Engaging Patient and Provider Stakeholders in a Comparative Effectiveness Trial to Increase Colorectal Cancer Screening

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Patient-Centered Outcomes Research Institute (PCORI): IHS-1507-31333
Objectives

- Review the problem of colorectal cancer and participation in screening
- Explain rationale for the comparative effectiveness trial
- Describe the study aims, design and interventions
- Describe the processes of engaging patients
- Describe the processes of engaging clinical stakeholders
- Summarize benefits of engaging patients and clinicians in CER
U.S. Colorectal Cancer Facts: 2017

- Second most common cancer affecting men and women
- Estimated # of new cases in 2017: 135,430
- Estimated # of deaths in 2017: 50,260

- Curable
  - 5-year survival is over 90% for early stage disease, but only 4 of 10 cases are diagnosed early

- Preventable
  - By removing precancerous polyp, but screening rates are suboptimal

## Survival Rates by Stage at Diagnosis

Survival rates by stage at diagnosis for colorectum. Among cases diagnosed from 2005 to 2011, followed through 2012.

<table>
<thead>
<tr>
<th>Stage</th>
<th>5-year relative survival (2005-2011)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All stages combined</td>
<td>65%</td>
</tr>
<tr>
<td>Localized</td>
<td>90%</td>
</tr>
<tr>
<td>Regional</td>
<td>71%</td>
</tr>
<tr>
<td>Distant</td>
<td>13%</td>
</tr>
</tbody>
</table>

**Data Sources:** Surveillance, Epidemiology, and End Results (SEER) 18 registries, National Cancer Institute, 2015

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CRC Incidence & Mortality Rates by State

Downloaded from https://cancerstatisticscenter.cancer.org/?_ga=1.35377953.1015905190.1426612483#

Incidence rates, 2008-2012
by state, for colorectum
Per 100,000, age adjusted to the 2000 US standard population

Death rates, 2008-2012
by state, for colorectum
Per 100,000, age adjusted to the 2000 US standard population

Data Sources: North American Association of Central Cancer Registries (NAACCR), 2015
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Data Sources: National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention, 2015
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Incidence & Mortality Rates by Race/Ethnicity

Incidence rates, 2008-2012
by race and ethnicity, for colorectum
Per 100,000, age adjusted to the 2000 US standard population

Non-Hispanic black: 50.7
American Indian and Alaska Native: 44.7
Non-Hispanic white: 41.3
Hispanic: 36.7
Asian and Pacific Islander: 33.5

Death rates, 2008-2012
by race and ethnicity, for colorectum
Per 100,000, age adjusted to the 2000 US standard population

Non-Hispanic black: 21.9
American Indian and Alaska Native: 17.1
Non-Hispanic white: 15.2
Hispanic: 12.2
Asian and Pacific Islander: 11

Data Sources: North American Association of Central Cancer Registries (NAACCR), 2015
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Data Sources: National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention, 2015
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## Colorectal Cancer Screening Guidelines For People with Average Risk

<table>
<thead>
<tr>
<th>Population</th>
<th>Test or Procedure</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 years +</td>
<td>FOBT* or FIT*</td>
<td>Annually</td>
</tr>
<tr>
<td></td>
<td>sDNA†</td>
<td>Every 3 years</td>
</tr>
<tr>
<td></td>
<td>Sigmoidoscopy†</td>
<td>Every 5 years</td>
</tr>
<tr>
<td></td>
<td>Double-contrast barium enema†</td>
<td>Every 5 years</td>
</tr>
<tr>
<td></td>
<td>Colonoscopy†</td>
<td>Every 10 years</td>
</tr>
<tr>
<td></td>
<td>CT Colonography†</td>
<td>Every 5 years</td>
</tr>
</tbody>
</table>

Visit [www.cancer.org](http://www.cancer.org) for more information about the American Cancer Society Guidelines for the Early Detection of Cancer

FOBT: fecal occult blood test. FIT: fecal immunochemical test. CT: computed tomography.
*Primarily detects cancer. †Included in recommendation based on approval of the Food and Drug Administration and study results of performance characteristics of the newest test available. The American Cancer Society will conduct a full evaluation of this test when the Society’s colorectal cancer screening guidelines are updated. ‡Detects both cancer and precancerous polyps.
## Cancer Screening Rates: % Up-to-Date

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Indiana</th>
<th>National Rank</th>
<th>U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammmography, women 40 years and older, 2014</td>
<td>67.4%</td>
<td>44</td>
<td>72.8%</td>
</tr>
<tr>
<td>Fecal occult blood test (FOBT/ FIT) or endoscopy, 50 years &amp; older, 2014</td>
<td>62.5%</td>
<td>43</td>
<td>67.6%</td>
</tr>
<tr>
<td>Pap test, women 21 to 65 years, 2014</td>
<td>78.0%</td>
<td>47</td>
<td>82.6%</td>
</tr>
</tbody>
</table>
Prevalence of Colorectal Cancer Screening*, Adults 50 Years and Older, by Race/Ethnicity† and Insurance Status‡, US, 2015

*Stool test within the past year or sigmoidoscopy within the past 5 years or colonoscopy within the past 10 years. Estimates are age adjusted to the 2000 US standard population. †Estimates for white, black, and Asian are among non-Hispanics. Estimates for Asians do not include Native Hawaiians or other Pacific Islanders. ‡Among adults age 50-64 years. Uninsured estimate for Asians not presented due to instability.

Source: National Health Interview Survey, see notes for citation.
Additional Rationale for the Study

- Prior study (R01 testing computer-tailored program delivered in primary care clinics) effectively increased CRC screening compared to standard brochure, yet 73% of African American primary care patients remained unscreened at 6 months.

- Medical record reviews showed that many participants received multiple referrals for colonoscopy.

- Discussions with Eskenazi colleagues revealed an almost 50% no show rate for screening colonoscopy appointments (at that time).

- Pilot study and further discussions with clinical stakeholders and community advisory board (CAB) members, many who received their care at Eskenazi, resulted in PCORI proposal.
RESEARCH TEAM

- Sylvia Strom, BA (CAB Chair)
- Sandra Bailey (CAB)
- Robert Breskow (CAB)
- Beatrice Cork (CAB)
- Thomas Griffin III (CAB)
- Juan Lagunes (CAB)
- Ruth Lambert (CAB)
- Jack Quick (CAB)
- Susan Rawl, PhD RN FAAHB FAAN
- Lisa Carter-Harris, PhD APRN
- Victoria Champion, PhD RN FAAN
- Hala Fatima, MD MBBS
- Kim Mitchell, RN MSN
- Rita Reynolds, RN BSN CGRN
- Connie Krier, BCCRP
- Mira Katz, PhD (OSU)
- Electra Paskett, PhD (OSU)
- Susan Perkins, PhD
- Peter Schwartz, MD PhD
- Rivienne Shedd-Steele, BA
- Alisha Jessup, RN MPA
- Jennifer Ferrell, RN MSN
- Kari Johnson, RN BSN
- Jereana Miller, RN BSN
- Yvonne Williams, RN BSN
- Monica Yearwood, RN BS
Specific Aims

1. Compare the effectiveness of two interventions designed to promote CRC screening among people at average risk for CRC - a mailed tailored DVD versus the DVD plus telephone-based patient navigation - to each other and to usual care.

   **Hypothesis 1.1:** Participants who receive the tailored DVD plus telephone-based PN intervention will have higher rates of colorectal cancer screening with fecal immunochemical test (FIT), colonoscopy, or either test compared to those who receive the tailored DVD alone.

   **Hypothesis 1.2:** Participants who receive either intervention will have higher rates of screening with fecal immunochromical tests (FIT), colonoscopy, or either test than those who receive usual care.

   **Hypothesis 1.3:** Participants who receive either intervention who complete colonoscopy will have: 1) better quality of bowel preparation; 2) less anxiety about the procedure; and 3) greater satisfaction with the colonoscopy experience than those who receive usual care.

2. Examine age, race/ethnicity, sex, and income as potential moderators of intervention effects.

3. Examine changes in knowledge and health beliefs (perceived risk, perceived benefits, perceived barriers, and self-efficacy) as potential mediators of intervention effects.
Study Details

- Project period: 4 years
- Design: 3-group RCT
- Sample size: n=750 (250 in each group)
- Recruitment site: Eskenazi Health System Endoscopy Department
- Data collection: Center for Survey Research, IU Bloomington
- Study schema
Letters introducing study mailed to patients approved for contact

Follow-up phone calls within 1 week to consent patients
Baseline (Time 1) interviews conducted, participants randomized

Tailored DVD (Group 1)
Tailored DVD *plus* Patient Navigator (Group 2)
Usual Care (Group 3)

Deliver Interventions

Process interview at 2 weeks post-intervention

Follow-up interview at 6 months post-baseline

Final interview at 12 months post-baseline

Study Design and Schema
Interventions

+ Tailored DVD

or

- Patient Navigation by Phone
Introduction to “Approaches to Colon Testing” (ACT) DVD

Assessment of user characteristics and risk factors for tailoring messages (sex, race/ethnicity, family history of CRC)

Description of colon anatomy, polyps, and how CRC develops

Benefits of screening and brief descriptions of FIT & colonoscopy

Tailored messages on CRC risk & risk-based screening recommendation

Assessment of screening test preference

Demonstration of FIT OR colonoscopy (tailored to user preference)

Assessment of barriers to preferred test

Information about what to expect after the test

Summary & Closing
Patient Navigation Intervention

- Based on research conducted by The Ohio State University team members
- Theory-based telephone intervention (minimum of 2 calls)
- Navigators will:
  - Increase knowledge, perceived benefits, and self-efficacy
  - Reduce barriers
  - Enhance access
  - Provide social support
- Population health nurses will serve as PNs for this study
CAB Member Contributions to Proposal Development

During Proposal Development...
- Recruited members by reaching out to CAB members from prior studies
- Invited to an informational meeting to discuss prior study results and ideas for addressing the problem of low CRC screening
- Discussed the proposed study, provided input into interventions, study design and selection of outcomes
- Consider joining the CAB for the proposed study and willingness to provide a LOS
AFTER project launch:

- Attend scheduled CAB meetings: 6 in year 1, quarterly in years 2-4
- Actively participate in meetings by providing critique and feedback
- CAB members were/will be engaged in:
  - Refining the DVD content
  - Reviewing the PN intervention
  - Reviewing and providing input to improve recruitment materials and strategies
  - Reviewing and providing input to improve surveys/questionnaires
  - Monitor study progress and troubleshoot challenges
  - Discuss results and next steps needed
Community Advisory Board Members

- Sylvia (Chair)
- Robert
- Sandra
- Juan
- Jack
- Beatrice
- Ruth
- Tom
Community Advisory Board Meetings
CAB Members Featured in DVD

If you know, you can fix it. If you don’t know, you cannot fix it.”

“I just cannot stress enough how important it is to get your colonoscopy done.”
Clinical Stakeholders & Collaborators

Kim Mitchell, RN, MSN
Clinical Nurse Manager
Endoscopy Department

Rita Reynolds, RN, BSN, CGRN
Nurse Navigator
Endoscopy Department

Hala Fatima, MD, MBBS
Medical Director
Endoscopy Department
Associate Professor of Clinical Medicine
Patient Navigators and Supervisors

Kari Johnson, RN BSN
Jereana Miller, RN BSN
Yvonne Williams, RN BSN
Monica Yearwood, RN BS
Alisha Jessup, RN MPA
Jennifer Ferrell, RN MSN
Benefits of Engaging Patients & Clinical Stakeholders in Research

- Patients (or members of the community) provide essential input to make interventions and all study materials (recruitment materials, data collection instruments) relevant, culturally sensitive, comprehensive and user-friendly.

- Clinicians are essential to developing interventions that are easily integrated and useful within health systems. Also provide guidance on identifying eligible patients and populations in need of intervention.

- Science and researchers benefit from their engagement and collaboration but... What’s in it for them??
Thank You...