Participating in the Webinar

All attendees will be muted and will remain in Listen Only Mode.

Type your questions here so that the moderator can see them. Not all questions will be answered but we will get to as many as possible.
How to Receive CME and MOC Points

LIVE VIRTUAL GRAND ROUNDS WEBINAR
ACG will send a link to a CME & MOC evaluation to all attendees on the live webinar.

ABIM Board Certified physicians need to complete their MOC activities by December 31, 2023 in order for the MOC points to count toward any MOC requirements that are due by the end of the year. No MOC credit may be awarded after March 1, 2024 for this activity.

MOC QUESTION

If you plan to claim MOC Points for this activity, you will be asked to: Please list specific changes you will make in your practice as a result of the information you received from this activity.

Include specific strategies or changes that you plan to implement. THESE ANSWERS WILL BE REVIEWED.
ACG Virtual Grand Rounds
Join us for upcoming Virtual Grand Rounds!

Week 12 – Thursday, March 23, 2023
Lynch Syndrome Awareness: Historical and Current Approaches to Identifying Individuals With Lynch Syndrome
Faculty: Peter Stanich, MD; and Heather L. Hampel, MS, CGC
Moderators: Julie L. Yang, MD; and Elana Levinson, MS, CGC
Host: Jessica Long, MD, CGC
At Noon and 8pm Eastern

Week 13 – Thursday, March 30, 2023
Colon Polypectomy Techniques: Big Polyps, Small Polyps, and Everything in Between
Faculty: Charles J. Kahi, MD, MSc, FACG
Moderator: Jennifer K. Maratt, MD
At Noon and 8pm Eastern

Please NOTE: there will be no ACG Virtual Grand Rounds on April 6 and 13 due to low attendance from Spring Breaks.

Visit gi.org/ACGVGR to Register
Disclosures

Aasma Shaukat, MD, MPH, FACP
Iterative Scopes Inc.: Advisory Board
Freenome: Consultant
Medtronic: Consultant
Motus GI: Consultant

Janice Cheong, MD
Dr. Cheong has no financial relationships with ineligible companies.

*All of the relevant financial relationships listed for these individuals have been mitigated

CRC Screening: How Can We Improve?

Aasma Shaukat, MD, MPH
Director GI Outcomes Research
Robert M. and Mary H. Glickman Professor of Medicine
Professor of Population Health
NYU Grossman School of Medicine
• National Women History Month
• National Peanut Month
• National Caffeine Awareness Month
• Irish American Heritage Month
• Fun fact: March and November dates fall on the same days of the week
• National Colon Cancer Awareness Month

FEBRUARY 28, 2023
A Proclamation on National Colorectal Cancer Awareness Month, 2023

During National Colorectal Cancer Awareness Month, we call attention to the second leading cause of cancer deaths in America — by sharing information about risk factors, promoting life-saving early screenings, and improving access to affordable treatment. In remembrance of every life cut short by this devastating disease, my Administration is determined to end cancer as we know it.
Objectives

- Review recent trends in Colorectal cancer (CRC) Incidence in the US
- Updates on recent evidence on CRC Screening
- Improving adherence to CRC screening
- Current and future options for CRC screening
- Take home points

CRC Mortality Over Time

When Should Screening Start For CRC?

**ACG**
- Recommended in all adults 50 to 75 years of age
- Suggest in all average risk adults 45 to 49 years of age
- Recommend decision to screen after 75 be individualized

**USPSTF**
- Recommended in all adults 50 to 75 years of age
- Recommended in adults 45 to 49 years of age
- Recommended that clinicians selectively offer screening in adults 76-85 years of age

**MSTF**
- Suggested to all average-risk adults ages 45 to 49
- For adults ages 76 to 85, the decision to start or continue screening should be individualized and based on prior screening history, life expectancy, CRC risk, and personal preference
- Screening is not recommended after age 85

2020: Percentage of Adults 50–75 Years fully meeting USPSTF recommendation for CRC Screening, by State
Behavioral Risk Factor Surveillance System, United States, 2020

Overall screening rates are 68%

Screening rates by Race:
Whites 71%  
AA 70%  
Asian 64%  
Hispanics 56%

Health Insurance:
Yes 71%  
No 40%

Regular HCP:
Yes 73%  
No 36%

21 million adults 45-49 yrs

CRC Screening NYC

Prevalence of timely colonoscopy among adults ages 50 and older, by race and ethnicity, New York City, 2003 and 2018

NYC Overall  
White  
Black  
Latino/a  
API

Timely colonoscopy is defined as having had a colonoscopy in the past 10 years. Comparison is not available for stool-based tests. White, Black, Asian/Pacific Islander (API) race categories exclude Latino/a ethnicity. Latino/a includes Hispanic or Latino/a of any race.

Source: New York City Community Health Survey, 2003 and 2018

CRC Screening Volumes Still Low

- Data come from Cosmos, a HIPAA-defined Limited Data Set of more than 126 million patients from 156 Epic organizations including 889 hospitals and 19,420 clinics, serving patients in all 50 states


What do we need to Build?
And who will come?

Newly Eligible + Overdue+ never screened
Endoscopic capacity+ Access
Ensuring Health Equity

What got us here may not be enough to get us there

80% in every Community
CRC Screening Options

<table>
<thead>
<tr>
<th>Modality</th>
<th>Sensitivity CRC</th>
<th>Sensitivity AA</th>
<th>Specificity</th>
<th>Invasive</th>
<th>USPSTF Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colonoscopy</td>
<td>96%</td>
<td>95%</td>
<td>90%</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>FIT</td>
<td>74%</td>
<td>24%</td>
<td>96%</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>mtsDNA stool</td>
<td>92%</td>
<td>42%</td>
<td>87%</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Septin-9</td>
<td>48%</td>
<td>-</td>
<td>91%</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Liquid Biopsy</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>N</td>
<td>TBD</td>
</tr>
</tbody>
</table>

Adherence is Key

- Emphasizes importance of adherence
- Quality of Colonoscopy
- Underpowered for CRC Mortality difference
- Put in context with other data

Message: Don’t let patients be discouraged or dissuaded

Adherence to colonoscopy: 42%
CRC incidence risk reduction 18%
NS difference in CRC mortality and all cause mortality
33% sustained reduction in CRC mortality; 89% adherence to 1+ stool test

How Effective is Polypectomy?

- Minnesota Screening trial n=46,551
- gFOBT+ → Colonoscopy and polypectomy
- Instrumental variable approach
- Polypectomy --> CRC incidence
- Any polypectomy 67% in CRC risk (95% CI 0.23–0.48)
- Adenomatous or advanced histology polyps: 70% in CRC risk (95% CI 0.20–0.44)
CRC Screening Reduces All-Cause Mortality

- Reduced all-cause mortality by 2% (RR, 0.98; 95% CI, 0.97–0.99)

Shaukat A et al. Effects of Screening Compliance on Long-term Reductions in All-Cause and Colorectal Cancer Mortality. CGH 2021;19:967-975

Approach to Colon Cancer Screening

1 Step Tests
- Colonoscopy

2 Step tests
- Stool Based
  - Imaging based: CTC
  - Colon Capsule
- *Blood based*

American College of Gastroenterology
ACG Clinical Guidelines: Colorectal Cancer Screening 2021

Aasma Shaukat, MD, MPH, FACP; Charles J. Kahi, MD, MSc, FACP, FASE; Carol A. Burke, MD, FACP; Linda Rabeneck, MD, MPH, MACG; Bryan G. Sauer, MD, MSc, FACP (GRADE Methodologist) and Douglas K. Rex, MD, MACG

19. We recommend organized screening programs to improve adherence to CRC screening compared with opportunistic screening.

Strong recommendation; low-quality evidence

20. We suggest the following strategies to improve adherence to screening: patient navigation, patient reminders, clinician interventions, provider recommendations, and clinical decision support tools.

Conditional recommendation; very low-quality evidence

Framework for Improving Adherence

Outreach with Colonoscopy vs. FIT vs. Usual Care

Organized Screening Program Improves Adherence

- Kaiser Permanente Northern California
- Screening before and after proactive outreach program (FIT and colonoscopy)
- 2000 to 2015

<table>
<thead>
<tr>
<th></th>
<th>Before</th>
<th>After</th>
<th>Absolute change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adherence</td>
<td>38%</td>
<td>82%</td>
<td>+44%</td>
</tr>
<tr>
<td>CRC incidence</td>
<td>95 per 100,000</td>
<td>71 per 100,000</td>
<td>-24%</td>
</tr>
<tr>
<td>CRC Mortality</td>
<td>30 per 100,000</td>
<td>14 per 100,000</td>
<td>-52%</td>
</tr>
</tbody>
</table>

Levin TR et al. Gastroenterology 2018;155:1383-91
Adherence is Key to Health Equity


CDC Community Guide

<table>
<thead>
<tr>
<th>Intervention/activities</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence-based interventions</td>
<td></td>
</tr>
<tr>
<td>Client reminders</td>
<td>Text-based (i.e., letter, postcard, e-mail) or telephone messages advising people that they are due (reminder) or overdue (recall) for screening.</td>
</tr>
<tr>
<td>Provider reminders</td>
<td>Prompts to inform healthcare providers that it is time for a patient’s cancer screening test (reminder) or that the patient is overdue for screening (recall).</td>
</tr>
<tr>
<td>Provider assessment and feedback</td>
<td>Evaluation of provider performance in offering and delivering screening to patients (assessment) and sharing the results with providers (feedback).</td>
</tr>
<tr>
<td>Reducing structural barriers</td>
<td>Reducing or eliminating noneconomic burdens or obstacles that impede access to screening by addressing things such as distance to service delivery (e.g., modifying clinic hours, offering services in alternative or nonclinical settings) or administrative procedures.</td>
</tr>
<tr>
<td>Supporting activities</td>
<td></td>
</tr>
<tr>
<td>Small media</td>
<td>Distribution of videos and printed materials such as letters, brochures, and newsletters.</td>
</tr>
<tr>
<td>Patient navigation</td>
<td>Individualized assistance offered to patients to help overcome healthcare system barriers and facilitate timely access to quality screening, follow-up, and initiation of treatment if diagnosed with cancer.</td>
</tr>
<tr>
<td>Professional development/provider education</td>
<td>Interventions such as distribution of educational materials or continuing medical education directed at healthcare staff and providers to increase their knowledge and to change attitudes and practices around cancer screening.</td>
</tr>
<tr>
<td>Community Health Workers (CHWs)</td>
<td>Community-based workers have a deep understanding of and are often from the community they serve. CHWs educate people about and promote cancer screening and provide peer support to people referred to cancer screening.</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Clinic screening policy</td>
<td>A screening policy in clinics or health systems includes a defined set of guidelines and procedures in place and in use to support CRC screening, a team responsible for implementing the policy, and a quality assurance structure.</td>
</tr>
<tr>
<td>Screening champion</td>
<td>A champion is an individual who takes a leadership role in a public health effort. Other variables include frequency of monitoring the CRC screening rate and frequency of implementation support provided to the clinic.</td>
</tr>
</tbody>
</table>
Makaroff KE et al. Patient Preferences for Colorectal Cancer Screening Tests in Light of Lowering the Screening Age to 45 Years, Clinical Gastroenterology and Hepatology (2022). DOI: 10.1016/j.cgh.2022.07.012

Ladabaum et al. Adenoma and Sessile Serrated Lesion Detection Rates at Screening Colonoscopy for Ages 45–49 Years vs Older Ages Since the Introduction of New Colorectal Cancer Screening Guidelines. 2022 DOI: https://doi.org/10.1016/j.cgh.2022.04.037
Screening Colonoscopy Volume Trends GIQUIC

% Colonoscopy volume

2019:
- total screening colonoscopies = 965,322
Nov 1 2021 – 10/2/22:
- total screening colonoscopies = 774,136

Unpublished data

Future Trends
### Blood Based CRC Screening Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Details of Technology</th>
<th>Special Considerations</th>
<th>Expected Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stool and blood based</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical genomics</td>
<td>Stool and blood-based biomarker (NCT00843375) for CRC and AN</td>
<td>Study plans to recruit 1800 average risk individuals 18 years+</td>
<td>• 2022</td>
</tr>
<tr>
<td>Blood-Based</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freenome</td>
<td>Cell free DNA plus artificial intelligence for CRC and AN (NCT04369053)</td>
<td>Aims to recruit 25,000 average risk individuals between 45-85</td>
<td>• 2022</td>
</tr>
<tr>
<td>Guardant</td>
<td>ctDNA LUNAR test to detect cell free tumor DNA in blood (NCT04136002)</td>
<td>Aims to recruit 10,000 average risk individuals between 45-84 years</td>
<td>• 2022</td>
</tr>
<tr>
<td>CancerSEEK</td>
<td>Multi-cancer detection test for 8 common cancers, including CRC</td>
<td>(NCT04213326) has enrolled 6399 cancer free as well as individuals with cancer, ages 50 and older since 2019</td>
<td>• 2022</td>
</tr>
<tr>
<td>GRAIL</td>
<td>Multi-cancer early detection test (breast, colorectal, pancreatic, lung and hematologic malignancies)</td>
<td>In validation study, specificity 99.5%, sensitivity for cancer 51.5%</td>
<td>Not covered by insurance and the list price is $949</td>
</tr>
</tbody>
</table>

Setting the Bar: CMS National Coverage Decision

### Decision Summary

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover a blood-based biomarker test as an appropriate colorectal cancer screening test once every 3 years for Medicare beneficiaries when performed in a Clinical Laboratory Improvement Act (CLIA)-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity for CRC</td>
<td>74%</td>
</tr>
<tr>
<td>Specificity for CRC</td>
<td>90%</td>
</tr>
<tr>
<td>FDA approval</td>
<td>✔️</td>
</tr>
</tbody>
</table>

Adherence to Blood Based Tests

413 randomized adults

**Blood Test Arm**

99.5% (CI95: 97.3%-100%) completed test

**FIT Arm**

88.1% (CI95: 83.0%-91.8%) completed test

=a difference of 11.4% (CI95: 6.9%-15.9%, p<.001)

Liles EG et al. Uptake of a colorectal cancer screening blood test is higher than of a fecal test offered in clinic: A randomized trial. 2017 Cancer Treatment and Research Communications;10: 27-31

**CRC Screening: Pie Gets Larger!**

- **50-75 year olds**
  - Colonoscopy: 48%
  - FIT: 10%
  - mtsDNA: 6%
  - Unscreeneed: 36%

- **45-75 year olds**
  - Colonoscopy
  - COL
  - Stool based
  - Blood based
  - FIT
  - mtsDNA
  - Unscreeneed
Back of the Envelope Calculations

**Current**
- 100 million 50-75
- 67 million screened; 33 million unscreened
- 20 million 45-49 unscreened
- 53 million unscreened

**Colonoscopy offered only**
- Adherence of 50%
- 26 million colonoscopies needed
- Current US capacity is 18 million/year

**Col + Non invasive tests offered**
- Adherence 80%; 7% abnormal initial test
- 42 million screened; 2.9 million positive test → Colonoscopy
- Over 10 years: 29 million colonoscopies
- Higher neoplasia yield (and more surveillance exams)

---

Getting to 80% in Every Community

- **Education/ awareness**
- **Removing barriers**
- **Research**
- **Advocacy**
- **Public Policy**

- **Covering Screening age 45**
- **Removing barriers to CRC screening Act 2020**
- **No Surprise Act 2022**

- Bloomberg: Screening Procedure Fails to Prevent Colon Cancer Deaths in Large Study
  - Colonoscopy offers small reduction in colon cancer risk: 18.2%
  - Previous studies toss significant risk reductions
Summary

• Screening for CRC is effective, current rates at 70%
• Programmatic approaches are needed to identify unscreened
• Adherence is key
• Demand for Colonoscopy will increase, indication may shift to surveillance

Thank you!