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# **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

# **Objectives**

- Review the problem of colorectal cancer in the U.S.
- Familiarize PCPs with the latest screening guidelines for colorectal cancer
- Present the evidence for the recommendations in each of the two new screening guidelines
- Explain why the PCP is essential for improving screening rates
- Discuss the possible impact of the new guidelines on PCP's screening recommendations

# Lecture Outline

- The problem
- Screening as a solution
- The new ACS/Multisociety Taskforce Guidelines
- The new USPSTF Guidelines
- The evidence for guideline recommendations
- The elephant in the screening test room •
- The role of the primary care physician
- Conclusions and Recommendations

### The Problem: Colorectal Cancer



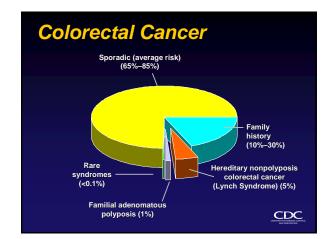
## The Problem: Colorectal Cancer

- High prevalence in patients  $\geq$  50 years
  - In 2008 it was estimated that there would be 149,000 new cases and 50000 deaths in U.S.
  - Accounts for about 60,000 deaths each year
  - Third most common cancer in women and men
  - Second leading cause of cancer death in U.S.
  - 67,000 cases and 28,600 (40%) deaths in women in the U.S. yearly

# **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 Colon Cancer Screening: Gastro 2000; 119:837-853. USPSTF Recommendations on Screening for CRCA 2002.



# **Colorectal Cancer Screening**

Arguments for screening:

- In most cases colorectal cancer develops slowly from a adenomatous polyp, a process which can take up to 10 years
- Polyps can be identified and removed before they become cancers
- Early stage tumors have good prognosis

# Pathway to Colorectal Cancer





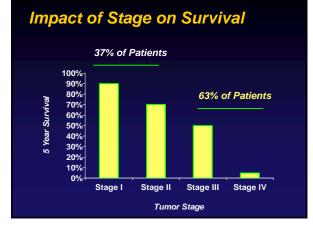


Normal

Carcinoma

25% of U.S. population by age 50 yrs have polyps

Adenoma



# **Colorectal Cancer Screening**

#### We have a problem in U.S.

- Compelling argument for screening
- Multiple effective screening tests are available
- Cost-effectiveness established
- but......50% of Americans of screening age have never been screened and a disproportionate number of advanced cancers are found in the uninsured and underserved population

# Average Risk Individuals

#### Menu of recommended screening tests:

- Stool Tests
  - Fecal occult blood testing (sensitive GT or FIT)
- Stool DNA test (sDNA)
- Structural Exams
  - Double-contrast barium enema
  - Flexible sigmoidoscopy
  - CT Colonography (CTC)
  - Colonoscopy

ACS/MSTF and ACR Guidelines Levin B, Lieberman D, McFarland B, Smith RA et al. CA Cancer J Clin 2008

# The Levels of Evidence

#### Level 1

- Evidence from one or more controlled trials
- Level 2
  - Evidence from cohort or case-control studies
- Level 3
  - Evidence from diagnostic accuracy studies or case series

Pignone M, Rich M, Teutsch MN, Berg AO, Lohr KN, Ann Intern Med. 2002;137:132-141.



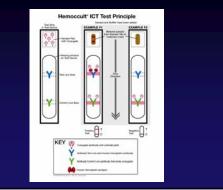
# Sensitive GT: Test Principle

- Detect the peroxidase activity of heme either as intact hemoglobin or free heme
- In the presence of heme and a developer (hydrogen peroxide) guaiac acid is oxidized producing a blue color
- Threshold for detection of peroxidase is set lower than that of the standard GT

#### The Fecal Immunochemical Test (FIT)

- Uses antibodies specific for human globin
- Specific for colonic bleeding
- Not affected by diet or medications
- FDA approved
- Authorized reimbursement by CMS for use in Medicare patients
- Some allow for quantification of fecal hemoglobin
- Can be read and developed by technicians or by automated readers and developers

# FIT : Test Principle



### Fecal Occult Blood Testing Guaiac Test (GT)

Data supporting use:

- 4 randomized controlled trials showing reduction in mortality from CRC
- Sensitivity of single guaiac FOBT for CRC is 30-50%, but sensitivity is better in a program of repeated FOBT testing

### Fecal Occult Blood Testing Guaiac Test (GT)

#### Mortality reduction:

- If offered yearly 33% reduction of CRC death at 13 years
- If offered bi-yearly 18% reduction of CRC death at 10 years
- People who actually did screening had greater benefit - many don't comply!

# Guaiac Testing and the Digital Rectal Exam (DRE)

- DRE itself is not associated with a reduction in mortality in distal rectal cancer
- Guidelines do not endorse DRE alone or FOBT testing of a specimen obtained by this method as colorectal cancer screening tests

Collins JF, Lieberman DA, Durbin TE, Weiss DG, Ann Intern Med. 2005;142:81-85.

# Comparison Test Card FOBT/FIT



## FIT Performance Characteristics

| Test   | Sensitivity<br>Percent (95% CI) | Specificity<br>Percent (95% CI) |
|--|---------------------------------|---------------------------------|
| Hemoccult Sensa<br>Carcinoma<br>Advanced Adenoma | 64 (36-86)<br>41 (33-50)        | 90 (89-90)<br>91 (89-91)        |
| FlexSure OBT<br>Carcinoma<br>Advanced Adenoma    | 82 (48-97)<br>30 (21-40)        | 97 (97-98)<br>91 (89-91)        |

Allison JE, Sakoda LC, Levin TR, et al. J Natl Cancer Inst 2007;99: 1-9.

# FIT Performance Characteristics

| Test<br>Magstream 1000 HP | Sensitivity<br>Percent (95% CI) | Specificity<br>Percent (95% CI) |
|---------------------------|---------------------------------|---------------------------------|
| Carcinoma                 | 66 (55-76)                      | 95 (94-95)                      |
| Advanced Adenoma          | 20 (17-23)                      |                                 |
| High grade dysplasia      | 33 (24-41)                      |                                 |

Morikawa T, Katao J, Yamafi Y et al Gastroenterology 2005;125:422-428

# FIT Advantages over Sensitive GT Evidence Level 3

- Superior sensitivity for CRC and superior specificity for CRC and advanced adenomas
- Dietary restriction is not necessary
- Specific for colorectal bleeding
- Can be developed and interpreted by automation
- Specimen collection allows for less stool handling
- Quantifiable so that sensitivity, specificity, and positivity rates can be adjusted for different screening populations



# Which FIT is Best?

- · Immunochemistry appears to be similar
- Performance characteristics in large average risk populations available for only a few
- Head to head comparisons in large average risk settings not available as yet
- Differences in sampling methods and development may be important

# FIT – Outstanding Issues

- Are quantitative FITs an advantage over qualitative FITS?
- At what level of Hemoglobin detection should FITs be set?
- Which sampling technique is most acceptable to patients
- How many stool specimens should be tested for optimal sensitivity and specificity?
- Are FITs best evaluated in the laboratory or the physician's office?
- Are FITs best interpreted by technicians or automated technology

# Fecal Occult Blood Testing Evidence Level 1 & 3

Recommendation:

Offer yearly screening with stool blood tests that have been shown in the scientific literature to detect the majority of prevalent CRC in an asymptomatic population.

ACS/MSTF and ACR Guidelines Levin B, Lieberman D, McFarland B, Smith RA et al. CA Cancer J Clin 2008

# Stool-based DNA Assays

#### What is it?

- Relies on DNA markers exfoliated from the neoplastic colonic epithelial cells
- PreGenPlus (V1) tests for 21 DNA mutations in the K-ras, APC, and p52 genes along with markers for microsatellite instability and long DNA that are known to be associated with colorectal cancer.
- Mutations identified from stool specimens using PCR amplification technologies

# The Fecal DNA Test The Opinion Leaders Speak

"Stool screening has historically relied on detection of occult blood, which has been proven to be an inherently insensitive and nonspecific marker for screen relevant neoplasia."

Osborn NK and Ahlquist DH, Gastroenterology 2005;128:192-206.

# Performance Characteristics Multi target DNA stool tests

|                                     | Test sensitivity: % (n)        |            |            |                        |
|-------------------------------------|--------------------------------|------------|------------|------------------------|
| Reference                           | Marker panel                   | Cancer     | Adenomas   | Test specificity, % (r |
| Pre-Gene-Plus                       |                                |            |            |                        |
| Abiquist et al 200044               | APC, Kras, p53; MSE Long DNA   | 91 (20/22) | 82(9/11)   | 93(26/28)              |
| Tagore et al 2000 <sup>90</sup>     | APC, Kiras, p53, MSE Long DNA  | 63 (33/52) | 57 (16/28) | 98.2(111/113)          |
| Syngal 4t al 200299.80% and 2003864 | APC, IKras, p53; MSI; Long DNA | 62 (40/65) | 27 (6/22)  |                        |
| Brand et al 2002124                 | APC, Kires, p53: MSE Long DNA  | 69(11/16)  |            |                        |
| Calistri et al 200378               | APC, IKras, p53: MSE Long DNA  | 62 (33/53) |            | 97 (37/38)             |
| Other Panels                        |                                |            |            |                        |
| Dong et al 200110                   | p53, Kras, MSI                 | 71 (36/51) |            |                        |
| Rengucci et al 2001130              | p53, Kres; M5I                 | 67 (31/46) |            | 100(18/18)             |
| Koshiji et al 2002134               | LOR: MSI                       | 97 (29/30) |            | 100 (30/30)            |

# Stool DNA Test: Performance Characteristics

| DNA Test                                 | # tested/<br>evaluated             | Sensitivity CA<br>(%)<br>(95% CI) | Specificity CA<br>(%)<br>(95% CI)                    | Sensitivity<br>Advanced<br>Adenoma<br>(95%CI) | Specificity<br>Advanced<br>Adenoma<br>(95%CI) |
|--|------------------------------------|-----------------------------------|--|---|---|
| PreGenPlus<br>™(Prototype)               | 61/61                              | 91<br>(71-99)                     | 93<br>(76-99)  | 82<br>(48-98)                                 | 93<br>(76-99)                                 |
| PreGenPlus<br>™(V1)                      | 4404/2507                          | 52<br>(35-68)                     |  | 15<br>(12-19)                                 | 94<br>(93-96)                                 |
| PreGenPlus<br>™(V1)                      | 3764                               | 25                                |  | 20  |   |
| PreGenPlus<br>™(V2)                      | 162                                | 88                                | 82   |   |   |
| Imperiale TF, Rans<br>Ahlquist DA, Sarge | ohoff DF, Itzko<br>nt DJ, Levin TF | R, Rex DK, et al Ann              | 227.<br>I J Med. 2004 Dec 23<br>Intern Med. 2008;149 | 9:441-450.                                    |   |

# Stool DNA Tests The Evidence Speaks

| Stool DNA<br>Test    | Sensitivity<br>CRCA<br>(%) | Sensitivity<br>Polyp≥1cm<br>(%) | Specificity<br>CRCA<br>(%) | Specificity<br>Polyp≥1cm<br>(%) |
|----------------------|----------------------------|---------------------------------|----------------------------|---------------------------------|
| Pre Gen<br>V1 (NEJM) | 52                         | 15                              |                            | 94                              |
| Pre Gen<br>V1(Mayo)  | 25                         | 20                              |                            |                                 |
| Magstream            | 66                         | 20                              | 95                         | 95                              |
| Hemoccult<br>ICT     | 82*                        | 30                              | 97                         | 97                              |

\* Left sided neoplasms

#### **Quantitative FIT** Fecal Hgb level of Lesions Found at Colonoscopy Lesion size (SD) {95%Cl}, mm Mean FIT result (SD) Characteristics Patients (n) 739 (73.9) **35** (143) {25-45} 74 (7.4) 12.6 (6.4) {11.2-14.1} 485 (744) {315-654} Colon Site 31 (12.7) 12.4 (6.8) {10.1-14.7} 499 (774) {227-772} 32 (17.2) 12.9 (6.2) {11.0-14.7} 501 (737) {229-724} 15 (88.2) 30.7 (9.3) {26.0-35.4} **1045** (777) {652-1439} 2 (11.8) 50.0 (7.10) {40.2-59.8} olon site 10 (58.8) 33.8 (10.30) {27.4-40.2} 701 (672) {285-1118} 7 (41.2) 31.7 (12.5) {22.4-41.0} Levi Z, Rozen P, Hazazi R, et al. Ann Intern Med 2007;146:244-255.

# sDNA Test Outstanding Issues

- FDA approval
- Demonstration of cost effectiveness by AHRQ analysis
- Final configuration of the test to be marketed
- Inconsistency in performance of PreGen+ (V1)
  demonstrated in large multicenter studies
- Do updated versions of the test need to be tested in large average risk populations?
- Suggested intervals between tests

# Flexible Sigmoidoscopy

Data supporting use:

- 4 case-control studies have shown mortality reduction primarily in the area examined but also some more proximally
- 60-80% mortality reduction for the area within its reach
- Reduction in CRC deaths maintained for up to 10 yrs after examination

# Flexible Sigmoidoscopy Evidence Level 2

#### Recommendation:

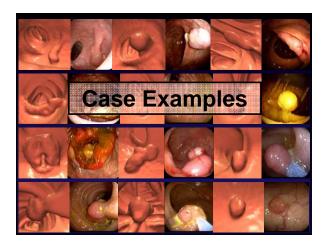
Offer flexible sigmoidoscopy every 5 years\* Offer flexible sigmoidoscopy every 5 years, with high-sensitivity FOBT testing every 3 years

\*ACS/MSTF and ACR Guidelines Levin B, Lieberman D, McFarland B, Smith RA et al. CA Cancer J Clin 2008 United States Preventive Services Guidelines Early-Release Articles: 7 October 2008 http://www.annals.org/

#### Virtual Colonoscopy

#### What is it?

Imaging procedure uses computer programming to combine multiple helical CT scans in order to create two- or threedimensional images of the interior of a patient's colon



# Virtual Colonoscopy

#### Issues surrounding it:

- 10% of cases have a false positive result due to stool, diverticula, prominent fold.
- Unknown ability to detect flat adenomas
- Any lesions seen require colonoscopy to remove
- Radiation exposure\*
  - -10mSV per exam. The harms at this dose unknown but the linear-no-threshold model predicts 1 additional individual per 1000 would develop cancer in their lifetime at this level of radiation
- Detects extracolonic findings (up to 16% in patients having their first CTC) that often trigger a diagnostic search that only sometimes identifies important disease \*

\*N Engl J Med 2007:357:2277-84. \*USMSTF 7 October 2008 http://www.annals.org/

# Virtual Colonoscopy

#### Data supporting use:

- Comparative cohort study shows that CTC identifies 90% of the participants with adenomas or cancers measuring 10 mm or more in diameter identified by optical colonoscopy.
- The evidence for its efficacy in reducing mortality from CRC is all indirect and, no prospective, randomized, controlled clinical trial has been initiated (nor is one planned).

Gastroenterology 2008; 134:1570–1595 Johnson CD, Chen MH, Toledano AY, Heiken JP, Dachman A, et al, N Engl J Med. 2008 Sep 18; 359(12):1207-17



**Cecal Stampede:** The Headlong Rush for Screening Colonoscopy



Lawson MJ, Tobi M Dig Dis Sci 2008;53(4):871-4

### The Opinion Leaders Speak 2009

- The American College of Gastroenterology 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

# Flexible Sigmoidoscopy The Opinion Leaders Speak

"There is suspicion among physicians that in recommending flexible sigmoidoscopy to screen persons for colorectal cancer, we are promoting a suboptimal approach. Relying on flexible sigmoidoscopy is as clinically logical as performing mammography of one breast to screen women for breast cancer.

The failure of insurance companies to cover the costs of colonoscopic screening is no longer tenable."

Podolsky DK Editorial NEJM 2000:343:207-208

# The Media Speaks

The Katie Couric Effect



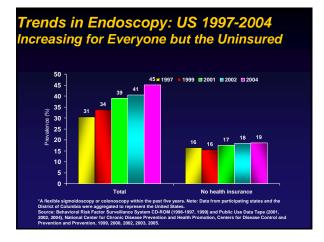
It's considered the most effective test for detecting colon cancer, and as Katie Couric says in her special report, "It really didn't hurt." Katie's first colonoscopy

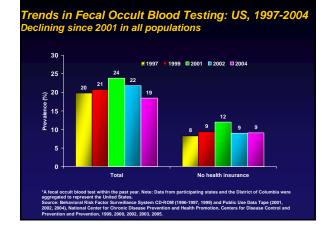
Cram P, Fendrick MA, Inadomi J, et al. Arch Intern Med 2003;1601-1605.

# The Media and Opinion Leaders Speak: The Aftermath

- Congress added colonoscopy to the covered colon cancer screening tests for Medicare patients
- Since Medicare began reimbursing for average-risk patients' screening colonoscopies in July 2001, the number of people undergoing the test has greatly increased and doctors are struggling to keep up with demand\*
- The proportion of persons age 50 and older who have had sigmoidoscopy or colonoscopy has increased from 33% in 1999 to 52% in 2004 but CRC screening rates still lag behind those for breast and cervical cancer

\*The New York Times July, 2002.





### Flexible Sigmoidoscopy

There has been the overused analogy of FS as being similar to screening for breast cancer with mammography of a single breast. The "1 breast" argument, while a catchy sound bite, is grossly misleading. If performing mammography on 1 breast detected 67% to 80% of breast cancers and adding an examination of the other breast required sedation, another specialist, a more difficult preparation, a driver, additional time lost from work, a longer wait for scheduling, and carried 15 times the risk of serious complications, cost 3 to 4 times more, and had substantially less supporting outcomes data, we might be performing (or in the United States, at least discussing) single-breast mammography.

Fisher DA 2007 Gastrointestinal Endoscopy 65:646-7

# Screening Colonoscopy Studies What's Wrong with the Message?

- Advanced neoplasia may be considered a convenient proxy for colorectal cancer but its use as an outcome measure may be misleading in screening studies because the natural history of this lesion is unknown
- The majority of screening colonoscopies will show no adenomas or cancers and highlight the need to identify a way to estimate absolute risk for individual persons so that screening colonoscopy may be more efficiently targeted to those with advanced neoplasia.

Kahi CJ, Rex DK, Imperiale TF Gastroenterology 2008:135:380-399

# Screening Colonoscopy Studies What's Wrong with the Message?

- Most polyps, even the "advanced" ones, do not directly lead to death from colon cancer
  - 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.

### **Overdiagnosis - Definition**

 Overdiagnosis — labeling innocuous tumors cancer and treating them as though they could be lethal when in fact they are not dangerous."

"Overdiagnosis is pure, unadulterated harm,"

Barnett Kramer MD , MD Associate Director for disease prevention NIH The NY Times October 21, 2009

# Screening Colonoscopy Studies What's Wrong with the Message?

- The most important value of one test over another is the incremental benefit of mortality reduction.
- Incremental risk of death from CR cancer in subjects screened with tests other than colonoscopy is not addressed in these studies
- If screening tests other than colonoscopy are used as directed, the incremental benefit of colonoscopy is small.

# Screening Colonoscopy: Issues to Consider

- A screening colonoscopy doesn't immunize a patient from getting or dying from colon cancer for 10 years
- Colonoscopy has a significant miss rate of its own

Shah HA, Paszat LF, Saskin R, Stukel T, Rabenek L Gastro 2007;132:2297-2303 Rex DK, Rahmani EY, et al. Gastroenterology 1997; 112:17-23. Bressler B, Paszat LE, Vinden C, Li C, He J, Rabaneck L. Gastroenterology 2004; 127: 452-456. Pickhardt PJ, Nugent PA, et al. Ann Intern Med 2004; 141:352-9. Robertson DJ Gastroenterology 2005; 129:34-41.

### Screening Colonoscopy: Issues to Consider

- Data suggests that the protection against cancer afforded by having a negative colonoscopy is quite small in the proximal colon (1-33%) but quite large in the distal colon (80%)
- Distal CRC in the U.S. have been steadily decreasing since 1985 while rates for proximal colon cancers have remained largely unchanged

Lakoff J, Paszat LF, Saskin R. Rabeneck L Clinical Gastro and Hepatology 2008;6:1117-1121 Singh H, Turner D, Xue L et al JAMA 2006, 295 (20):2411-2 Cotterchio M, Manno M, Nar N Cancer Causes control 2005;16(7):865-75 Cress R, Morris C, Ellison G et al Cancer 2006;10(75 Suppl):1142-52 Baxter NN, Goldwasser MA, Paszat LF, et al Ann Intern Med. 2009 Jan 6;150(1):1-8.

## Screening Colonoscopy: The Case for Caution

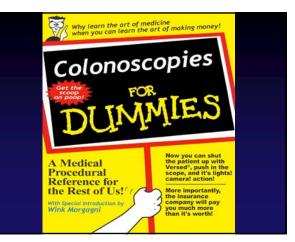
- The risk (2.8 in 1000) of serious complications (perforations, hemorrhage, diverticulitis, CV events, severe abdominal pain and death) detracts from any benefit colonoscopy may have over other less invasive screening options
- Evidence suggests the manpower necessary to provide a skilled colonoscopic examination for all eligible U.S. citizens is inadequate.
- Since Medicare's decision to reimburse for screening colonoscopy, some gastroenterologists are spending up to 50% of their practice time simply performing colonoscopy

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.

# Screening Colonoscopy: Issues to Consider

- Unqualified examiners could absorb the overflow and the increased inaccuracy and complications could undo the small incremental benefit that the test offers
- The Medicare reimbursement for a half-hour primary care visit in Boston is \$103.42; for a colonoscopy requiring roughly the same time, a gastroenterologist receives \$449.44.

A. Bruce Steinwald The New York Times April 5,2008



### Colonoscopy

#### Data supporting use:

- No prospective randomized controlled studies showing that screening colonoscopy alone reduces incidence or mortality from CRC in people at average risk
- Case control and cohort studies do show decreased incidence of and decrease mortality from CRC

### Colonoscopy Evidence Level 2

#### Recommendation:

Offer colonoscopy every 10 years

ACS/MSTF and ACR Guidelines Levin B, Lieberman D, McFarland B, Smith RA et al. CA Cancer J Clin 2008

### Colonoscopy

#### Why 10 year interval?

- Progression from adenomatous polyp to CRC in most cases takes years
- Case control studies of sigmoidoscopy showed protection from CRC in areas examined up to 10 years

### ACS/USMSTF and ACR 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."

### Average Risk Individuals

#### Menu of recommended screening tests:

- Fecal occult blood testing (FOBT)
- Flexible sigmoidoscopy
- Double-contrast barium enema
- Colonoscopy
- CT Colonography (CTC)
- Stool DNA test (sDNA)

ACS/MSTF and ACR Guidelines Levin B, Lieberman D, McFarland B, Smith RA et al. CA Cancer J Clin 2008

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ACS/MSTF and ACR Guidelines Levin B, Lieberman D, McFarland B, Smith RA et al. CA Cancer J Clin 2008

# Average Risk Individuals

Menu of recommended screening tests:

- Colonoscopy
- Stool DNA test (sDNA)

ACS/MSTF and ACR Guidelines Levin B, Lieberman D, McFarland B, Smith RA et al. CA Cancer J Clin 2008

# Average Risk Individuals

Menu of recommended screening tests:

Colonoscopy

Levin B, Lieberman D, McFarland B, Smith RA et al. CA Cancer J Clin 2008

# Average Risk Individuals Age 50 - 75

Menu of recommended screening tests:

- Stool Tests
  - Fecal occult blood testing
  - Fecal Immunochemical Test (FIT) or Sensitive Guaiac Test (Hemoccult Sensa)
- Structural Exams
  - Flexible sigmoidoscopy + sensitive GT or FIT
  - Colonoscopy

United States Preventive Services Guidelines Early-Release Articles: 7 October 2008 http://www.annals.org/

# Role of the Primary Care Physician in Colon Cancer Screening

#### Educate and Facilitate:

- Recommend colorectal cancer screening
- Discuss available screening options
- Test patient yourself or refer to appropriate specialist
- Be sure all positive tests are evaluated with colonoscopy

# **Conclusions**

- It is unrealistic to believe that any one screening test will detect all advanced neoplasms
- At a time when budget deficits are in the trillions of dollars and medical resources are limited, 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 screening has been demonstrated to save lives, screening by any means should be acceptable at this time

# Conclusions

- The screening test(s) selected should be at the discretion of the physician and of his/her patient
- The new ACS/Multisociety Taskforce Guidelines makes it problematic for a PCP to recommend a screening test other than colonoscopy
- The new USPSTF guidelines continue to support the effectiveness of tests other than colonoscopy and support a menu of screening options.

"Colonoscopy is the most common screening technique for colon cancer, but a better option might be the fecal immunochemical tests (FIT), which could be easy, non-invasive, effective, low-risk and inexpensive."

Douglas K. Rex, MD, FACP, FACG, professor of medicine University of Indiana DDW Plenary Session Chicago, IL May, 2009 as quoted in DDW News Can we, with good conscience, recommend screening tests other than colonoscopy to our average risk patients ?



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# FIT Performance Characteristics

| Test             | Sensitivity<br>Percent (95% CI) | Specificity<br>Percent (95% CI) |
|------------------|---------------------------------|---------------------------------|
| Hemoccult II     |                                 |                                 |
| Carcinoma        | 37 (22-55)                      | 98 (97-98)                      |
| Advanced Adenoma | 32 (22-40)                      | 98 (97.7-98.4)                  |
| Hemoccult Sensa  |                                 |                                 |
| Carcinoma        | 79 (64-95)                      | 87 (86-87)                      |
| Advanced Adenoma | 69 (59-78)                      | 88 (86.7-88.2)                  |
| HemeSelect       |                                 |                                 |
| Carcinoma        | 69 (51-86)                      | 94 (94-95)                      |
| Advanced Adenoma | 67 (57-76)                      | 95 (95-96)                      |

Allison JE, Tekawa IS, Ransom LJ, Adrain AL. N Engl J Med 1996; 334:155-9.

# **Basic Ingredients for CTC**

• Bowel prep:



- Colonic distention:
- MDCT: ≥ 4-8 detector-row
- VC software: Capable of 3D detection

