests are less likely to prevent cancer compared with the invasive tests”



***Colorectal Cancer Awareness Month
Baltimore, MD March, 2012***

The Message: **“Get a Colonoscopy”** not
“ Be screened for Colorectal Cancer”

Colorectal Cancer Screening

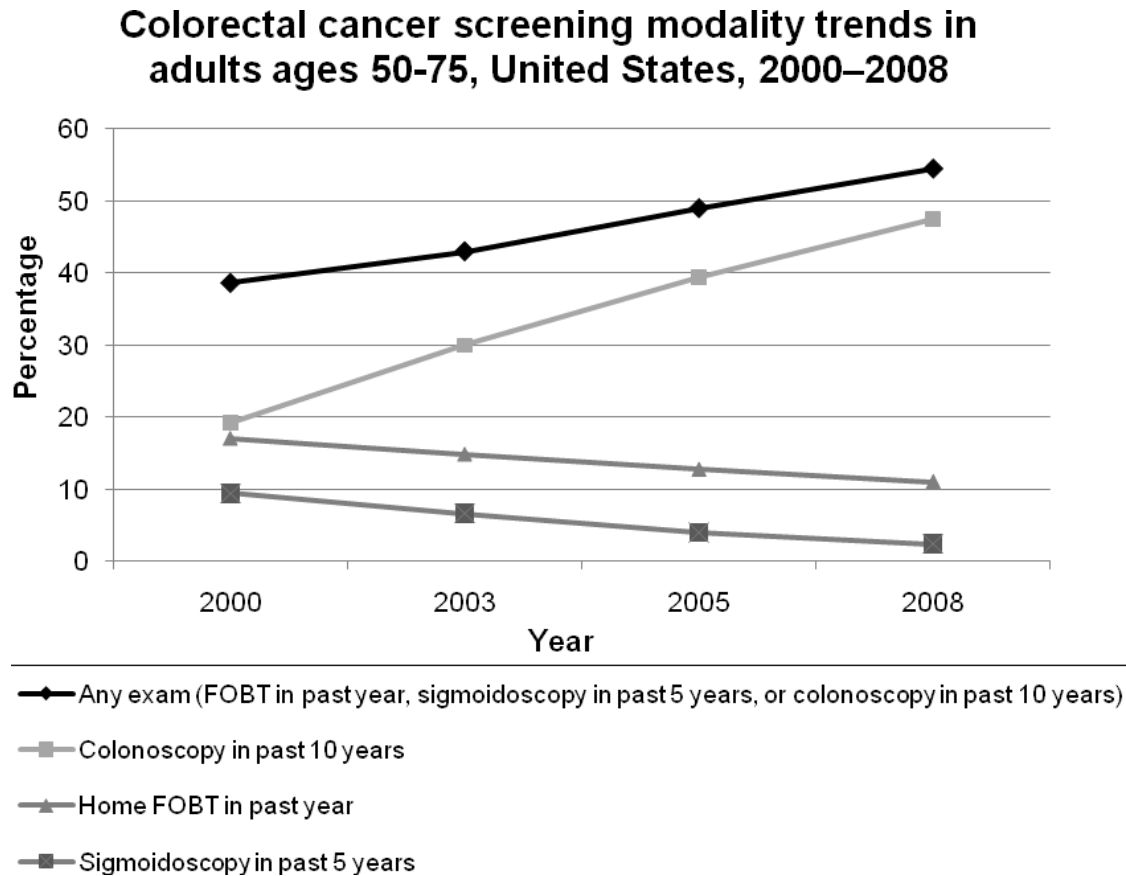
NCI Cancer Bulletin August 21, 2007

The Imperative of Improving Colorectal Cancer Screening Rates

It's a troubling fact that colorectal cancer screening rates continue to lag well behind those for other cancers

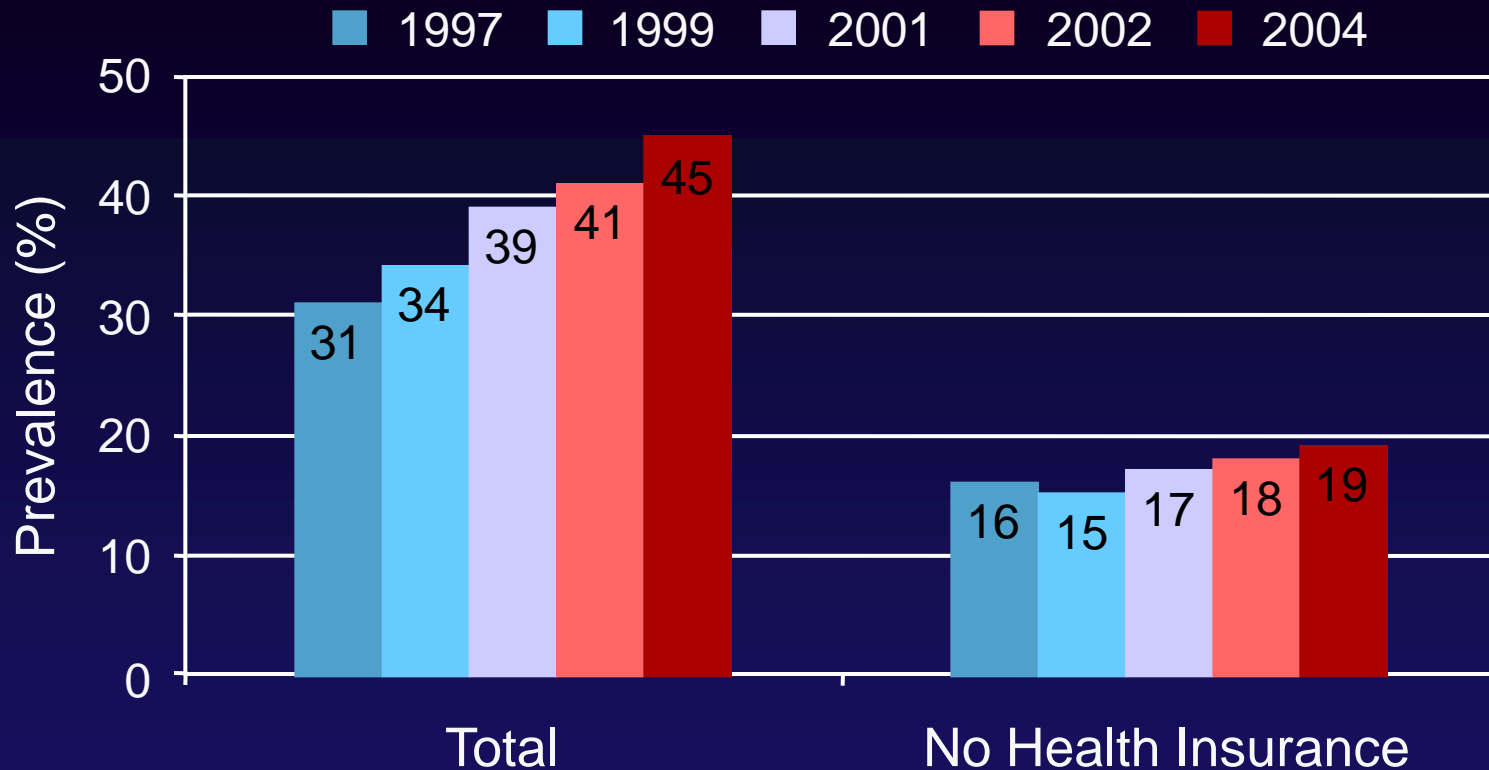
*The reasons behind this shortfall are complex, but there is widespread agreement that if significant improvements in colorectal cancer screening are to be realized, **the primary care setting** will be the most crucial contributor*

CRC Screening Test Trends 2000 - 2008



Trends in Endoscopy: US 1997-2004

Increasing for Everyone but the Uninsured



A flexible sigmoidoscopy or colonoscopy within the past five years.

Source: Behavioral Risk Factor Surveillance System CD-ROM (1996-1997, 1999) and Public Use Data Tape (2001, 2002, 2004), National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention and Prevention, 1999, 2000, 2002, 2003, 2005.

Is Colonoscopy the Best Screening Test?

- *Although two randomized controlled trials are in progress, there is no evidence yet proving the assertion that there is one best screening test.*
- *In 2008 a decision analysis using 2 microsimulation models supported the idea that CRC screening with annual sensitive FOBT (FIT) was as effective as colonoscopy screening every 10 years*
- *Data suggests that the protection against cancer afforded by having a negative colonoscopy is quite different in the proximal (right) colon (29-56%) than in the left colon (80%).*

Zauber AG, Lansdorp-Vogelaar I, et al Ann Intern Med. 2008 Nov 4;149(9):659-69

Lakoff J, Paszat LF, Saskin R, et al Clinical Gastro and Hepatology. 2008;6:1117-1121.

Baxter NN, Rabeneck L, J Natl Cancer Inst. 2010 Jan 20;102(2):70-130.

Brenner H, Chang-Claude J, Seiler CM, et al Ann Intern Med. 2011;154:22-30.

Samadder NJ., Curtin K, Tuohy TME Gastro 2014;146:950-960

Explanations

Colonoscopy: reduction in benefit for proximal CRC

- *Many proximal lesions are sessile, pale, and difficult to identify and remove completely*
- *Quality of bowel preparation is often less optimal in the proximal colon*
- *CRC surveillance recommendations are predicated upon a slow transition from adenoma to carcinoma but some proximal CRCs develop rapidly through microsatellite instability and CpG island Methylator phenotype pathways*
- *The precursor for this rapidly developing CRC is likely the serrated adenoma, a lesion difficult to visualize with colonoscopy and more likely found in the proximal colon*

Is Colonoscopy the Best Screening Test?

- *The risk (2.8 in 1000) of serious complications (perforations, hemorrhage, diverticulitis, CV events, severe abdominal pain and death) detracts from any benefit colonoscopy may have over other less invasive screening options*
- *Evidence suggests the manpower necessary to provide a skilled colonoscopic examination for all eligible U.S. citizens is inadequate.*

Seef LC, Manninen DL, et al. Gastroenterology 2004; 127:1661-1669.

Levin TR, Editorial Gastroenterology 2004; 127:1841-1849.

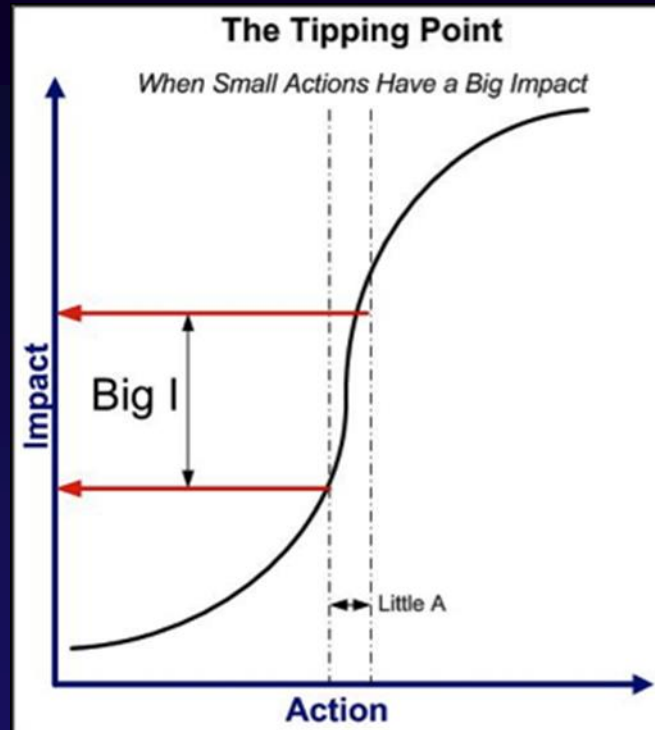
Lieberman, DA, et al. N Engl J Med 2000; 343:162-8.

Summary of Messages

2000 - 2012

- Colonoscopy every 10 years, beginning at age 50, remains the preferred CRC screening strategy because it is the best test
- Relying on flexible sigmoidoscopy is as clinically logical as performing mammography of one breast to screen women for breast cancer
- If fecal tests are used the opportunity for CRC prevention is limited and incidental
- Fecal occult blood tests have been proven to be inherently insensitive and nonspecific markers for screen relevant neoplasia.
- FOBT require repeated testing that is unlikely to be done.

2012 – *The Tipping Point*



Source: Malcolm Gladwell. *The Tipping Point: How Little Things Can Make a Big Difference*. Little, Brown and Company, 2000

The New Messages

2012 – 2018 and beyond

- No CRC screening strategy has been shown to be superior but, colonoscopy is the predominant method for CRC screening in the U.S.
- Primary-care providers are the most common source for a CRC screening recommendation. Many providers believe that colonoscopy is the best test option and do not offer other screening tests to their patients
- The potential to increase screening rates exists if health-care providers identify the test that their patient is most likely to complete and consistently **offer all** recommended screening tests

2012 NCCRT /ACS

FOBT Clinician's Reference Resource

- FOBT has been shown to decrease both incidence of and mortality from CRC
- Modeling studies suggest years of life saved through a high-quality FOBT screening program are the same as with a high-quality colonoscopy screening program
- These elements make FOBT a reasonable choice for patients

“Shared decision making is important when selecting a screening test because the currently available colorectal cancer screening tests are believed to be similarly efficacious.”

*Screening for Colorectal Cancer:
A Guidance Statement from
the American College of Physicians*

Ann Intern Med. 2012;156:378-386.

JAMA PATIENT PAGE / Options for CRC Screening

Evidence does not yet support any one screening test over another, so in deciding which screening option is best for you, consider your personal health situation and talk with your doctor

GIE 2013

Screening and Surveillance for CRC: state of the art

- Colonoscopy remains the dominant CRC screening strategy in the U.S. but is less effective at preventing right sided CRC than previously thought
- FIT has emerged as an effective low cost alternative to colonoscopy and is considered by some an equivalent or superior approach to screening as compared to colonoscopy

Reaching 80% Screening By 2018

“A Public Health Goal We Will Reach”



Richard C. Wender, MD
Chair, NCCRT



Djenaba Joseph, MD, MPH Medical Director
CDC's CRC Control Program

The new NCCRT messages

Tweets and FB posts

- There are several ways to get screened for CRC including simple take home options. Talk to your doc about **#savinglives**
- Preventing colon cancer, or finding it early, doesn't have to be expensive. There are simple, affordable tests available. Get screened.
#80by2018
- A colonoscopy isn't the only way to get screened for CRC. Your doctor can even give you a kit to take and use at home! Read more and talk to your doctor:<http://ow.ly/HY99v>

CRC Screening Options

USPSTF CRC Guidelines 2017

- Average-risk individuals aged 50 -75*:
 - ◆ High-sensitivity fecal occult blood test (FOBT) including fecal immunochemical tests (FIT) annually or Multitarget Stool DNA Test every 3 years
 - ◆ Colonoscopy every 10 years
 - ◆ Sigmoidoscopy every 5 years plus interval FOBT/FIT

N.B. The Affordable Care Act (ACA) mandates that screening tests recommended by the USPSTF be covered with no out-of-pocket costs. A colonoscopy done for a positive FIT is considered a “diagnostic” colonoscopy subject to cost sharing.

*based on US Preventive Services Task Force Recommendations

Fecal Immunochemical Test for Hemoglobin

Principle

- Detect blood by immunoassay
- An antibody specifically recognizes the globin component of human hemoglobin
- FIT can detect smaller levels of bleeding and thus smaller cancers and more adenomas
- High specificity therefore less false positives
- The globin detected by FIT is prone to degradation from UGI proteases thus FIT are less likely to present false positive results from upper gastrointestinal tract bleeding

FIT Sensitivity: Essential Information

- Sensitivity is the proportion of actual positives correctly identified (e.g. % of patients with CRC who are correctly identified as having the condition).
- Reported test sensitivity is either application sensitivity (test performed once only) or programmatic sensitivity (test performed repeatedly in a program of screening over time)
- CRC is a particularly good target for screening programs because evidence exists that most cases develop from preexisting benign adenomas
- Benign adenomas (polyps) have long intervals between their benign and malignant states
- Most CRCs are slow growing with a doubling time of more than 600 days and this allows for a program of repeated screens every year or 2 years using FIT to be as effective as a screening program of colonoscopy every 10 years

Choosing A FIT for your Screening Program

The critical information you must know

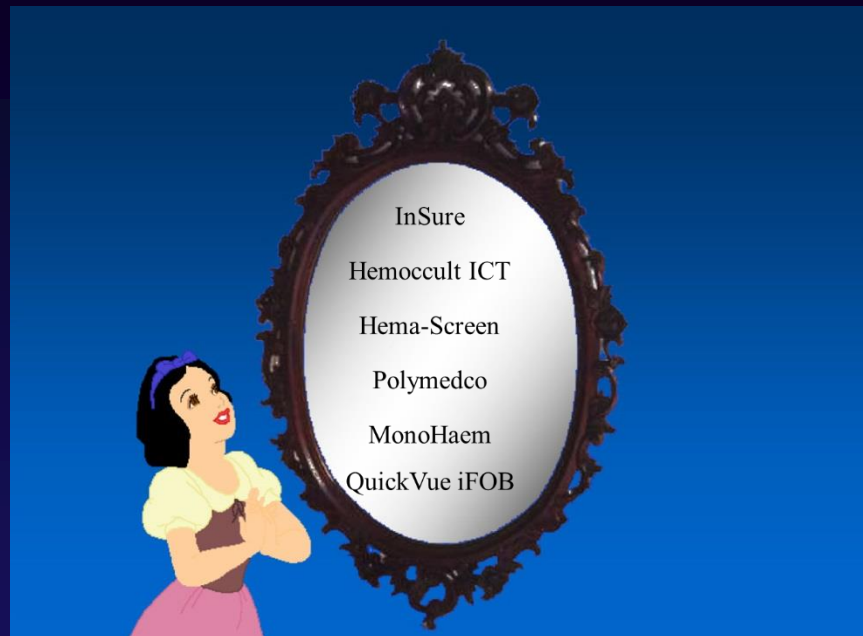
- All FIT are different and should not be considered as a class
- Different FIT have
 - Different antibodies to different epitopes of hemoglobin
 - Different specimen collection techniques – wet and dry
 - Different preservative techniques
 - Different number of samples required
 - Different hemoglobin cutoffs for a positive test
- The FDA evaluates FIT as tests for blood and not for advanced colorectal neoplasms (advanced adenomas and CRC)
- If stool tests are shown to detect blood (hemoglobin) they are “cleared” by the FDA for laboratory use, not approved by the FDA, recommended or, endorsed
- Most FDA approved CLIA waived point of care Qualitative FIT have no evidence of their claimed performance characteristics or quality of development and interpretation in large average risk populations

Caution: Buyer beware!
Available on Amazon.com - Price: \$22.99
Second Generation FIT for Colorectal Cancer

● Features

- Amazingly accurate with 98% sensitivity and 96% specificity
- Easy to use with results in 5 minutes in the privacy of your home
- This is the same test as physicians, hospitals, and labs use for colorectal cancer screening, now available without a prescription or visit to the doctor
- 93% as effective as colonoscopy when performed annually. This is the same test used by physicians to effectively diagnose diverticulitis, colitis, ulcerative colitis, irritable bowel disease, and irritable bowel syndrome.
- FDA cleared for over the counter (home) use and CLIA waived

Mirror Mirror on the wall Which is the Best FIT - Test of them all?



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

Ann Intern Med. 2014;160:171-181.

FIT with data on performance characteristics in large average risk populations

Table 1. Characteristics of Included Studies in Meta-analysis

Study, Year (Reference)	FIT Brand	Country	FIT Samples, <i>n</i>	Cutoff Value for a Positive Test Result, $\mu\text{g/g}$	Cohort Size, <i>n</i>	CRC Cases, <i>n</i>
Sohn et al, 2005 (14)	OC-Hemodlat	Korea	1	20	3794	12
Levi et al, 2011 (15)	OC-Micro	Israel	3	14	1204	6
Allison et al, 1996 (31)	HemeSelect†	United States	3	100	7493	35
Allison et al, 2007 (32)	FlexSure OBT	United States	3	300	5356	14
Levi et al, 2007 (33)	OC-Micro	Israel	3	15	80	3
Cheng et al, 2002 (34)	OC-Light	Taiwan	1	10	7411	16
Morikawa et al, 2005 (35)	MagStream HemSp	Japan	1	67	21 805	79
Nakama et al, 1999 (36)	Monohaem	Japan	1	20	4611	18
Nakama et al, 1996 (37)	Monohaem	Japan	1	20	3365	12
Launoy et al, 2005 (38)	MagStream HemSp	France	2	67	7421	28
Itoh et al, 1996 (39)	OC-Hemodlat	Japan	1	10	27 860	89
Nakazato et al, 2006 (40)	OC-Hemodlat	Japan	2	16	3090	19
Park et al, 2010 (41)	OC-Micro	Korea	1	20	770	13
de Wijkerslooth et al, 2012 (42)	OC-Micro	The Netherlands	1	20	1256	8
Parra-Blanco et al, 2010 (43)	OC-Light	Spain	1	10	1756	14
Chlu et al, 2013 (44)	OC-Light	Taiwan	1	10	8822	13
Chiang et al, 2011 (45)	OC-Light	Taiwan	1	10	2796	28
Brenner and Tao, 2013 (46)	OC-Micro	Germany	1	6.1	2235	15
Brenner and Tao, 2013 (46)	Ridascreen Haemoglobin	Germany	1	24.5	2235	15

CRC = colorectal cancer; FIT = fecal immunochemical test; LR = likelihood ratio.

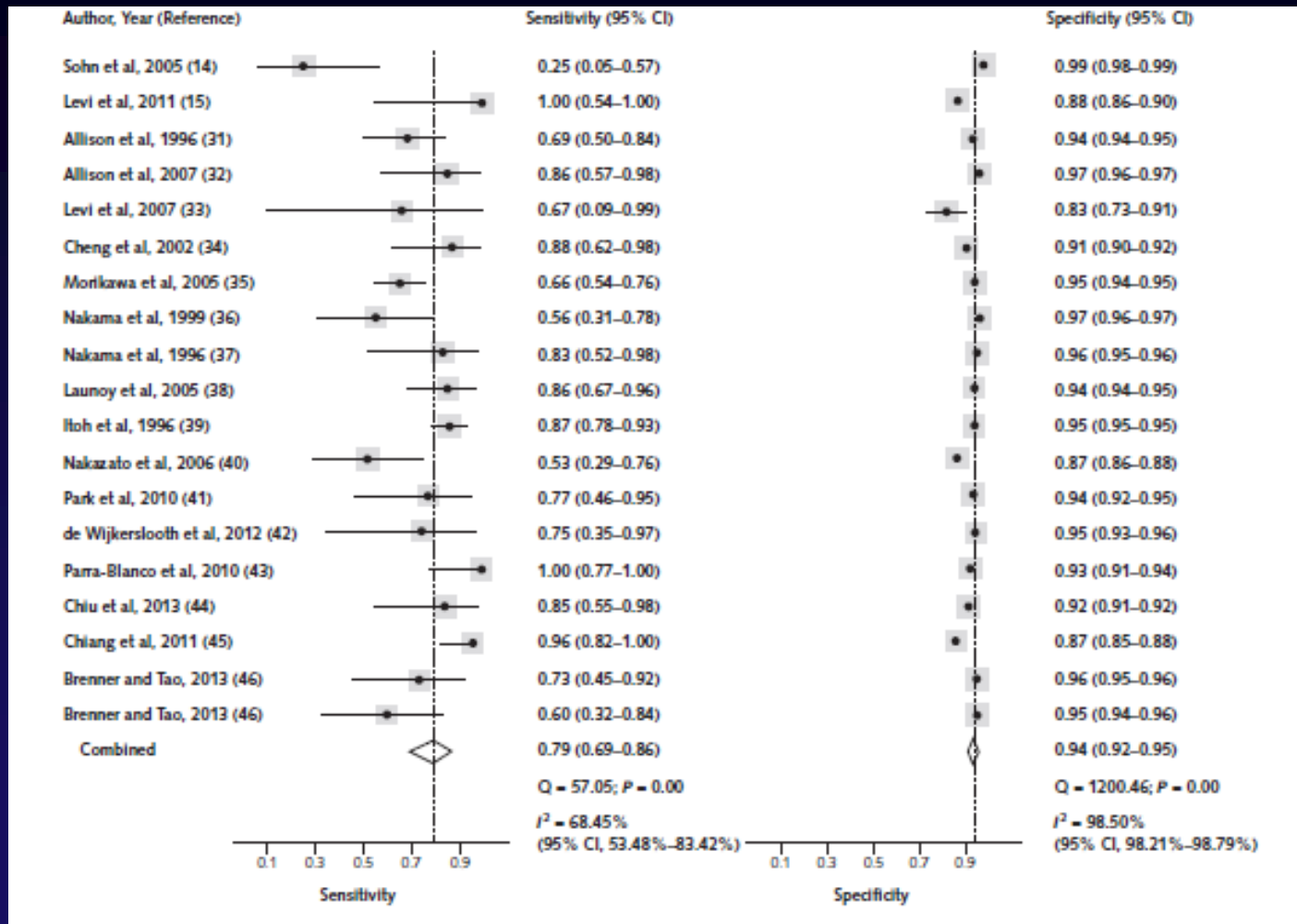
* Either a colonoscopy (detects CRC and adenomas) or a 2-y longitudinal follow-up using a cancer registry (only detects CRC) was used for patients with negative FIT results.

† Discontinued and no longer in production in the United States.

‡ Mean age >45 y because inclusion criteria for patients had to be ages >50 y.

§ Mean age >45 y because only 21% of their cohort participants were aged 40–49 y.

Accuracy of Fecal Immunochemical Tests Systematic Review and Meta-analysis



Pooled sensitivity for CRC: 79% (69%-86%)

Pooled specificity for CRC: 94% (92%-95%)

FIT performance review

FIT test	% positive ^a	Sensitivity ^b	Evaluated in large numbers
OC-Micro	3.3 – 6.0%	88.0%	√
OC-Light	8.4 – 14.2%	88 – 96%	√
Insure	4.6 – 5.6%	87.5%	√
Hemoccult ICT	3.2 – 9.0%	82 – 98%	√
Hemosure	Not available	Not available	
Consult Diagnostics	Not available	Not available	
QuickVue	Not available	Not available	
One-Step +	Not available	Not available	

Additional document on Oregon Health Authority website contains detailed information about FITs

^a Positivity rate is the proportion of test that have a positive result.

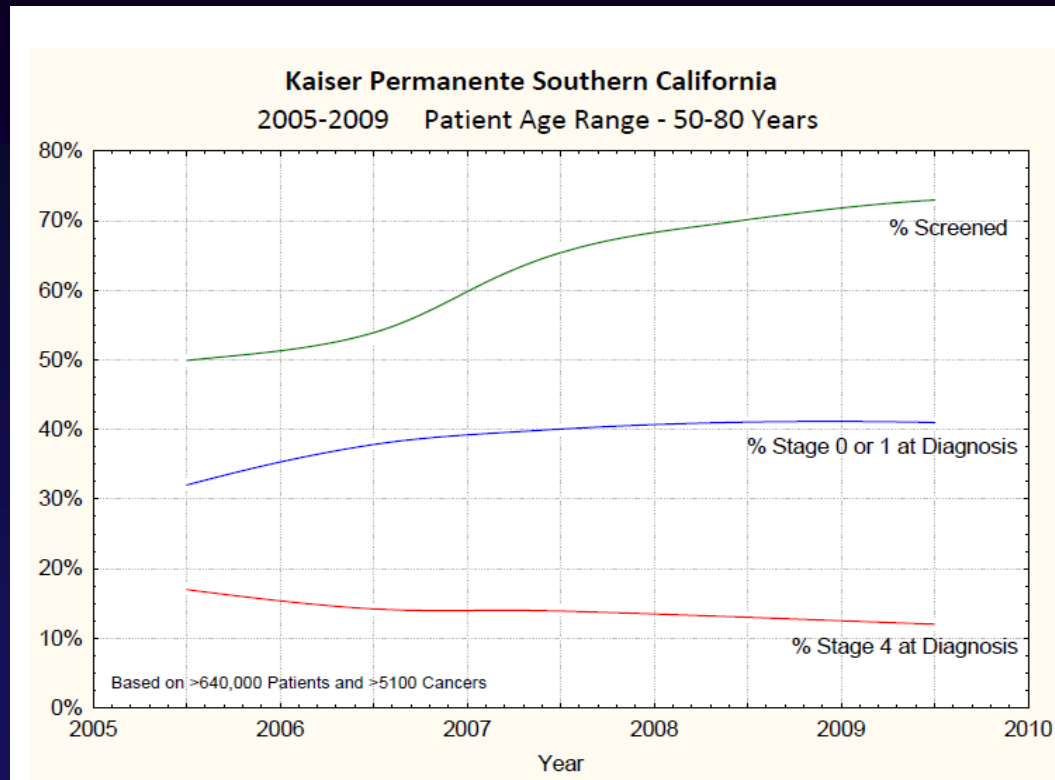
^b Sensitivity is the proportion of actual positives correctly identified (e.g. % of patients with colorectal cancer who are correctly identified as having the condition).

The Best FIT

2016 USPSTF Recommendation

- The FDA cleared OC-Light and OC FIT-CHEK family of tests have the most evidence to support their use
 - Manual tests developed and interpreted by tech, nurse or MD at POC
 - Automated tests developed and interpreted in a qualified laboratory by trained lab techs using automation and reported as qualitative FIT (yes/no result) in the U.S. <http://www.eiken.co.jp/en/product/>
- New names since 2014
 - *OC Auto® Micro 80 FOBT is now OC-Auto® Micro 80 iFOB Test*
 - *OC Sensor Diana iFOBT is now OC-Auto® Sensor Diana iFOB Test*
 - *OC FIT-CHEK® is now OC-Auto® Personal Use kit (patient sample collection pack)*

Kaiser FIT Screening Program



Stage at Diagnosis			
Year	0/1	4	Screened
2005	32%	17%	50%
2006	38%	14%	53%
2007	40%	14%	66%
2008	41%	13%	70%
2009	41%	12%	73%

Benefit of FIT-based program South Carolina

Outcome	Colonoscopy program	Annual FIT program	Relative difference
Individuals screened	2,747	21,153	7.7
Colonoscopies performed	2,747	1,540	0.6
CRC cases prevented	13	30	2.4
CRC deaths prevented	6	26	4.1
Life-years gained	68	258	3.8

*Assumes fixed state funding of \$1 million over 2 years for uninsured, low income population aged 50 – 64

Source: van der Steen A et al. Optimal Colorectal Cancer Screening in States' Low-Income, Uninsured Populations – The Case of South Carolina. Health Services Research, June 2015.

Health Center Data and Trends

- *CRC screening rates generally much lower in community health centers (CHCs) – but steadily improving*
- *Nationwide UDS CRC Screening Rates*
 - ◆ *2012: 30.2%*
 - ◆ *2013: 32.6%*
 - ◆ *2014: 34.5%*
- *2015 Nationwide Average 38.3%*
- *19 FQHCs report rates >80%*
- *Maine to California, and all points in between*

Table 1
Participant Characteristics and Participation Rates

	Year 1	Year 2	Year 3	Year 4
Mailed, <i>n</i>	383,657	122,456	105,711	92,254
Returned, %	46.8	76.1	83.7	87.0
Female, %	53.5	54.1	55.0	55.4
White, %	60.1	62.4	62.3	62.2
Age, yrs <i>Mean (SD)</i>	58.5 (5.7)	60.2 (5.7)	61.2 (5.8)	62.1 (5.8)

Role of the Primary Care Physician in Colon Cancer Screening

Educate and Facilitate:

- *Recommend colorectal cancer screening*
- *Provide information on the screening options*
 - ◆ *Group classes lead by NP, PA or yourself*
 - ◆ *Refer to website: practice, HMO, AHRQ, CDC*
 - ◆ *Automated phone*
- *Be sure all positive tests are evaluated with colonoscopy*

Summary

- FIT is a CRC screening test with proven effectiveness for both early detection and prevention
- FIT are a cheap, effective and currently available way to estimate absolute risk for individual persons so that screening colonoscopy may be more efficiently targeted to those with advanced neoplasia
- Effective repeated screenings can be achieved in large average risk populations

Conclusions

- *It is unrealistic to believe that any one screening test will detect all advanced neoplasms*
- *Decisions on how to population screen for colon cancer should take into consideration upfront costs, patient preferences, and the potential risks of screening tests for otherwise healthy people*
- *As of 2017, human blood detected by FIT is an excellent marker for advanced neoplasms and one effective tool for increasing screening rates in population screening for CRC*

Conclusion: Time To Get FIT



Recommended References

NYS Conference

- NCCRT Guidance on Implementing FIT-based Screening Programs – Coronado and Brooks-<https://www.youtube.com/watch?v=FLaQecqyNVg&feature=youtu.be>
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