Carmen E. Guerra, M.D., MSCE, FACP

Disclosure of Commercial Interest

It is the policy of the Prevent Cancer Foundation and the Nurse Practitioners in Women’s Health that the education presented at CE-certified activities will be unbiased and based on scientific evidence. To help participants make judgments about the presence of bias, the Prevent Cancer Foundation provides information that faculty have disclosed about financial relationships they have with commercial entities that produce or market products or services related to the content of this educational activity.

There will not be any off-label and/or investigational use of products discussed within the content at any of the presentations at this conference.

Considerations about the Current Colorectal Cancer Screening Guidelines from the American Cancer Society

Dr. Carmen Guerra has indicated she has no relevant financial relationships within the past 12 months.
Considerations about the 2018 Colorectal Cancer Screening Guidelines from the American Cancer Society

Carmen E. Guerra, M.D., M.S.C.E., F.A.C.P.
Associate Professor and Vice Chair of Diversity and Inclusion
Department of Medicine
Associate Director of Diversity and Outreach
Abramson Cancer Center
Perelman School of Medicine of the University of Pennsylvania
carmen.guerra@uphs.upenn.edu

Dialogue for Action on Cancer Screening and Prevention
Crystal City, VA
April 26, 2019
Disclosures

- No financial disclosures
- Volunteer as ACS, Inc. Board Scientific Officer, Chair of Mission Outcomes Committee, Member of the Guidelines Development Group
The ACS recommends that adults aged **45 years and older** with an average risk of colorectal cancer undergo regular screening with **either a high-sensitivity stool-based test or a structural (visual) exam**, depending on patient preference and test availability.

- The recommendation to begin screening at age **45 y** is a **qualified** recommendation.
- The recommendation for regular screening in adults aged **50 y and older** is a **strong** recommendation.
ACS 2018 Recommendations for CRC Screening

- The ACS recommends that average-risk adults in good health with a life expectancy of greater than 10 years continue colorectal cancer screening through the age of 75 years. *(qualified recommendation)*

- The ACS recommends that clinicians individualize colorectal cancer screening decisions for individuals aged 76 through 85 years, based on patient preferences, life expectancy, health status, and prior screening history. *(qualified recommendation)*

- The ACS recommends that clinicians discourage individuals over age 85 years from continuing colorectal cancer screening. *(qualified recommendation)*
 ACS 2018 Recommendations for CRC Screening

❖ Options for CRC screening
  • Stool-based tests:
    – Fecal immunochemical test (FIT) every year
    – High sensitivity guaiac-based fecal occult blood test (HS-gFOBT) every year
    – Multi-target stool DNA test (mt-sDNA) every 3 years
  • Structural (visual) exams:
    – Colonoscopy (CSY) every 10 years
    – CT Colonography (CTC) every 5 years
    – Flexible sigmoidoscopy (FS) every 5 years

❖ As a part of the screening process, all positive results on non-colonoscopy screening tests should be followed up with timely colonoscopy.
# CRC Screening Guidelines for Average Risk Adults: ACS (2018); USPSTF (2016)

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>ACS, 2018</th>
<th>USPSTF, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age to start screening</strong></td>
<td><strong>Age 45y</strong>&lt;br&gt;Starting at 45y (Q)&lt;br&gt;Screening at aged 50y and older - (S)</td>
<td>Aged 50y (A)</td>
</tr>
<tr>
<td><strong>S-strong Q-Qualified</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Choice of test</strong></td>
<td>High-sensitivity stool-based test or a structural exam.</td>
<td>Different methods can accurately detect early stage CRC and adenomatous polyps.</td>
</tr>
<tr>
<td><strong>Acceptable Test options</strong></td>
<td>• FIT annually, &lt;br&gt;• HSgFOBT annually&lt;br&gt;• mt-sDNA every 3y&lt;br&gt;• Colonoscopy every 10y&lt;br&gt;• CTC every 5y&lt;br&gt;• FS every 5y&lt;br&gt;<strong>All positive non-colonoscopy tests should be followed up with colonoscopy.</strong></td>
<td>• HSgFOBT annually&lt;br&gt;• FIT annually&lt;br&gt;• mt-sDNA (aka FIT-DNA) every 1 or 3 y&lt;br&gt;• Colonoscopy every 10y&lt;br&gt;• CTC every 5y&lt;br&gt;• FS every 5y&lt;br&gt;• FS every 10y plus FIT every year</td>
</tr>
<tr>
<td><strong>Age to stop screening</strong></td>
<td>Continue to 75y as long as health is good and life expectancy 10+y (Q)&lt;br&gt;76-85y individual decision making (Q)&lt;br&gt; &gt;85y discouraged from screening (Q)</td>
<td>76-85 y individual decision making (C)</td>
</tr>
</tbody>
</table>
What Informed the GDG Decisions? GRADE

- Quality of evidence
  - Evidence on the *burden of disease* by age and race
  - High-quality studies of *test performance* and effectiveness of screening
  - Modeling studies (*Same models used by USPSTF*)

- Balance between desirable and undesirable effects – for each of the included screening modalities, *benefits significantly exceed harms*.

- Values and preferences – Since there is no single test that is consistently preferred by adults in the U.S., the GDG emphasized the *importance of offering choice*, rather than ranking tests based solely on quality of evidence for individual tests.
The ACS also:

- Examined disease burden data & trends in incidence in <55yo
- Conducted supplemental literature reviews to identify:
  - New literature since the publication of the USPSTF systematic review
  - Literature on risk associated with age, gender, and racial and ethnic subgroups

“For all modalities, strategies with screening beginning at age 45 years predominated on the efficient frontier; that is, these strategies generally provided additional LYGs at a lower number of additional colonoscopies than strategies with screening beginning at later ages.” However, beginning screening at age 45 years while maintaining the 10-year screening interval, resulted in an increase in the estimated lifetime number of colonoscopies. USPSTF judged the additional LYG as “modest”
Rationale – Disease Burden of CRC by Sex

*Trends in Colorectal Cancer Incidence Rates by Age and Sex, 1975-2014*

From 1994-2014 there is ~50% incidence in CRC in <50yo

**Aged 20-49 years**

**Aged 50+ years**

Rationale – Disease Burden of CRC in <50 yo by Race

Figure 1. Trends in Colorectal Cancer Incidence Rates in Adults Younger than Aged 50 years by Race, 1975-2014

CRC Incidence Among U.S. Adults Aged 45 & 50 Years, SEER, 1975-2015

Age-specific incidence is about the same for a 45 year old in 2015 as it was for a 50 year old in 1993, about 30 per 100,000.
Some Observations about CRC in Adults aged 45-49

- In 2018, an estimated 16,450 new CRC cases will be diagnosed in adults younger than 50.

- In 2014, approximately 43% of CRC cases under age 50 were in ages 45-49.

Source: Based on ACS estimated total cases in 2018 (140,250) and the proportion of cases < 50 in SEER 9 registries during 2014 (0.117253).
Percentage of Years of Potential Life Lost Due to Death from Colorectal Cancer by Age at Diagnosis (incidence-based mortality 2010-14 with follow-up 20 years after diagnosis)

~ 10% of all LYL is due to a diagnosis of CRC between ages 45-49 vs. 13% for ages 50-54
Among 9 efficient and 5 near-efficient colonoscopy strategies, the strategy recommended by the model under the increased-risk scenario was screening every 10 years from ages 45 to 75 years, which, compared with screening every 10 years from ages 50 to 75 years, had 6.2% more LYGs and 17% more colonoscopies per 1000 adults over a lifetime of screening.

The Impact of the Rising Colorectal Cancer Incidence in Young Adults on the Optimal Age to Start Screening: Microsimulation Analysis I to Inform the American Cancer Society Colorectal Cancer Screening Guideline

Elisabeth F.P. Peterse, MSc; Reinier G.S. Meester, PhD; Rebecca L. Siegel, MPH; Jennifer C. Chen, MPH; Andrea Dwyer, BS; Dennis J. Ahnen, PhD; Robert A. Smith, PhD; Ann G. Zauber, PhD; and Iris Lansdorp-Vogelaar, PhD

Optimizing Colorectal Cancer Screening by Race and Sex: Microsimulation Analysis II to Inform the American Cancer Society Colorectal Cancer Screening Guideline

Reinier G. S. Meester, PhD; Elisabeth F. P. Peterse, MSc; Amy B. Knudsen, PhD; Anne C. de Weerdt, BS; Jennifer C. Chen, MPH; Anna P. Lietz, BA; Andrea Dwyer, BS; Dennis J. Ahnen, MD; Rebecca L. Siegel, MPH; Robert A. Smith, PhD; Ann G. Zauber, PhD; and Iris Lansdorp-Vogelaar, PhD
Starting CRC Screening at Age 45: Conclusions

- Modeling convincingly demonstrates that, due to the rising incidence of CRC in younger individuals, screening all average-risk persons between the ages of 45 and 75 reduces mortality from CRC with an acceptable risk (as measured by number of colonoscopies per LYG).

- The trend of increasing CRC incidence in successively younger birth cohorts suggests that the recommended starting age of 45 will continue to be appropriate.

- The benefit-burden balance strongly favors changing the starting age from 50 to 45.
Screening for CRCS in <45 yo is cost-effective

- Initiating screening colonoscopies at age 45 years averted four CRCs and two deaths due to CRC per 1,000 persons. It resulted in a gain of 14 quality-adjusted life years (QALYs) at a cost of $33,900 per QALY gained.

- Fecal immunochemical test (FIT), followed by colonoscopies for abnormal results, and found that initiating FIT at age 45 years instead of 50 years would cost $7,700 per QALY gained.

Criticism of Reducing the Age to Begin CRCS

On 30 May 2018, scores of media outlets ran headlines like “Cancer Group Calls for Colorectal Cancer Screening Starting at Age 45” in response to updated guidelines for colorectal cancer (CRC) screening from the American Cancer Society (ACS). Whereas nearly all previous guidelines recommended screening beginning at age 50 years, the ACS added the qualified recommendation that an additional 22 million Americans aged 45 to 49 years also participate in screening (1).

Screening for CRC starting at age 50 years can reduce CRC incidence and mortality (2, 3). The ACS advocates any of several screening tests, either fecal-based (guaiac, immunochemical, or DNA) or structural (colonoscopy, sigmoidoscopy, or computed tomography colonography) (1). Despite wide variation in effect size and evidence quality among tests, the ACS argues that screening participation may be enhanced when patients can choose a test that aligns with their preferences (1).

What new evidence prompted this age shift? Screening participation may partly explain why CRC incidence rates for persons aged 54 years or older have steadily decreased in the United States since the early 1990s (4). However, CRC incidence in younger persons has increased over the same time frame. The ACS cites Figure. CRC incidence and mortality rates per 100 000 person-years and percentage of persons aged 20 to 49 years screened for CRC, United States, 1975 to 2015.
What concerns have been raised about the new guideline?

- CRC is a different disease in adults under 50
- Burden of disease is very small in this age group; high costs and many harms for a small benefit
- No empirical evidence; recommendations based on modeling
- Important to concentrate further on adults 50+
- The new guideline will worsen existing disparities
- The new guideline will strain existing capacity
- Insurance coverage may not be available for adults 45-49
New Decision Aids for CRC Screening

Summary for Clinicians

American Cancer Society Guideline for Colorectal Cancer Screening: A Summary for Clinicians

The American Cancer Society recommends:

- Adults ages 45 and older with an average risk of colorectal cancer (CRC) should undergo regular screening with either a sigmoidoscopy and fecal occult blood test or a colonoscopy every 10 years.
- Adults ages 50 and older with an average risk of CRC should undergo regular screening with either a sigmoidoscopy and fecal occult blood test or a colonoscopy every 5 years.
- Adults ages 50 and older with a high risk of CRC should undergo regular screening with either a sigmoidoscopy and fecal occult blood test or a colonoscopy every 5 years.
- Adults ages 50 and older with a high risk of CRC who are non-Hispanic white and have a family history of CRC should undergo regular screening with either a sigmoidoscopy and fecal occult blood test or a colonoscopy every 5 years.

Understanding colorectal cancer screening: Using conversation cards to help your patients select an option for colorectal cancer screening

- These Conversation Cards are to be used with patients who have not previously screened or are scheduled for their next test.
- Each Conversation Card features the attributes of a different colorectal cancer screening test option.

Understanding colorectal cancer screening: Colorectal cancer screening: Which test is right for you?

- COLONOSCOPY is the second-leading cause of death from cancer in the U.S. for men and women combined. The best way to prevent death from colorectal cancer is to stay current with screening.
- There are many screening tests for colorectal cancer. You and your healthcare provider have a decision to make about which screening test is right for you. The test you choose will depend on your preferences and whether you have a family history of colorectal cancer.

Recommended tests and screening intervals

- High-risk: Sigmoidoscopy
  - Initial: 50 years of age
  - Recurrence: Every 5 years
- Faecal occult blood test
  - Initial: 50 years of age
  - Recurrence: Every 5 years
- Multi-target fecal immunochemical test (MultiFIT)
  - Initial: 50 years of age
  - Recurrence: Every 3 years

How to use the cards:

Step 1: Use the conversation cards to help patients make an informed decision about colorectal cancer screening.

Understanding colorectal cancer screening: Patient decision aid

- Use the Conversation Cards to help patients make an informed decision about colorectal cancer screening.

Understanding colorectal cancer screening: Patient decision aid

West Philadelphia
West Philadelphia CRCS Patient Navigation Program

- Reduce disparities in CRCS by:
  - Hire/train a patient navigator
    - Harold Freeman Patient Navigation Institute, Bronx, NY
  - Foundation grants for resources for program and patient care expenses
    - cell phone and service, computer, printer, printing, stationary, software, etc.
    - free prep, Septa tokens
    - video colonoscopy instructions
      - https://www.youtube.com/watch?v=M5t8lhZ-aoY
  - Conduct studies to determine program feasibility, acceptability, effectiveness
## Demographics

<table>
<thead>
<tr>
<th>Age (mean, s.d.)</th>
<th>N=690</th>
<th>60.2, 8.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>427</td>
<td>(61.9)</td>
</tr>
<tr>
<td>African American</td>
<td>621</td>
<td>(90)</td>
</tr>
</tbody>
</table>

### Marital Status

<table>
<thead>
<tr>
<th>Status</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single</td>
<td>320</td>
</tr>
<tr>
<td>Married</td>
<td>178</td>
</tr>
</tbody>
</table>

### Education

<table>
<thead>
<tr>
<th>Level</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;High School</td>
<td>125</td>
</tr>
<tr>
<td>High School</td>
<td>316</td>
</tr>
</tbody>
</table>

### Annual Income

<table>
<thead>
<tr>
<th>Income</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;$10,000</td>
<td>240</td>
</tr>
<tr>
<td>10,000-29,999</td>
<td>242</td>
</tr>
</tbody>
</table>

## Screening Colonoscopy Results

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal/no pathology or hyperplastic polyp(s)</td>
<td>353   (46.3%)</td>
</tr>
<tr>
<td>At least one adenomatous polyp</td>
<td>327  (42.9%)</td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>5     (0.7%)</td>
</tr>
<tr>
<td>Repeat</td>
<td>16    (2%)</td>
</tr>
<tr>
<td>Other</td>
<td>30    (4%)</td>
</tr>
<tr>
<td>Pending scheduling</td>
<td>32    (4%)</td>
</tr>
</tbody>
</table>

## CRC Stage

<table>
<thead>
<tr>
<th>Stage</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage I</td>
<td>1</td>
</tr>
<tr>
<td>Stage II</td>
<td>0</td>
</tr>
<tr>
<td>Stage III</td>
<td>3</td>
</tr>
<tr>
<td>Stage IV</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
</tr>
</tbody>
</table>

Using community outreach to explore health-related beliefs and improve surgeon-patient engagement
## Financial Sustainability

<table>
<thead>
<tr>
<th></th>
<th>HUP</th>
<th>PPMC</th>
<th>UPHS Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>80</td>
<td>40</td>
<td>120</td>
</tr>
<tr>
<td>Outpatient Net Revenue</td>
<td>$84,401</td>
<td>$59,557</td>
<td>$143,958</td>
</tr>
<tr>
<td>Direct Expenses</td>
<td>$91,955</td>
<td>$45,114</td>
<td>$137,089</td>
</tr>
<tr>
<td>Contribution Margin</td>
<td>($7,555)</td>
<td>$14,444</td>
<td>$6,869</td>
</tr>
<tr>
<td>Indirect expenses</td>
<td>$30,251</td>
<td>$11,653</td>
<td>$41,904</td>
</tr>
<tr>
<td>Net gain (loss)</td>
<td>($37,806)</td>
<td>$2,791</td>
<td>($35,015)</td>
</tr>
<tr>
<td>Downstream Contribution Margin</td>
<td>$115,004</td>
<td>($947)</td>
<td>$114,057</td>
</tr>
<tr>
<td>Total Gain/Loss including Downstream</td>
<td>$77,198</td>
<td>$1,843</td>
<td>$79,042</td>
</tr>
</tbody>
</table>
Sustainability of cancer screening programs

Cost-Effectiveness Analysis of the First Year of a Colorectal Cancer (CRC) Screening Patient Navigation Program at an Academic Medical Center

Ramos, Joshua N., BA1; Mehta, Shivan J., MD, MBA1; Lamanna, Alicia A., BA1; Kochman, Michael L., MD1; Guerra, Carmen E., MD, MSCE 1
1. Department of Medicine, Perlman School of Medicine at the University of Pennsylvania, Philadelphia, PA, United States.

Abstract

Introduction. We evaluated the first year of the CRC screening Patient Navigation Program at the University of Pennsylvania Health System (UPHS), analyzing the cost of the program and cost per patient who successfully completed a colonoscopy (SC).

Methods. This is a retrospective cost-effectiveness analysis of data gathered during the first full year (2012) of the navigation program. For this analysis, the outcome of interest was SC completion within a month of program enrollment. To perform the cost-effectiveness analysis, the database of the navigation program was reviewed, and the costs were divided by the number of patients enrolled, scheduled, and screened (both unadjusted and adjusting for an estimate of those who would have completed SC without navigation).

Results. The cost per patient enrolled was $43.12 and the cost per patient screened was $70.34. After adjusting for completion without navigation, the cost was $39.29 per additional patient screened. Compared with the cost per successfully screened patient.

Conclusions. Although the navigation program significantly increased the percentage of patients who had a SC for this vulnerable environment and underscores concern, there is a significant cost to this navigation program, driven largely by labor costs. However, significant costs and interventions may be worthwhile to improve health outcomes.

Background

Patient navigation programs have been shown to be effective in increasing colorectal cancer (CRC) screening rates, particularly for underserved populations.

Objective

1. To determine the cost-effectiveness of the first year of a CRC screening patient navigation program.

Methods

Figure 2: Cost-Effectiveness Decision Tree

- The outcome of interest was SC completion within 3 months of program enrollment.
- Both program participants and those who declined navigation were followed and the number of canceled, missed, and completed SC appointments was recorded.
- To perform the cost-effectiveness analysis, the total costs of the navigation program were recorded, including the navigation program cost, patient's cost, and patient's out-of-pocket cost for transportation.
- The costs were divided by the number of patients enrolled, scheduled, and screened (both unadjusted and adjusting for an estimate of those who would have completed SC without navigation).

Figure 3: Target Population—West Philadelphia

Table 1: Demographics

<table>
<thead>
<tr>
<th>Table 2: Clinical Effectiveness Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>Total sample, n</td>
</tr>
<tr>
<td>Average Number of Previous SCs</td>
</tr>
<tr>
<td>Patents with a Scheduled SC</td>
</tr>
<tr>
<td>Patients with Cancelled Appointments</td>
</tr>
<tr>
<td>Patients with Missed Appointments</td>
</tr>
</tbody>
</table>

Conclusions

Although the navigation program significantly increased the percentage of completed CRCs, this previously non-adherent and underserved cohort, there is a significant cost to this navigation program, driven largely by labor costs. However, significant cost and interventions may be beneficial in health-care populations like West Philadelphia patients, given the above-average adenoma detection rate of 40%.

Limitations

- Since we were only able to recruit about 30% of the contacted patients for the program, our results may be subject to participation bias.

Acknowledgments

- Anonymous donor
- American Cancer Society- Wisconsin Foundation Grant
- Abramson Cancer Center
- 2012 Bach Fund Grant
- Colon Cancer Alliance
- Colon Cancer Coalition
Acknowledgements

- Dr. Robert Smith, ACS Guideline Development Group, Staff
- Dr. Michael Kochman, co-director of CRCS Navigation Program
- Alicia Lamanna and Diann Boyd, patient navigators