Colorectal Cancer Screening in Primary Care
A Focus on STOP CRC

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Key talking points

- Direct-mail programs improve CRC screening;
- Design and preliminary findings from STOP CRC
  - STOP CRC is potentially a high-impact study
  - Recruitment of clinics into pragmatic research
  - Implementation and adaptations: Plan-Do-Study-Act cycles
- STOP CRC Reach
- Conclusion
Screening Options for CRC

- Screening saves lives, several recommended colon cancer screening tests
- Fecal testing is an important component of a colon screening program
  - Patients prefer it
  - Less expensive
  - Can find high-risk patients
- Colonoscopy is (still) important; choice is important

<table>
<thead>
<tr>
<th>Screening test</th>
<th>Mortality reduction*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colonoscopy every 10 years</td>
<td>65%</td>
</tr>
<tr>
<td>FIT every year</td>
<td>64%</td>
</tr>
<tr>
<td>Flex sigmoidoscopy every 5 years</td>
<td>59%</td>
</tr>
<tr>
<td>Flex sigmoidoscopy every 5 years plus FIT every 3 years</td>
<td>66%</td>
</tr>
</tbody>
</table>
**Promising Interventions in Vulnerable Populations (N = 27)**

<table>
<thead>
<tr>
<th>Intervention Classification</th>
<th>N studies</th>
<th>Does Intervention Improve FOBT/FIT Screening?</th>
<th>Strength of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Mail</td>
<td>9</td>
<td>Yes</td>
<td>High</td>
</tr>
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<td>2</td>
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<td>Clinic processes</td>
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</tr>
<tr>
<td>Patient Navigator</td>
<td>2</td>
<td>Yes (overall screening)</td>
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</tr>
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<td>Mixed (FOBT only)</td>
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</tr>
<tr>
<td>Education at clinic visit</td>
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<td>Mixed</td>
<td>Low</td>
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<td>Education with lay health advisors</td>
<td>4</td>
<td>Unclear</td>
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</tr>
<tr>
<td>Education with media (community)</td>
<td>1</td>
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</tr>
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Davis et al. 2015 Systematic Review
Background on STOP CRC
STOP CRC aims

- **Aim 1.** Assess the effectiveness of a large-scale, three-arm CRC screening program among diverse FQHC patients.
  - Automated Strategies (Auto) plus PDSA
  - Usual care

- **Aim 2.** Assess the costs and long-term cost-effectiveness of the Auto and Auto Plus interventions, relative to usual care.

- **Secondary Aim 1:** Assess adoption, implementation, reach and potential maintenance and spread of the program (RE-AIM), using a mixed-method rapid assessment process, field notes, and other ethnographic data.

- Evaluation is guided by RE-AIM framework.
Effectiveness – Implementation hybrid designs

1. Type 1: tests effects of a clinical intervention while observing implementation

2. Type 2: dual testing of clinical and implementation interventions/strategies

3. Type 3: test an implementation strategy while observing clinical intervention’s impact

Curran, Mittman, 2015
STOP CRC Activities

What?

- Create learning collaborative
- Develop EMR tools
- Deliver Intervention
- Refine the intervention: PDSA
- Refine EMR tools
- Spread Research to Practice & Sustain

Who is involved?

- Advisory Board (clinicians, policymakers, payers)
- EMR Specialists
- CHR, Virginia Garcia, MCHD, OCHIN, EMR specialists, and clinicians.
- Clinics, OCHIN, payers
- CHR, Clinics, OCHIN
- Clinics, OCHIN network, policymakers, payers, national organizations, state CRC screening programs
STOP CRC intervention

EMR tools in Reporting Workbench, driven by Health Maintenance;
Step-wise exclusions for:
• Invalid address
• Self-reported prior screening
• Completion of CRC screening
Improvement cycle (e.g. Plan-Do-Study-Act)
Using real-time data in FQHC setting

- Real-time tools, designed in Reporting Workbench, updated daily
- Use lab, procedure and diagnoses codes, and Health Maintenance;
- Define ‘active patients’ as those with clinic visit in past year;
- Some clinics updated health record with historical colonoscopy using Medicaid claims;
- Can bulk order FIT tests for all patients on list.

Currently eligible patients

Patients newly eligible due to age, clinic visit, CRC screening

Patients newly ineligible due to age, clinic visit, CRC screening
Participating clinics*

Open Door Community Health Centers (4)
Multnomah County Health Department (6)
La Clinica del Valle (3)
Mosaic Medical (4)
Virginia Garcia Memorial Health Center (2)
Community Health Center Medford (3)
Benton County Health Department (2)
Oregon Health & Science University (OHSU) (2)
Sea Mar Community Health Centers (4; secondary analysis)

*Overall: colonoscopy screening in past 10 years: 5%;
fecal testing in past year: 7.5%
EMR tools and training videos
Promising STOP CRC pilot findings
STOP CRC Pilot showed 38% improvement

**STOP CRC Pilot results**

<table>
<thead>
<tr>
<th></th>
<th>Auto Intervention</th>
<th>Auto Plus Intervention</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>Reminder calls delivered</td>
<td>NA</td>
<td>30*</td>
</tr>
<tr>
<td><strong>FIT kits complete</strong></td>
<td>44 (39.3%)**</td>
<td>37 (36.6%)**</td>
</tr>
<tr>
<td><strong>Positive FIT result</strong></td>
<td>5 (12.5%)</td>
<td>2 (5.7%)</td>
</tr>
</tbody>
</table>
Direct-mailing reduces health disparity

Response to direct-mail program (n = 1034)
Health disparities persist in f/u colonoscopy receipt

- Based on 56 patients with positive FIT test results (27 non-Hispanic and 29 Hispanic) who received care at Virginia Garcia
STOP CRC health center recruitment

Adapted CONSORT

- Total N potential FQHCs
- FQHCs eligible (n and %)
  - FQHCs who participate (n and %)
  - FQHCs who decline (n, %, and reasons)
  - Excluded by investigator (n, %, and reason)
  - Other (n and %)
Recruiting clinics into pragmatic research

- Partnered with OCHIN
  - Health information network, spanning 18 states and serving over 4,500 physicians.
  - Provides a shared-version of Epic to small clinics
  - Can develop EMR tools

- Opportunity to assess the health center recruitment using systematic approach

- Reporting relied on criteria developed by Gaglio et al.:
  - % of sites approached that agreed to participate, characteristics of participating and nonparticipating sites, and
  - qualitative summaries of notes taken during “recruitment” meetings with leadership teams (both participating and nonparticipating).
List of 41 health centers

Eligible health centers (n = 11)

Participating health centers (n = 8)
Participating clinics (26)

Excluded due to:
- Size* = 13
- Geography** = 17

Declined = 3

* having <2 clinics with 450+ patients
** Outside of Oregon, N California or Washington
## Health center characteristics, by participation

<table>
<thead>
<tr>
<th>Participating sites</th>
<th>% Hispanic</th>
<th>% uninsured</th>
<th>% Medicaid</th>
<th>CRC screening rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Center 1</td>
<td>9</td>
<td>49</td>
<td>15</td>
<td>20</td>
</tr>
<tr>
<td>Health Center 2</td>
<td>7</td>
<td>38</td>
<td>17</td>
<td>23</td>
</tr>
<tr>
<td>Health Center 3</td>
<td>17</td>
<td>50</td>
<td>14</td>
<td>20</td>
</tr>
<tr>
<td>Health Center 4</td>
<td>14</td>
<td>33</td>
<td>37</td>
<td>39</td>
</tr>
<tr>
<td>Health Center 5</td>
<td>10</td>
<td>40</td>
<td>15</td>
<td>33</td>
</tr>
<tr>
<td>Health Center 6</td>
<td>5</td>
<td>2</td>
<td>19</td>
<td>53</td>
</tr>
<tr>
<td>Health Center 7</td>
<td>2</td>
<td>11</td>
<td>20</td>
<td>33</td>
</tr>
<tr>
<td>Health Center 8</td>
<td>36</td>
<td>37</td>
<td>26</td>
<td>34</td>
</tr>
<tr>
<td>Health Center 9</td>
<td>4</td>
<td>23</td>
<td>12</td>
<td>16</td>
</tr>
<tr>
<td>Health Center 10</td>
<td>37</td>
<td>30</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>Health Center 11</td>
<td>15</td>
<td>30</td>
<td>16</td>
<td>14</td>
</tr>
</tbody>
</table>

Coronado et al. 2015
## Reasons for participation & non-participation

### Participation

<table>
<thead>
<tr>
<th>CFIR* construct</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>External context</strong></td>
<td></td>
</tr>
<tr>
<td>- Colorectal cancer screening is a high priority</td>
<td></td>
</tr>
<tr>
<td><strong>Internal setting</strong></td>
<td></td>
</tr>
<tr>
<td>- Program will provide support for needed change</td>
<td></td>
</tr>
<tr>
<td>- Program can catalyze additional change</td>
<td></td>
</tr>
<tr>
<td><strong>Intervention attributes</strong></td>
<td></td>
</tr>
<tr>
<td>- Clinics are offered choice and flexibility</td>
<td></td>
</tr>
<tr>
<td>- Success of pilot demonstrates credibility and supports efficacy</td>
<td></td>
</tr>
</tbody>
</table>

### Non-participation

<table>
<thead>
<tr>
<th>CFIR* construct</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>External context</strong></td>
<td></td>
</tr>
<tr>
<td>- Concerns about the cost of testing or follow-up care for uninsured patients</td>
<td></td>
</tr>
<tr>
<td><strong>Internal setting</strong></td>
<td></td>
</tr>
<tr>
<td>- Concerns about clinic capacity</td>
<td></td>
</tr>
<tr>
<td>- Competing priorities</td>
<td></td>
</tr>
<tr>
<td><strong>Intervention attributes</strong></td>
<td></td>
</tr>
<tr>
<td>- Concerns with randomization of clinics</td>
<td></td>
</tr>
<tr>
<td>- Direct-mail program may not work -- “our patients are different”</td>
<td></td>
</tr>
</tbody>
</table>

*Consolidated Framework for Implementation Research*
Plan-Do-Study-Act Cycles were important

STOP CRC IMPLEMENTATION
## STOP CRC Implementation

<table>
<thead>
<tr>
<th>STOP CRC clinics (n = 26)</th>
<th>Patients ever eligible (n)</th>
<th>Mailed FIT (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Center 1</td>
<td>859</td>
<td>65.3</td>
</tr>
<tr>
<td>Health Center 2</td>
<td>1921</td>
<td>17.2</td>
</tr>
<tr>
<td>Health Center 3</td>
<td>2751</td>
<td>33.5</td>
</tr>
<tr>
<td>Health Center 4</td>
<td>7640</td>
<td>47.1</td>
</tr>
<tr>
<td>Health Center 5</td>
<td>1971</td>
<td>21.7</td>
</tr>
<tr>
<td>Health Center 6</td>
<td>6748</td>
<td>23.1</td>
</tr>
<tr>
<td>Health Center 7</td>
<td>3375</td>
<td>19.7</td>
</tr>
<tr>
<td>Health Center 8</td>
<td>2487</td>
<td>36.1</td>
</tr>
</tbody>
</table>

Based on data from 2-years of STOP CRC
Process Improvement: Plan –Do –Study –Act

1. Plan
   - Plan the intervention

2. Do
   - Try the intervention on a small scale

3. Study
   - Refine the intervention
   - Prepare for further implementation
   - Study the results

4. Act
   - Plan the intervention
   - Try the intervention on a small scale
Plan-Do-Study-Act (PDSA) Approach in Pragmatic Research with Health Systems

- Describe the process of using PDSAs in STOP CRC, the PDSA topics selected by clinic leaders, and reactions to using a PDSA cycle/process (qualitative)

- PDSA plans fell into three main categories:
  - **Improve staffing needs and workflow of the intervention.** (3 health systems)
  - **Increase rate of FIT kits returned by patients.** (4 health systems)
  - **Increase usability of FIT kits returned.** (1 health system)
FIT samples can be improperly collected

Improperly collected FIT tests: Plan-Do-Study-Act Cycle

Data source: Multnomah County Health Department
Dear Client,

There is a simple test that can find signs of colon cancer before you have symptoms. This test can be done at home and can save your life. You will get this test if you are between the ages of 50 and 74 and have not had a colonoscopy in the past 9 years.

Here is your home FIT test. Do the test at home and send it back to us. The test will look at all the health of your colon to see if there is any blood in your poop. Finding these warning signs early gives you the best chance for successful treatment.

For the test:

- Start with a clean, empty toilet. Flush it once before you start. Make sure there are no cleaning products in the toilet water.
- Use 2 different poop samples; 1 for slot A and a different 1 for slot B.
- Write the date on the checker at the time you do each test.
- Send back the test in the pre-paid yellow envelope in 3 days after finishing the test.

If you have any questions, please call your care team at 503-988-5558.

Thank you,

Marty Grasmader, MD
Medical Director
MULTONOMAH COUNTY HEALTH DEPARTMENT #503-988-5558
Action taken: Added Reminder with Instruction

- Don’t forget to put the date you collected your poop sample
- No olvide poner la fecha en la que recolectó la muestra de popó.
- 別忘了填寫您採集大便樣本的日期。
- Не забудьте указать дату, когда вы собрали анализ кала
PDSA feedback

“But the [PDSA] process itself, we kind of do that organically already without calling it a PDSA. So now it’s nice to have a form and a template that we can work by so that we can get feedback... and come up with questions like what about if we did this or who’s going to do that. So it’s good to have that template to work from.”

– Quality Improvement manager
PDSA Method Conclusions

- Gave research team insight into the implementation challenges (i.e., refining the staffing model and workflow)
- Help clinics deal with complex implementation
  - Trialability
  - Adapting interventions that leverage EHRs
- Clinical staff had positive reactions to the use of PDSA cycles
  - Helped engage the clinics more fully in research
  - Helped focus on planning needed to implement/refine intervention
- Limitations
  - Want better systems for tracking PDSA outcomes
  - PDSAs are typically iterative and our study was single test of change
STOP CRC Reach

- Reach is a patient-level measure

- “Patient Willingness to Participate in a Study”* - Will the individual sign up for the study? Will the individual participate in the program that is offered? What is the representativeness of those participating?

- This definition has limitations in pragmatic trials, particularly cluster trials like STOP
  - Consent was waived – theoretically almost all age eligible patients would receive the intervention whether they were willing to participate or not
  - Minimal exclusions (end-stage renal failure)
  - People could not opt out

*http://re-aim.org/about/what-is-re-aim/reach/
However not everyone age eligible for screening received the intervention

- Lack of ‘reach’ was related to cohort definitions (eligible population)
  - Community clinics define their patient’s as individuals with a clinic visit in the prior 12 months (health plans define patients based on enrollment).

- Epic upgrade – delayed all clinics’ start-up by 4 months.
  - Many patients on the original list (date of randomization of clinics) fell off the list because there last visit was >12 months.
  - Clinics would not see these patients on their list.

- Lack of ‘reach’ was also related to delays in and lack of clinic implementation

- These patients likely were still needing CRC screening but were not reached

- How do we take these factors into account?
Is willingness to participate a good measure of reach?

Reach = Percent Reached

<table>
<thead>
<tr>
<th>Reason Not Reached</th>
<th>Percent of People</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>No or bad address</td>
<td>5%</td>
<td>95% Reach</td>
</tr>
<tr>
<td>Not on clinic list</td>
<td>14%</td>
<td>81% Reach</td>
</tr>
<tr>
<td>Clinics did not mail kit</td>
<td>35-80%</td>
<td>20-65% Reach</td>
</tr>
<tr>
<td>Individuals willing to participate (return FIT)</td>
<td>In Process</td>
<td>Effectiveness as Practiced</td>
</tr>
<tr>
<td>Effectiveness % completing based on everyone targeted</td>
<td>In Process</td>
<td>Intent to Treat Effectiveness</td>
</tr>
</tbody>
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“Patient Willingness to Participate in a Study”*

- The classic definition of REACH (willingness to participate) does not work well for STOP CRC.

- Grey area between reach and implementation – what to do about patients who were removed by system delays?

- These issues will be important in the interpretation of STOP CRC results (Does the intervention work if it is delivered, and for whom? Why was it not delivered? Reasons for variation among clusters? What are the next steps?)
On-going STOP CRC activities

- Primary outcome analysis
- Provider survey analysis
- Qualitative interviews with patients who had a positive FIT test
- Chart abstraction to assess rates of colon cancer, adenomas
- Cost and cost-effectiveness analysis
Dissemination to OCHIN-affiliated clinics and beyond

STOP CRC SPREAD
STOP CRC Spread

- **STOP CRC tools:**

<table>
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<tbody>
<tr>
<td>Reporting Workbench, customized for CRC screening</td>
</tr>
<tr>
<td>Batch communication (mailing)</td>
</tr>
<tr>
<td>Bulk ordering</td>
</tr>
</tbody>
</table>

- **STOP CRC tool dissemination:**

<table>
<thead>
<tr>
<th>Type of health system</th>
<th>N sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinics within STOP CRC health centers</td>
<td>39 clinics</td>
</tr>
<tr>
<td>OCHIN-affiliated clinics</td>
<td>Network includes 89 health centers</td>
</tr>
<tr>
<td>Non-OCHIN-affiliated clinics</td>
<td>34 Sea Mar clinics</td>
</tr>
</tbody>
</table>
SPREAD TO SEA MAR CHC
Sea Mar Community Health Centers, a statewide non-profit organization, provides medical services in 34 clinics and centers in Washington’s Puget Sound region.

In 2015, Sea Mar provided medical services to over 250,000 patients in clinics in Western Washington. 37% of patients are Hispanic. Sea Mar uses Allscripts EMR.
Conclusion

• Direct-mail programs improve CRC screening;
• STOP CRC is a potentially high-impact study, with promising pilot findings;
• STOP CRC is a direct-mail program adapted for community clinics, and uniquely used Plan-Do-Study-Act cycles;
• Level of implementation differed by health center;
• Reach was impacted by definition of active patient.
Funding & Acknowledgements

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