Colorectal Cancer Screening Modalities and Guidelines

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Disclosures

- None

Objectives

- Review colorectal cancer screening guidelines and modalities
- Discuss cognitive biases associated with colon cancer screening
- Suggest a clinical approach to colorectal cancer screening

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- Review colorectal cancer screening guidelines and modalities
  - **United States Preventive Services Task Force (USPSTF)**
- Discuss cognitive biases associated with colon cancer screening
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Colorectal Cancer Screening Strategies for Average-Risk Patients

USPSTF recommendation: Asymptomatic individuals ≥50 years of age

Modality	Frequency	Detects Polyps
Colonoscopy	Every 10 years	✓
Fecal Immunochemical test	Yearly	
CT colonography	Every 5 years	✓
Flexible sigmoidoscopy	Every 5 years	✓ (in distal colon)
Double-contrast barium enema	Every 5 years	✓ (but less sensitive than colonoscopy or CT colonography)
Stool DNA test	Every 3 years	
Capsule colonoscopy	Every 5 years	✓
Blood-based Septin 9 Assay	Yearly	

Adapted from United States Preventative Services Task Force Guidelines released in 2016

Who is not average risk? Individuals with…

- Inflammatory bowel disease
- A history of colorectal polyps or cancer
- Family members with adenomatous polyps or cancer
- Certain familial cancer syndromes
  - Lynch Syndrome
  - Hereditary polyposis syndromes (e.g. *APC*-associated, *MUTYH*-associated, Cowden Syndrome)

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USPSTF screening recommendations

- Colorectal cancer screening has a grade A recommendation
- For average risk individuals, offer screening to
  - Everyone from ages 50-75 years of age
  - To some between ages of 75-85 years of age
  - No one over 85 years of age
    - THESE ARE NOT THE STOPPING RECOMMENDATIONS FOR SURVEILLANCE
- Do not rank the tests in any way

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Email Exchange

- Me: “Would it be ok for my talk to focus on colorectal cancer screening modalities and guidelines? This is something that I have personally had questions about regarding the evidence behind each one (especially on the colorectal side) and, since we have started this email exchange, have had providers and medical students ask me questions about so I assume it would be of interest to the crowd.”
- Calvin Thigpen: “Excellent choice! I’ve had the same experience in (General) Med clinic and have questioned the evidence.”

Overchoice (or Choice Overload)

- When many equivalent choices are available, making a decision becomes overwhelming due to the many potential outcomes and risks that may result from making the wrong choice.
  - Mentally draining because each option must be weighed against alternatives to select the best one.
- The satisfaction of choices by number of options available can be described by an inverted "U" model.
  - No choice results in very low satisfaction.
  - Initially more choices lead to more satisfaction, but as the number of choices increases it then peaks and people tend to feel more pressure, confusion, and potentially dissatisfaction with their choice.

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- **Suggest a clinical approach to colorectal cancer screening**
  - **Refine the list**

Weeding out a couple of modalities

- **Flexible sigmoidoscopy**
- Double-contrast barium enema
- Blood-based Septin 9 assay

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Not a static population

- Historically
  - Majority of colorectal cancers occurred in the rectum and left colon
  - Patients with right-sided colon cancers had left-sided polyps.
- Now, the distribution of colon cancers has changed in the United States
  - Large American studies of colonoscopy for screening of average-risk individuals show that cancers are roughly **equally** distributed between left and right colon
  - Half of patients with right-sided lesions have no polyps in the left colon.
- "Visualization of the entire colon thus appears to be the optimal strategy for colorectal cancer screening and prevention."

Song L, Topazian M. Gastrointestinal Endoscopy. In: Jameson J, Fauci AS, Kasper DL, Hauser SL, Longo DL, Loscalzo J. eds. *Harrison's Principles of Internal Medicine, 20e* New York, NY: McGraw-Hill.

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- ~~Flexible sigmoidoscopy~~
- **Double-contrast barium enema**
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Not truly equivalent options

- “CT colonography has replaced double-contrast barium enema as the test of choice for colorectal imaging for nearly all indications. CT colonography is more effective than barium enema and better tolerated.”

Weeding out a couple of modalities

- ~~Flexible sigmoidoscopy~~
- ~~Double-contrast barium enema~~
- **Blood-based Septin 9 assay**

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Not equal in cost or ability: Septin9 assay

- Disadvantages
  - Lower sensitivity for cancer detection than FIT
  - Inability to detect advanced adenomas
  - Low cost-effectiveness relative to other screening tests.
- Uncertainties regarding the true clinical utility of Septin 9 makes shared decision-making difficult.
- Best frequency for performing the test is uncertain.

Weeding out a couple of modalities

- ~~Flexible sigmoidoscopy~~
- ~~Double-contrast barium enema~~
- ~~Blood-based Septin 9 assay~~

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- Review colorectal cancer screening guidelines and modalities
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- **Suggest a clinical approach to colorectal cancer screening**
  - Refine the list
  - **Know your tests**
    - **Polyp detection**

Modified List of Colorectal Cancer Screening Strategies for Average-Risk Patients

USPSTF recommendation: Asymptomatic individuals ≥50 years of age

Modality	Frequency	Detects Polyps
Colonoscopy	Every 10 years	✓
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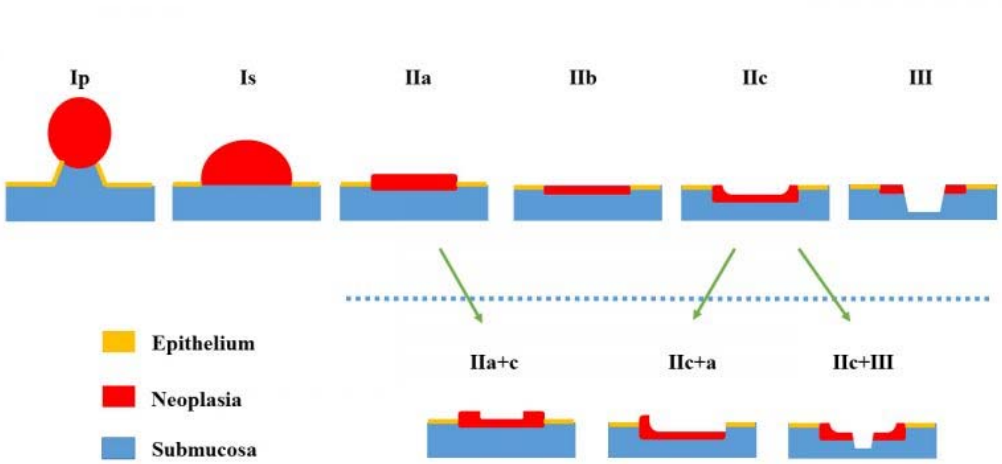
Features of Precancerous Colorectal Polyps

2 Major Classes of Colorectal Polyps	Histologic Classifications
Conventional adenomas	• Dysplasia Grade (High/Low) • Villousity (Tubular/Tubulovillous/Villous)
Serrated lesions	• Sessile serrated polyp (with/without cytologic dysplasia) = sessile serrated adenoma • Traditional serrated adenoma - *rare*

Adenoma Shape is Related to Detection Rate and Location in Colon

Paris Shape – Cartoon Representations of What an Endoscopist Sees



Lesion	Paris Shape	Typical Dysplasia	Greater on
Traditional adenomatous polyps	Ip Is	Usually with low grade dysplasia	
Flat adenoma	IIa	Low grade	Right colon
Depressed adenoma	IIc IIa + IIc IIc + IIa	High grade dysplasia or invasive cancer	Right colon
Sessile serrated polyp	Is or IIa	Varies	Right colon

https://www.endoscopy-campus.com/en/klassifikationen/paris-classification-of-superficial-gi-cancers-introduction-and-overview/

Modified List of Colorectal Cancer Screening Strategies for Average-Risk Patients

USPSTF recommendation: Asymptomatic individuals ≥50 years of age

Modality	Frequency	Detects Polyps	Operator Dependent
Colonoscopy	Every 10 years	✓	✓ (Can vary 10 fold in adenomas detected)
Fecal Immunochemical test	Yearly		
CT colonography	Every 5 years	✓	✓
Stool DNA test	Every 3 years		
Capsule colonoscopy	Every 5 years	✓	✓

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Colonoscopy Operator Dependence – Cancer Prevention

- Using Kaiser Permanente data, evaluated the associations between the adenoma detection rate and the risks of colorectal cancer diagnosed 6 months to 10 years after colonoscopy and of cancer-related death.
- 314,872 colonoscopies, 712 interval colorectal cancers, 147 deaths
- Highest quintile of detection versus lowest quintile of detection: Hazard Ratio of 0.52 for any interval cancer
- Each 1.0% increase in adenoma detection rate was associated with a 3.0% decrease in risk of cancer death

Corley DA et al. Adenoma Detection Rate and Risk of Colorectal Cancer and Death. N Engl J Med 2014; 370: 1298-1306

Take Home Point

- Ask your doctor his/her adenoma detection rate

Colonoscopies Impact on Colorectal Cancer Incidence and Mortality

Colorectal Cancer Incidence

Author Year	Country	Study Design	Residual Risk
Kahi 2009	United States	Cohort	0.33
Mulder 2010	Netherlands	Case Control	0.56
Brenner 2011	Germany	Case Control	0.23

Colorectal Cancer Mortality

Author Year	Country	Study Design	Residual Risk
Baxter 2009	Canada	Case Control	0.63
Singer 2010	Canada	Cohort	0.71
Baxter 2012	United States	Case Control	0.40

At present, no randomized controlled trials of FIT versus colonoscopy

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Fecal Immunochemical Test (FIT)

- Reacts with antibodies specific for the globin portion of the human hemoglobin molecule
  - Special dietary restrictions to avoid false-positive tests are not needed.
- Sensitivity and specificity for detection of colorectal cancer ranges from 47.1% to 69% and from 88.2% to 97.1%, respectively
  - Wide variability in detecting advanced adenomas, ranging from 25% to 72% based on the type of immunochemical test used

Lim R, Syngal S, Kastrinos F. Colorectal Cancer Screening. In: Greenberger NJ, Blumberg RS, Burakoff R. eds. *CURRENT Diagnosis & Treatment: Gastroenterology, Hepatology, & Endoscopy, 3e* New York, NY: McGraw-Hill; . http://accessmedicine.mhmedical.com/content.aspx?bookid=1621&sectionid=105184173

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Pathogenesis of Colon Cancer: 3 Distinct Molecular Pathways

- Chromosomal instability (CIN)
- Microsatellite instability (MSI)
- CpG island methylator phenotype (CIMP)

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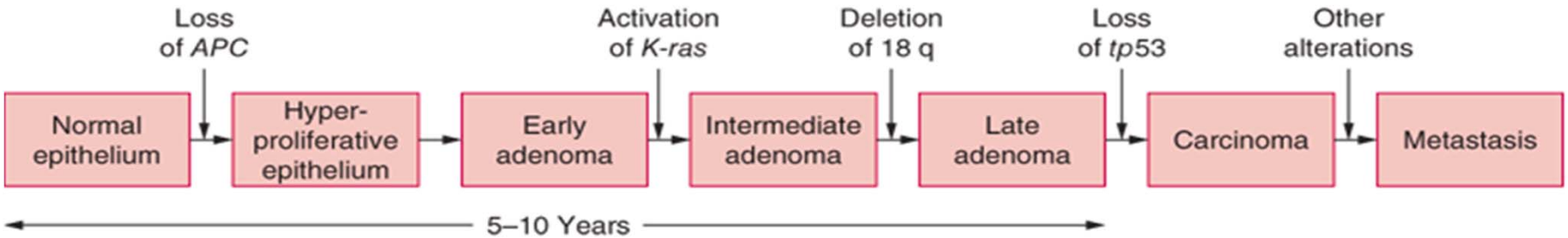
Chromosomal Instability (CIN) Pathway

- Contributes to the development of 60% of sporadic colorectal tumors arising from preexisting **adenomatous** polyps.



Source: N. J. Greenberger, R. S. Blumberg, R. Burakoff: CURRENT Diagnosis & Treatment: Gastroenterology, Hepatology & Endoscopy, 3rd Edition.
www.accessmedicine.com

Originally appeared in:
Fearon ER, Volgelstein B. A genetic model for colorectal tumorigenesis. Cell 1990 Jun 1; 61(5): 759-767.

Microsatellite Instability (MSI) Pathway

- Errors introduced into the genome through mispairing of nucleotides, which can occur during normal DNA replication, are corrected by a DNA “mismatch repair” (MMR) system.
- When either of these DNA repair processes is dysfunctional, deleterious mutations can accumulate in genes that directly control cellular growth and proliferation.
- A germline mutation in one of the MMR genes is responsible for Lynch syndrome
- Somatic mutation or hypermethylation silencing of MMR genes accounts for approximately 15% of sporadic CRC.

Lim R, Syngal S, Kastrinos F. Colorectal Cancer Screening. In: Greenberger NJ, Blumberg RS, Burakoff R. eds. *CURRENT Diagnosis & Treatment: Gastroenterology, Hepatology, & Endoscopy, 3e* New York, NY: McGraw-Hill; . http://accessmedicine.mhmedical.com/content.aspx?bookid=1621&sectionid=105184173.

Difference in Malignant Potential of Adenomas of the CIN Pathway and Adenomas of the MSI Pathway?

- TIME
  - CIN pathway: 5-10 years
  - MSI pathway: 1-2 years

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CpG island methylator phenotype (CIMP)

- Epigenetic alterations which alter gene expression or function without altering the DNA sequence can occur.
- Aberrant hypermethylation of gene promoter regions (CpG islands) may result in gene silencing of tumor suppressor genes.

Lim R, Syngal S, Kastrinos F. Colorectal Cancer Screening. In: Greenberger NJ, Blumberg RS, Burakoff R. eds. *CURRENT Diagnosis & Treatment: Gastroenterology, Hepatology, & Endoscopy, 3e* New York, NY: McGraw-Hill; . http://accessmedicine.mhmedical.com/content.aspx?bookid=1621&sectionid=105184173.

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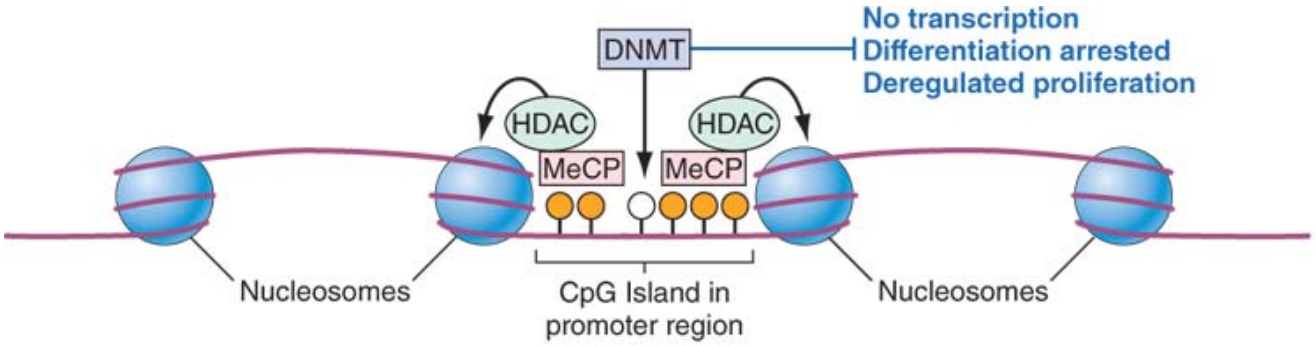
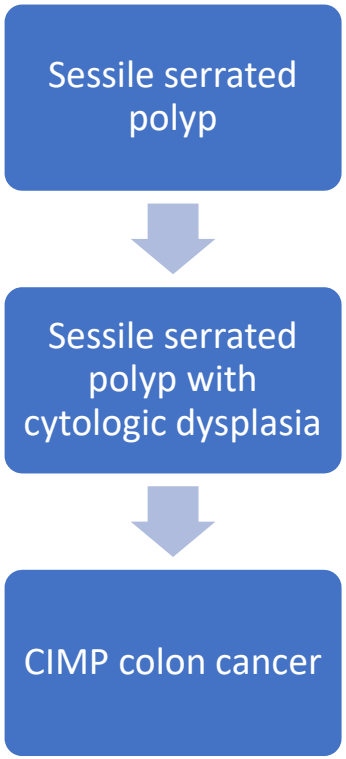


Tumor-suppressor genes are epigenetically silenced in cancer cells when

- CpG island within the promoter and enhancer regions of the gene has been methylated →
- Recruitment of methyl-cytosine binding proteins (MeCP) and complexes with histone deacetylase (HDAC) activity →
- Chromatin is in a condensed, nonpermissive conformation that inhibits transcription.

CpG island methylator phenotype (CIMP)

- CIMP-high CRCs are strongly associated with *BRAF* mutations, developing from a **sessile serrated polyp**.
- Time frame of development 10 -20 years
- Process occurs more often in proximal colon



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Lash J Clin Path 2010

Colorectal Cancer Pathway

Pathway	Genes	MSI	Precursor	Speed
CIN	*APC* *K-ras* *P53*	No	Adenoma	Slow
MSI/Lynch	*MLH1* *MSH2* *MLH6* *PMS2*	Yes	Adenoma	Fast
CIMP	*BRAF*	~ 50%	Serrated	Can be fast

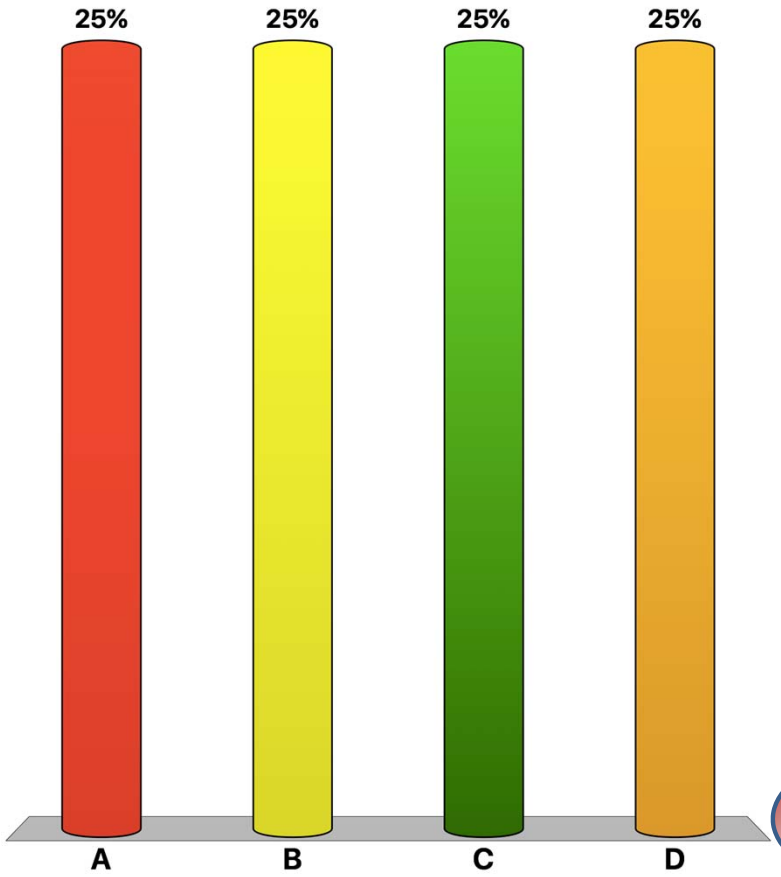
What does the Cologuard ® test consist of?

A. A multitarget stool DNA test

✓ B. A multitarget stool DNA test and a fecal immunochemical test

C. A multitarget stool DNA test and a capsule endoscopy

D. A multitarget stool DNA test and a blood based test evaluating levels of methylated Septin 9



Cologuard ® test – Improved Sensitivity versus FIT alone

- Noninvasive, multitarget stool DNA test with a fecal immunochemical test (FIT) component
  - Includes quantitative molecular assays for *KRAS* mutations, aberrant *NDRG4* and *BMP3* methylation, and β-actin, plus a hemoglobin immunoassay.
- **RESULTS:** Compared to one-time FIT alone in persons at average risk for colorectal cancer.
  - Sensitivity for detecting colorectal cancer was 92.3% with Cologuard ® and 73.8% with FIT (P=0.002).
  - Sensitivity for detecting advanced precancerous lesions was 42.4% with Cologuard ® and 23.8% with FIT (P<0.001).

Cologuard ® test – Reduced Specificity versus FIT alone

- Specificities with DNA testing and FIT were
  - 86.6% with DNA testing and 94.9% with FIT among participants with nonadvanced or negative findings (P<0.001)
  - 89.8% with DNA testing and 96.4%, with FIT among those with negative results on colonoscopy (P<0.001).
- **CONCLUSIONS:** In asymptomatic persons at average risk for colorectal cancer, multitarget stool DNA testing detected significantly more cancers than did FIT but had more false positive results

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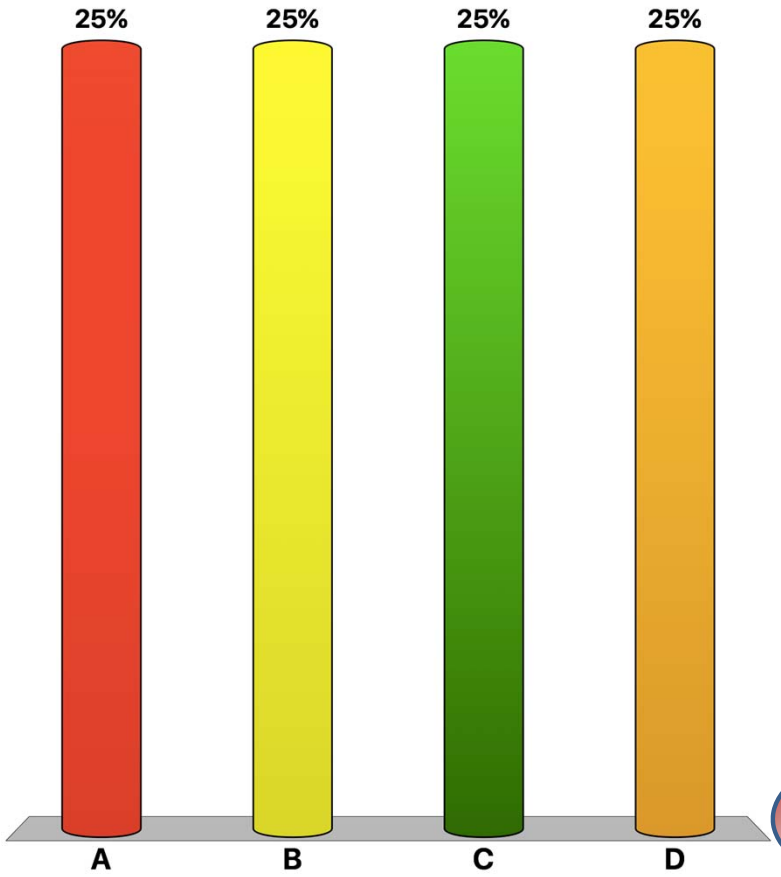
    - Polyp detection
    - **Polyp properties**

Which precancerous lesion has typically no or only isolated blood vessels on its surface?

A. Hyperplastic polyp
B. Tubular adenoma with high-grade dysplasia
C. Villous adenoma with high-grade dysplasia
✓ D. Sessile serrated polyp



8

Features of Colorectal Polyps

2 Major Classes of Colorectal Polyps	Histologic Classifications
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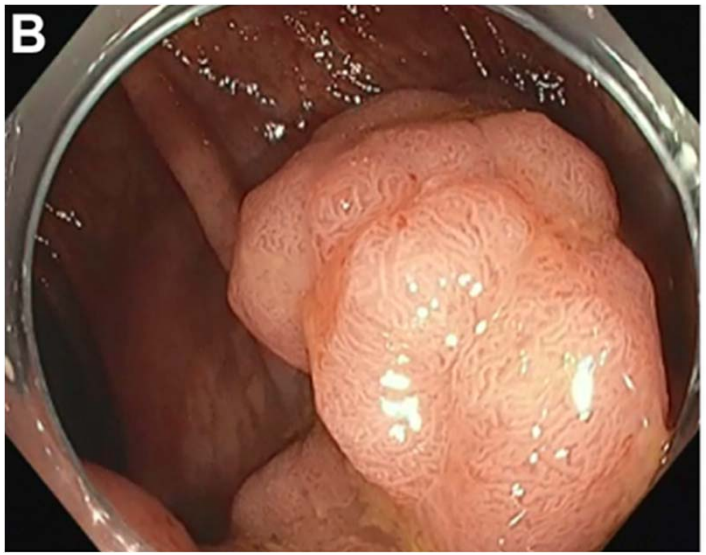
- Endoscopic Appearance



A portion of a 40-mm advanced conventional adenoma. The red lines are surface blood vessels.

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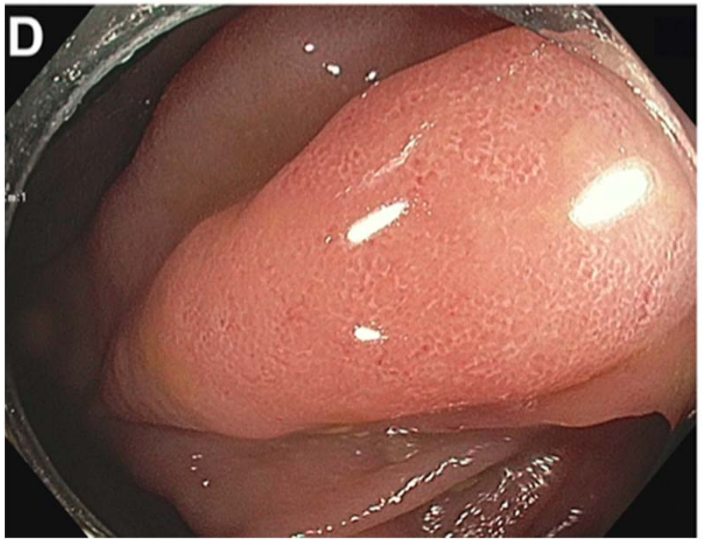

A sessile serrated polyp without cytologic dysplasia. Note the absence of blood vessels on the surface.

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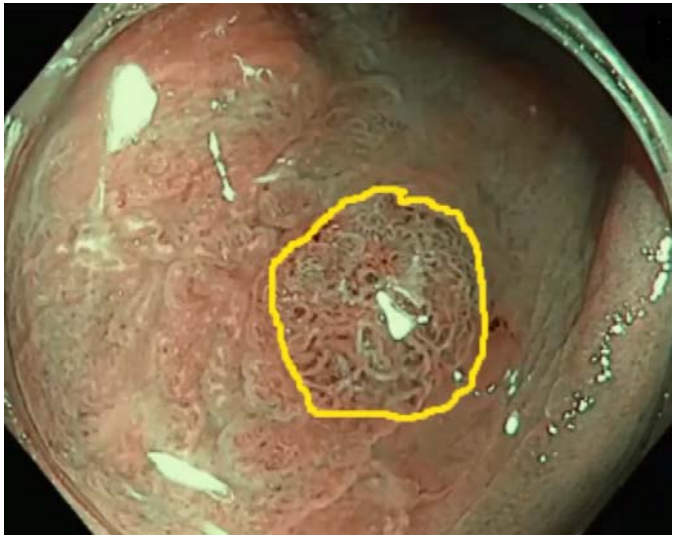

A sessile serrated polyp with cytologic dysplasia.

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  - Sensitivity for detecting advanced precancerous lesions was 42.4% with Cologuard ® and 23.8% with FIT (P<0.001).
    - Rate of detection of polyps with high-grade dysplasia was 69.2% with DNA testing and 46.2% with FIT (P=0.004)
    - **Rates of detection of serrated sessile polyps measuring 1 cm or more were 42.4% and 5.1%, respectively (P<0.001).**

Colorectal Cancer Screening Strategies for Average-Risk Patients

USPSTF recommendation: Asymptomatic individuals ≥50 years of age

Modality	Frequency	Deficiency in Detection of Sessile Serrated Polyps (SSPs)
Colonoscopy	Every 10 years	Because lesions tend to be flat
Fecal Immunochemical test	Yearly	Because lesions tend to have no or few surface blood vessels with less tendency to bleed than conventional adenomas
CT colonography	Every 5 years	Because lesions tend to be flat
Flexible sigmoidoscopy	Every 5 years	Because SSPs are predominantly in the proximal colon
Stool DNA test	Every 3 years	Better than FIT, likely because it detects methylation of some genes, but not as good as colonoscopy

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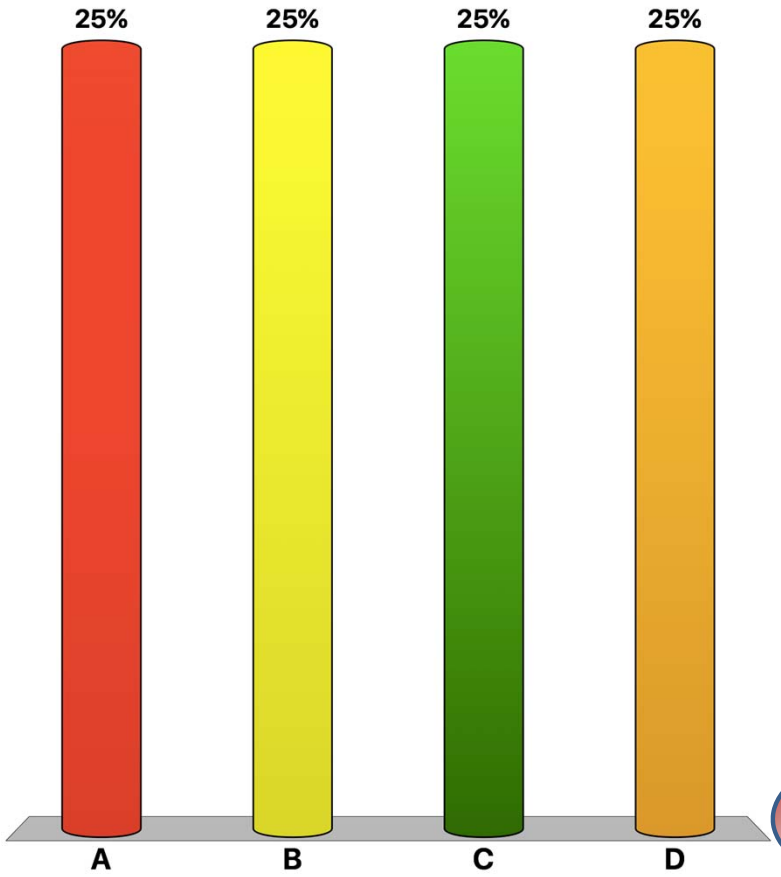
  - **Know your tests**
    - Polyp detection
    - Polyp properties
    - **What to do with a positive test**

Question

Samantha is a 53 year old woman with no family history of colon cancer. She underwent a screening colonoscopy three years ago notable for two tubular adenomas that were 12 mm and 14 mm in size. She would like to know when she should undergo a repeat evaluation. Based on guidelines developed by the US Multi-Society Task Force on Colorectal Cancer, what should you tell her?

Answers

A. She is due for a colonoscopy this year
B. She is due for a colonoscopy in 2 years
C. She is due for a colonoscopy in 7 years
D. Her colonoscopy was due 2 years ago and we are behind schedule



Colorectal Cancer Surveillance

Baseline Colonoscopy: Most Advanced Finding(s)	Recommended surveillance interval (*y*)
No polyps	10
Small (< 10 mm) hyperplastic polyps in rectum or sigmoid	10
1-2 small (< 10 mm) tubular adenoma	5-10
3-10 tubular adenomas	3
> 10 tubular adenomas	< 3
One or more tubular adenomas > 10 mm	3
One or more villous adenomas	3
Adenoma with high grade dysplasia	3
Sessile serrated polyp(s) < 10 mm with no dysplasia	5
Sessile serrated polyp(s) > 10 mm OR Sessile serrated polyp with dysplasia OR Traditional serrated adenoma	3
Serrated polyposis Syndrome	1

Lieberman DA et al. **Guidelines for Colonoscopy Surveillance After Screening and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology 2012.**

Objectives

- Review colorectal cancer screening guidelines and modalities
  - **Multi-Society Task Force**
- Discuss cognitive biases associated with colon cancer screening

- **Suggest an approach to colorectal cancer screening**
  - **Clinically**
    - **Refine the list**
    - Know your tests
  - Politically

Multi-Society Task Force

- There professional societies
  - American College of Gastroenterology
  - American Gastroenterology Association
  - American Society for Gastrointestinal Endoscopy
- Rank colorectal cancer screening tests by
  - Effectiveness
  - Cost-effectiveness
  - Evidence of uptake
  - Practical Features

2017 Multi-Society Task Force Ranking of Current Colorectal Cancer Screening Tests

Tier	Test	Frequency
Tier 1	Colonoscopy	Every 10 years
	Fecal Immunochemical Test	Yearly
Tier 2	CT colonography	Every 5 years
	Stool DNA test (Cologuard®)	Every 3 years
	Flexible sigmoidoscopy	Every 5 or 10 years
Tier 3	Capsule colonoscopy	Every 5 years
Not currently recommended	Blood-based Septin 9 Assay	Yearly

Colorectal Cancer Screening: Recommendations for Physicians and Patients From the U.S. Multi-Society Task Force on Colorectal Cancer. DK Rex et al. 2017. Gastroenterology. https://doi.org/10.1053/j.gastro.2017.05.013

Adapted Colorectal Cancer Screening Chart

Tier	Test	Frequency
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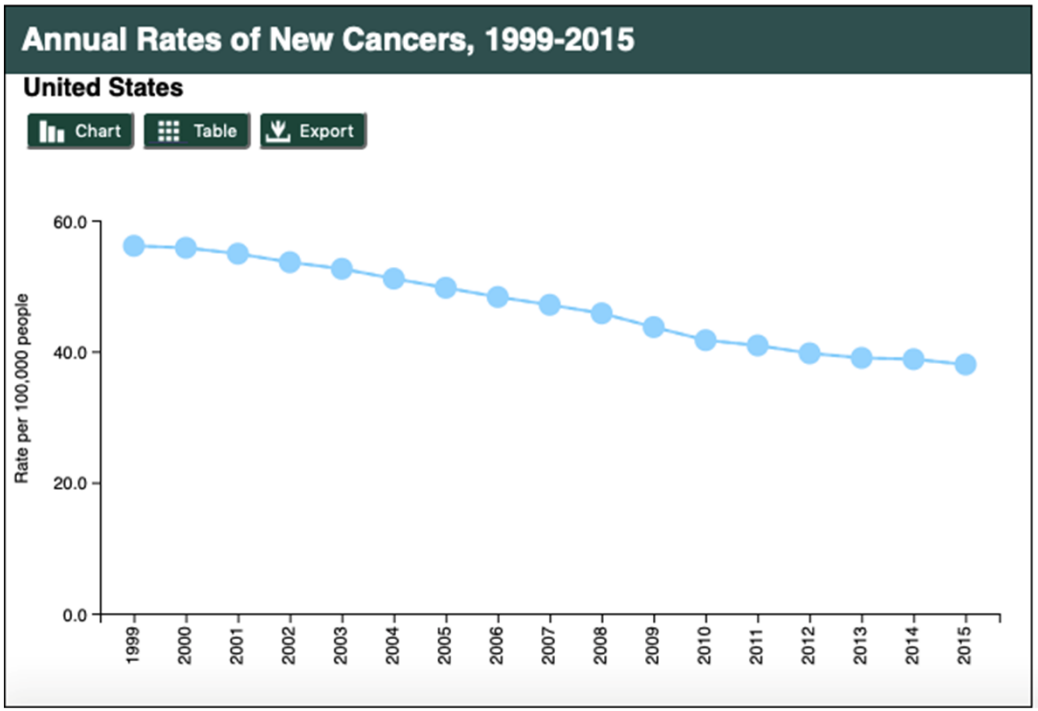
Objectives

- **Review colorectal cancer screening guidelines and modalities**
  - **American Cancer Society**
- Discuss cognitive biases associated with colon cancer screening
- Suggest a clinical approach to colorectal cancer screening

When to start screening?

Colorectal Cancer Incidence Rates



https://gis.cdc.gov/Cancer/USCS/DataViz.html

However…

- While overall incidence rates have decreased, this has been a tale of two age groups
  - Incidence rates in patients > 50 years of age have declined at rate of 3-4% per year from 2000 to present
  - Incidence rates in patients < 50 years of age have doubled since 2000

American Cancer Society (ACS)

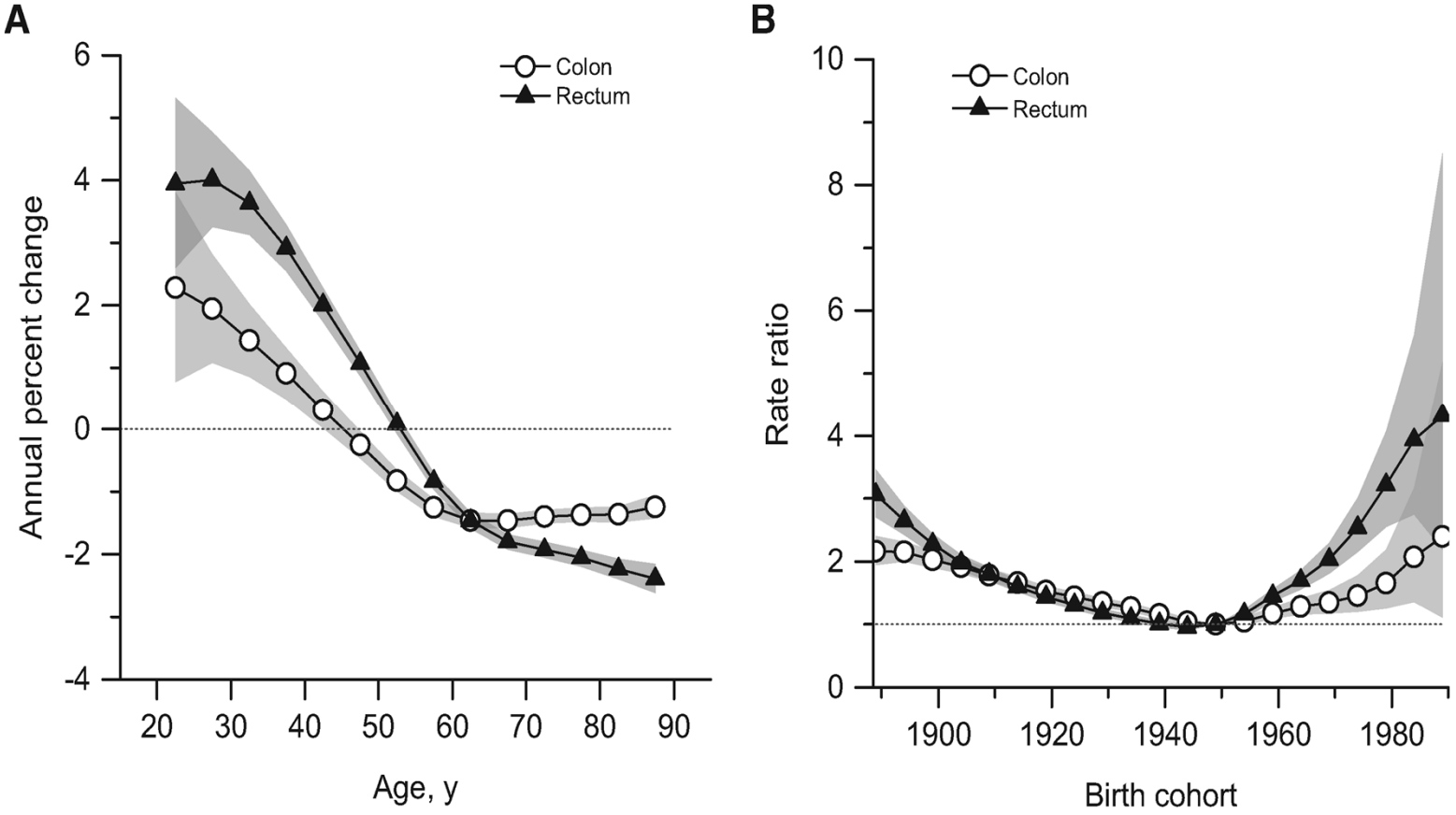
Updated recommendations – March, 2018

- "The ACS recommends that people at average risk of colorectal cancer **start regular screening at age 45**."
- "Qualified recommendation"
- Based on modeling of new data on incidence rates

Birth Cohort Effect

- Relative increase is greater in the younger age groups

Summary age-specific annual percent change (i.e., local drift) and birth cohort rate ratios of colorectal incidence rates in the United States.



JNCI: Journal of the National Cancer Institute, Volume 109, Issue 8, August 2017, djw322, https://doi.org/10.1093/jnci/djw322

Objectives

- Review colorectal cancer screening guidelines and modalities
- Discuss cognitive biases associated with colon cancer screening
- **Suggest a clinical approach to colorectal cancer screening**
  - Refine the list
  - Know your tests
  - **Structured**

Approaches to screening

Approach	Usually based on	Example	Follow-Up
Organized (programmatic)	Fecal Immunochemical Test	Kaiser Permanente	Program
Opportunistic (office based)	Colonoscopy	Most practices in United States	Provider

Objectives

- Review colorectal cancer screening guidelines and modalities
- Discuss cognitive biases associated with colon cancer screening
- Suggest a clinical approach to colorectal cancer screening
  - Refine the list
  - Know your tests
  - **Structured**
    - **Choices offered**

Choosing Between Competing Strategies and Adherence

- Participants (N= 997, of which 58% complete a strategy)
  - Recommended colonoscopy completed screening at a significantly lower rate (38%) versus those
  - Recommended FOBT (67%) (P < .001) or those
  - Given a choice between FOBT or colonoscopy (69%) (P < .001).
- Over 3 years, the completion of screening was
  - Annual FOBT: 14% versus
  - Colonoscopy: 38% (P<0.001)
  - Choice between two (42%, P<0.001)
- Patient navigation is crucial to achieving adherence to CRC screening, and FOBT is especially vulnerable because of the need for annual testing.

Inadomi JM et al. Arch Intern Med. 2012 Apr 9;172(7):575-82. doi: 10.1001/archinternmed.2012.332.
Liang PS et al. Am J Gastroenterol. 2016 Jan;111(1):105-14. doi: 10.1038/ajg.2015.367. Epub 2015 Nov 3.

Ways to offer screening

- Multiple options
  - Offering 2 did not decrease uptake over offering 5 in a small (n=62) pilot trial
- Sequential screening
  - Offer the screening test you feel is most appropriate
    - If not taken, offer the second most appropriate screening test

Griffith JM et al. The effect of offering different numbers of colorectal cancer screening test options in a decision aid: a pilot randomized trial. BMC Med Inform Decis Mak. 2008 Jan 24;8:4.

Summary

- Choice overload
  - Can impact a provider's ease of the number of colorectal cancer screening options
  - May influence why a patient has just as much uptake when offered two screening methods as five methods
- The Multi-Society Task Force places colonoscopy and FIT as Tier 1 colorectal cancer screening tests

Questions