STOP CRC in the context of an ethical framework for learning health systems

Gloria D. Coronado, PhD
Jen DeVoe, MD, DPhil
Beverly Green, MD, MPH
# Acknowledgements

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<tr>
<td>Tanya Kapka</td>
<td>Jennifer DeVoe</td>
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<td>Bill Vollmer</td>
<td>Jon Puro</td>
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<td>Rich Meenan</td>
<td>Jennifer Lembach</td>
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<td>Jennifer Schneider</td>
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<td>Adrianne Feldstein</td>
<td>Virginia Garcia</td>
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<td>Sally Retecki</td>
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<td><strong>Group Health</strong></td>
<td><strong>Josue Aguime</strong></td>
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<tr>
<td>Beverly Green</td>
<td><em>STOP CRC Advisory Board</em></td>
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Outline

- Preliminary findings from the STOP Colorectal Cancer (CRC) pilot program;
- The Faden et al. ethical framework for learning health systems;
- Application of Faden et al. framework to STOP CRC.
PRELIMINARY FINDINGS FROM STOP CRC
Colorectal cancer background

- Colorectal cancer (CRC) is the second leading cause of cancer death in the US
- CRC screening rates are low
  - In 2010, 41% of adults aged 50–75—nearly 35 million people—were not up-to-date with CRC screening*;
  - Almost 30% have never had any type of CRC screening.**
- The lowest screened population subgroups generally receive care at FQHCs.

*National Health Interview Survey, 2010
** MMWR 2008;57(10):253-258.
STOP CRC Phase 1: Aims

- **Define Codes** and methods to identify eligible patients and track relevant CRC outcomes.

- **Conduct Pilot** Test the feasibility, effectiveness, and cost of an EHR-based, two-arm CRC screening intervention in 100 patients in two pilot clinics.

- **Prepare for Pragmatic trial** Use results from the pilot intervention to prepare a large-scale, cluster-randomized pragmatic trial across 24+ community clinics.
External facilitators for CRC screening

- CRC screening became a HEDIS and UDS measure in 2012
- The USPSTF recommends CRC screening
- CRC screening is an incentivized metric for the CCOs.

*IOM Report 2012
Difference between explanatory study and pragmatic study

**Explanatory Study**
- Eligible population
- Exclusions, non-response, etc.
- Efficacy, among a defined subset

**Pragmatic Study**
- Eligible population
- Exclusions, non-response, etc.
- Effectiveness, in a broad subset
Clinic partnership

- Founded in 1975
- Provides over 132,000 office visits to 34,000+ patients per year in Washington and Yamhill Counties
- Operates 4 primary care clinics, 3 dental offices, and 2 school-based health centers.

<table>
<thead>
<tr>
<th>Clinic</th>
<th>N Patients aged 50-74 and had a visit in past year</th>
<th>% Hispanic aged 50-74</th>
<th>% aged 50-74 who obtained FIT or FOBT</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>1287</td>
<td>37%</td>
<td>3.7%</td>
</tr>
<tr>
<td>#2</td>
<td>714</td>
<td>77%</td>
<td>3.9%</td>
</tr>
<tr>
<td>#3</td>
<td>1479</td>
<td>55%</td>
<td>5.2%</td>
</tr>
<tr>
<td>#4</td>
<td>1427</td>
<td>34%</td>
<td>7.6%</td>
</tr>
</tbody>
</table>

Virginia Garcia Memorial Health Center
STOP CRC advisory board

- Participatory approach
- Engaged stakeholders
  - Representatives of interested clinics
  - Policy-makers
  - Patient advocates
  - Providers of low-cost colonoscopy services
  - Gastroenterologists
  - EHR experts
- 4 phone meetings and 1 in-person meeting in YR 01
STOP CRC pilot design

Auto Cornelius Clinic
- Identify eligible patients
- Mail intro letter
- Mail fecal test
- Mail reminder postcard

Auto Plus Hillsboro Clinic
- Identify eligible patients
- Mail intro letter
- Mail fecal test
- Mail reminder postcard
- Deliver theory-based phone counseling

Patients not contacted or decline (Reach)
- Patients complete fecal test (Effectiveness)
  - Patients not contacted or decline (Reach)
  - Patients complete fecal test (Effectiveness)

Reach = N patients contacted/ N anticipated
Effectiveness = N patients tested/ N anticipated

© 2013, KAISER PERMANENTE CENTER
Dear patient,

There is a simple test that can find signs of colon cancer before you have symptoms. Even so, many people do not get tested. 58-year-old Julio—like many residents of Washington County—used to be one of them. But he's glad he got tested, and the family is happy too.

"I was embarrassed and didn’t get checked."

Julio learned that the test looks for blood in the stool, and can be done at home. Julio knew he should get checked, but he did not know it was so easy.

"I didn’t know that there was a way you can check for cancer at home."

Julio’s test was positive and his doctor recommended another kind of test—a colonoscopy. The colonoscopy showed an early form of colon cancer. Julio was able to get treated and now has a 99% chance of survival.

Are you between the ages of 50 and 74? If so, you may be due for a stool test. This test can find early forms of colon cancer. Early detection gives you the best chance for successful treatment.

In a few weeks, we will mail you a free stool test. You can do the test at home.

If you have had a colonoscopy in the past 9 years or prior that we did not mail you a test, please contact us at 503-601-7701 (Wildwood) or 503-352-8922 (Cornelius).

Thank you.

Ann Turner, MD, Co-Director
Inge Hindel, MD

Estimado paciente,

Hay una prueba sencilla que se puede encontrar signos de cáncer de colon antes de tener síntomas. Aun así, muchas personas no se hacen la prueba. 58 años de edad, Julio—como los demás residentes del Condado de Washington, es uno de ellos. Pero él está contento que hizo la prueba, y la familia está contenta también.

"Yo estaba avergonzado y no hice la prueba." Julio aprendió que la prueba revisa si hay sangre en su excremento, y se puede hacer en casa. Julio sabía que debía hacerse una prueba, pero no sabía que fuera tan fácil.

"Yo no sabía que podría hacer la prueba en casa." La prueba de Julio fue positiva, así que su médico le recomendó otro tipo de prueba: una colonoscopia. La colonoscopia mostró una forma temprana de cáncer de colon. Julio pudo recibir tratamiento y ahora tiene un 99% de posibilidad de sobrevivir.

¿Usted tiene entre 50 y 74 años? Si es así, puede ser tiempo para hacer su prueba de excremento. La prueba de excremento es una manera de saber si tiene problemas del colon.

En unas pocas semanas, le enviaremos por correo una prueba de excremento gratis. Usted puede hacer la prueba en casa.

Si ha tenido una colonoscopia en los últimos 9 años, o prefiera no lo envíamos una prueba, por favor contáctenos al 503-601-7701 (Wildwood) o al 503-352-8922 (Cornelius).

Gracias,

Ann Turner, MD, Co-Director
Inge Hindel, MD

Screen to Prevent is a free program of Virginia Garcia Memorial Health Center, Kaiser Permanente, Center for Health Research, OCHIN, and Group Health Cooperative.

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STOP CRC materials: FIT kit instructions

1. Label the FIT container with your name, date of birth (DOB), and date of collection (MM/DD/YY).
2. Insert the swab into the FIT container and fill it with stool sample.
3. Return the FIT container in the pre-paid envelope within 3 days.

© 2013, KAISER PERMANENTE CENTER FOR HEALTH RESEARCH
STOP CRC materials: Reminder postcard

Return your free stool test today!

This simple test can ensure that your colon is healthy—and that’s one less thing you have to worry about.

If you recently returned the stool test to us, please ignore this reminder. If you have questions, please call the Virginia Garcia Memorial Health Center at 503-352-8592.

¡Mande por correo su prueba fecal gratis hoy!

Esta sencilla prueba puede asegurar que su colon está saludable—es una cosa menos que usted tiene de qué preocuparse.

Si usted acaba de mandar la prueba fecal, por favor, no haga caso a esta carta. Si usted tiene preguntas por favor llame a la Virginia Garcia Memorial Health Center al 503-352-8592.
STOP CRC materials: Telephone script

“Would it be okay if I asked you some questions about your willingness to complete the FIT kit?”
• “What are your thoughts?”
• “Why do you think it’s a good idea to do this test?”
• “What concerns do you have about doing the test?”

Open-ended questions: Assess facilitators/barriers

Summary
• Ask “Did I get it all?”
• “Now that we have spent a few minutes talking about the FIT kit, I wonder what you’re thinking about completing the test at this point.”
• “What’s the next step you feel comfortable taking?”

Reflection
• “Show your appreciation by thanking the patient for their willingness to talk with you today.”
• “I’m confident that if and when you make a decision and commitment to complete the test you’ll find a way to do it.”

Open-ended questions: Assess readiness

“May I answer any questions you have about the test?” [ANSWER QUESTIONS ONLY IF ASKED]

Reinforce self-efficacy
### Demographic characteristics of patient population (n = 213)*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>%</th>
<th>Characteristic</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Insurance status</strong></td>
<td></td>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Uninsured</td>
<td>59</td>
<td>Hispanic</td>
<td>59</td>
</tr>
<tr>
<td>Medicaid</td>
<td>19</td>
<td>Language</td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>23</td>
<td>Spanish</td>
<td>58</td>
</tr>
<tr>
<td>Private</td>
<td>7</td>
<td><strong>Federal Poverty Level</strong></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>&lt; 100%</td>
<td>80</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td>100 – 200%</td>
<td>18</td>
</tr>
<tr>
<td>50-64</td>
<td>79</td>
<td>&gt; 200%</td>
<td>2</td>
</tr>
<tr>
<td>65-75</td>
<td>21</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*active patients selected for pilot from Cornelius or Hillsboro clinics*
### Preliminary findings

<table>
<thead>
<tr>
<th></th>
<th>Cornelius (Auto)</th>
<th>Hillsboro (Auto Plus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letters mailed</td>
<td>112</td>
<td>101</td>
</tr>
<tr>
<td>FIT kits mailed</td>
<td>109</td>
<td>97</td>
</tr>
<tr>
<td>Reminder postcards mailed</td>
<td>95</td>
<td>84</td>
</tr>
<tr>
<td>Phone counseling delivered</td>
<td>NA</td>
<td>27</td>
</tr>
<tr>
<td>FIT kits complete</td>
<td>38 (34.9%)</td>
<td>32 (33.0%)</td>
</tr>
<tr>
<td>Positive FIT results</td>
<td>5 (13.2%)</td>
<td>1 (3.1%)</td>
</tr>
</tbody>
</table>
## Possible impact of STOP CRC

<table>
<thead>
<tr>
<th></th>
<th>N patients aged 50-74</th>
<th>% screened as part of STOP CRC*</th>
<th>N anticipated screened*</th>
<th>N anticipated positive test result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1 clinics (n = 2)</td>
<td>2,193 (213 included in pilot)</td>
<td>34%</td>
<td>70</td>
<td>6*</td>
</tr>
<tr>
<td>Phase 2 clinics (n = 24)</td>
<td>29,431</td>
<td>34%</td>
<td>10,006</td>
<td>450**</td>
</tr>
</tbody>
</table>

*based on pilot findings to date

** based on positivity rate of 4.5% for OC Micro
Next steps for pilot:

- Patient interviews – non-responders
- Interviews with clinic staff involved in pilot
- Refine RWB and training materials
- Create video of pilot project
- Recruit clinics for phase 2
ETHICAL FRAMEWORK FOR LEARNING
HEALTH SYSTEMS
Learning Health Systems: The intersection of research and practice

- Research and practice are not fundamentally different enterprises;
- Institutional Review Boards and consent forms were designed to protect patients, but have evolved to protect institutions;
- Inconsistencies in IRBs across institutions create burdens for multi-site research;
- Learning health care system by definition at intersection of research and practice
  - “knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care.”*  

*Faden et al. 2013
Learning Health System ethical framework

[Learning Health Systems] set a moral priority on learning... Includes an obligation to address problems of unjust inequalities in health care – “an obligation that reaches beyond the demands of justice in traditional and contemporary codes of research and clinical ethics”

Justice

Quality

Value

*Faden et al. 2013
Obligations of a Learning Health System*

1 – respect the rights and dignity of patients
2 – respect the clinical judgment of clinicians
3 – provide optimal care to each patient
4 – avoid imposing nonclinical risks and burdens on patients
5 – **reduce health inequalities among populations**
6 – conduct responsible activities that foster learning from clinical care and clinical information
7 – contribute to the common purpose of improving the quality and value of clinical care and health care systems

*Faden et al. 2013
Address health inequalities*

<table>
<thead>
<tr>
<th>Parties bearing the obligation</th>
<th>Synopsis of the obligation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researchers, clinicians, health care systems administrators, payers, purchasers</td>
<td>Assess whether the risks and burdens of a learning activity will fall disproportionately on patients who are already disadvantaged.</td>
</tr>
<tr>
<td></td>
<td>Assess whether the learning activity will disproportionately benefit patients who are already socially or economically advantaged.</td>
</tr>
<tr>
<td></td>
<td>Assess whether a learning activity will help advance the goal of reducing unjust inequalities in health and health care or can be designed to do so.</td>
</tr>
</tbody>
</table>

*Faden et al. 2013
APPLICATION OF ETHICAL FRAMEWORK TO STOP CRC
Summary of ethical considerations

- Clinic-level randomization; no patient consents are needed;
- All entities (clinics, OCHIN, Group Health Research Institute) cede to KPNW;
- Our main concerns relate to supporting “justice” in a health care system with high uninsured patient population.

Figure 1: Schematic of IRB process for STOP CRC project

Kaiser Permanente NW IRB (co-PI: Gloria Coronado)

Cede to KPNW IRB via authorization agreement

OCHIN (co-PI: Jen DeVoe)

Group Health Research Institute (co-PI: Bev Green)

Phase 1 pilot: Virginia Garcia Memorial Health Center (n = 2 clinics)

Phase 2 trial:
- Virginia Garcia Memorial Health Center
- Sea Mar Community Health Center
- Community Health Centers – Medford
- Multnomah County Health Department
- Open Door Community Health Centers (n = 18 clinics)
## Comparison of Usual Care to STOP CRC

<table>
<thead>
<tr>
<th>Usual Care – Opportunistic screening</th>
<th>STOP CRC – Automated system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only patients who have clinic visit are offered CRC screening</td>
<td>All active patients are offered CRC screening</td>
</tr>
<tr>
<td>Most clinics are beginning to offer FIT</td>
<td>gFOBT/FITs is mailed to home</td>
</tr>
<tr>
<td>Informed decision-making possible (patient preferences)</td>
<td>Minimal opportunity for informed decision-making (patient preferences)</td>
</tr>
</tbody>
</table>
### Ethical scenarios for STOP CRC

<table>
<thead>
<tr>
<th>Scenario #1</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FIT is provided free to insured patients;</td>
</tr>
<tr>
<td></td>
<td>FIT costs $12-47 for uninsured patients</td>
</tr>
<tr>
<td>Scenario #2</td>
<td>FIT is offered to insured patients;</td>
</tr>
<tr>
<td></td>
<td>FOBT is offered to uninsured patients</td>
</tr>
</tbody>
</table>
CRC screening tests differ

- All USPSTF screening options are similarly effective with 100% adherence (high sensitivity fecal test, colonoscopy, sigmoidoscopy plus fecal testing);
- Screening options differ in cost (both patient and health system) and in adherence rates.

<table>
<thead>
<tr>
<th>Test</th>
<th>Insured patient costs</th>
<th>Uninsured patient costs</th>
<th>Medicare reimbursement</th>
<th>Adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIT</td>
<td>Free</td>
<td>$12-47</td>
<td>$23</td>
<td>Highest</td>
</tr>
<tr>
<td>gFOBT</td>
<td>Free</td>
<td>$5-12</td>
<td>$13*</td>
<td>Higher</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>Free</td>
<td>varies</td>
<td>$549-710</td>
<td>Low</td>
</tr>
</tbody>
</table>

*$4.60 per card (3 cards are standard)
CRC screening rates are highest if patients offered fecal testing or choice

Inadomi et al. 2012
CRC screening rates higher with FIT vs. FOBT

- A recent systematic review of randomized trials comparing adherence of FIT and gFOBT found 6 of 7 studies reported increased adherence with FIT versus gFOBT:
  - Adherence was **11.4-16.3** percentage points higher in 6 studies
  - Adherence was **15.4-16.3** percentage points higher in studies (n = 3) that compared a 1-sample FIT to 3-sample gFOBT

*Studies that compared 1-sample FIT to 3-sample gFOBT

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Implications

• In deciding whether to undergo screening, patients might weigh various factors:
  • Costs – health care coverage and financial resources for testing or follow-up care
  • Test characteristics – ease, level of disgust
  • Awareness of the need for screening
  • Provider recommendation for screening
  • Psychosocial factors – fear, perception of pain

• How does a mailed approach to screening (where patient preference is not considered) impact the screening disparity?
# Ethical scenarios of STOP CRC

<table>
<thead>
<tr>
<th>Scenario #1</th>
<th>FIT is provided free to insured patients; FIT costs $12-47 for uninsured patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scenario #2</td>
<td>FIT is offered to insured patients; FOBT is offered to uninsured patients</td>
</tr>
</tbody>
</table>
## Scenario #1: What would **YOU** do?

<table>
<thead>
<tr>
<th>Options*</th>
<th>Assumption</th>
<th>Advantages</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Do nothing – bill uninsured patients</td>
<td>Price attractive enough to get some screened; though cost is still a problem.</td>
<td>Some uninsured will complete mailed test; consistent with usual care at some sites</td>
<td>Structural barriers assures lower rate in uninsured; may widen disparity.</td>
</tr>
<tr>
<td>B: Require clinics/labs to cover cost of FIT processing for the uninsured</td>
<td>If the test is free, no tradeoff made between cost and adherence.</td>
<td>Removes cost as a barrier for uninsured – more “just”.</td>
<td>Might overemphasize the importance of patient cost; clinic burden may be high; may be unsustainable</td>
</tr>
</tbody>
</table>

*All options could allow the patient to call the clinics to receive an alternate test.*
## Ethical scenarios of STOP CRC

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<th>Scenario #1</th>
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</tr>
<tr>
<td>Scenario #2</td>
<td>FIT is offered to insured patients; FOBT is offered to uninsured patients</td>
</tr>
</tbody>
</table>
Scenario #2: What would **YOU** do?

<table>
<thead>
<tr>
<th>Options*</th>
<th>Assumption</th>
<th>Advantages</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Do nothing — Mail FITs to insured; gFOBTs to uninsured</td>
<td>Price attractive enough to get some screened; though lower adherence still a problem.</td>
<td>Some of uninsured will complete gFOBT; would not otherwise have been screened.</td>
<td>Differential adherence assures lower rate in uninsured.</td>
</tr>
<tr>
<td>B: Mail FITs to all — add cost language to materials</td>
<td>Offer the best test with greatest adherence to all; added cost may be an important deterrent.</td>
<td>Same test used for all.</td>
<td>Cost of screening is a barrier for uninsured, though price sensitivity is unknown.</td>
</tr>
<tr>
<td>C: Require clinics to cover cost of FIT processing</td>
<td>If the test is free, no tradeoff made between test type and adherence.</td>
<td>Removes cost as a barrier for uninsured – more “just”.</td>
<td>Might overemphasize the importance of patient cost; clinic burden may be high; may be unsustainable.</td>
</tr>
<tr>
<td>D: Call patients in advance of mailing to obtain preference</td>
<td>Informed choice will optimize screening response.</td>
<td>Patient preference is considered.</td>
<td>Adds costs; net benefit is unknown.</td>
</tr>
</tbody>
</table>

* All options could allow the patient to call the clinics to receive an alternate test.
How to support the “just” delivery of care in community clinics

• Can an automated home-based learning activity advance the goal of reducing health inequalities among populations? If so, how?
**Conclusion**

- STOP CRC has substantially raised rates of CRC screening in pilot project patients;
- A clinic-wide roll out to the 2 pilot clinics is planned;
- If successful, STOP CRC could screen 10,000 patients, and raise awareness among many more;
- On-going challenges relate to the reduction of structural barriers for the uninsured.