Fidelity and Adaptation Case Study:
*Designing and Testing a Colorectal Cancer Screening Program
*with D&I in Mind*

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The first clinical questions (2004):

What primary care colorectal cancer screening outreach program could be

(a) effective for the targeted/unscreened population
(b) acceptable to clinical providers and staff
(c) feasible to implement with limited resources
(d) sustainable after the researchers leave
(e) adaptable and scalable for diverse settings
The first research question (2005):

In average risk adults over 50, is the time of influenza vaccination a missed opportunity to offer colorectal cancer screening with annual fecal occult blood tests?
Potential increase in CRC screening for adults 50-80 if offered with influenza vaccination (Combines CA BRFSS and SF General Hospital Data)

Presented at the SF Bay Area Clinical Research Symposium, 2006
The second research question (2006):

Can a “FLU-FOBT Program” in a flu shot clinic work?
SF General Hospital – Family Health Center
Flu is Preventable! Colon Cancer is Preventable!
• Yearly home stool tests are easy to do.
• Yearly home stool tests could save your life.
• All our doctors and nurses recommend Colon Screening for healthy men and women aged 50 to 79.
• When you should get tested? We will tell you today.

¡La Gripe es prevenible! ¡El cancer del colon es prevenible!
• Es fácil hacerse exámenes anuales de defecación.
• Los exámenes anuales de defecación le pueden salvar la vida.
• Todos nuestros doctores y enfermeras recomiendan un chequeo del colon para hombres y mujeres en buen estado de salud entre los 50 y 79 años.
• Cuando necesita ser chequeado? Nosotros se lo podemos decir hoy.

流感是可以預防的！結腸癌也是可以預防的！
每年檢查糞便一次，簡單並容易進行。
每年檢查糞便一次，可以保護您的生命。
我們的醫生及護士一致推薦，50歲至79歲的健康男仕 及女仕們，應接受結腸檢查。
你何時需要測試? 我們就今天告訴你。

Có Thể Ngừa Được Cúm!
Có Thể Ngừa Được Ung Thư Ruột Giá!
• Xét nghiệm phân hàng năm làm để đăng.
• Xét nghiệm phân hàng năm có thể cứu sinh mạng quý vị.
• Bác sĩ và y tá đề nghị làm xét nghiệm ung thư ruột gia cho những người khỏe mạnh từ 50 đến 79 tuổi.
• “Quý vị nên đi khám lúc nào? Chúng tôi sẽ cho quý vị biết hôm nay!”

Грипп можно предотвратить! Рак толстой кишки можно предотвратить!
• Проводить ежегодно анализ кала очень просто.
• Проведение анализа кала ежегодно может спасти вам жизнь.
• Обследование с целью предотвращения рака толстой кишки рекомендуется докторами всем женщинам и мужчинам в возрасте от 50 до 79 лет.
• Когда нужно сделать тест? Мы скажем Вам об этом сегодня.
Results – SFGH Flu Shot Clinic Randomized Trial

6-month outcomes

<table>
<thead>
<tr>
<th>Intent-to-treat analysis, all patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td><strong>FLU Only Arm</strong></td>
</tr>
<tr>
<td><strong>N=246</strong></td>
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<tr>
<td><strong>FLU-FOBT Arm</strong></td>
</tr>
<tr>
<td><strong>N=268</strong></td>
</tr>
<tr>
<td>CRCS Up-to-Date Before (Oct 2006)</td>
</tr>
<tr>
<td>52.9%</td>
</tr>
<tr>
<td>54.5%</td>
</tr>
<tr>
<td>CRCS Up-to-Date After (Mar 2007)</td>
</tr>
<tr>
<td>57.3%</td>
</tr>
<tr>
<td>84.3%</td>
</tr>
<tr>
<td>Change: p&lt;0.001</td>
</tr>
<tr>
<td>+4.4 points</td>
</tr>
<tr>
<td>+29.8 points</td>
</tr>
</tbody>
</table>

Odds Ratio for Unscreened Becoming Screened in Multivariate Analysis: 11.3 (5.8-22.0)

CRCS up to date: FOBT within 12 months, FSIG within 5 years or colonoscopy within 10 years

*Potter MB et al., Annals of Family Medicine, 2009.*
The next research questions (2008-2012) in pursuit of external validity:

1. Can it work with less hand-holding?
2. Can it be integrated with primary care?
3. Can it work in managed care?
4. Can it work in pharmacies?
5. Can it be sustained where it is introduced?
FLU-FOBT and FLU-FIT Projects

• San Francisco Dept of Public Health
  – CDC R18 (2008-2011) “Translation of an Evidence-Based Colorectal Cancer Screening Intervention to Primary Care Settings Where Disparities Persist”

• Kaiser Permanente Northern California
  – ACS Research Scholars Grant (2009-2012) “Colorectal Cancer Screening with FIT During Annual Flu Shot Clinics at Kaiser Permanente”

• Walgreens Pharmacies
  – Alexander and Margaret Stewart Trust (2008-2009) “A Pharmacy-Based Intervention to Increase Colorectal Cancer Screening”
One word answers to the research questions (*email if you want more complete answers!*):

1. Can it be implemented with less hand-holding? -- often

2. Can it be integrated with primary care in resource-limited community health centers? -- yes

3. Can it work in managed care? -- yes

4. Can it work in pharmacies? -- probably

5. Can it be sustained where it is introduced? -- often
FLU-FOBT publications since 2009


**Clinical Outcome:** >25,000 FOBT/FIT Kits dispensed thru our research sites from 2007-2011.
FLU-FOBT Program Components and Logic Model

**Goal:** Increase colorectal cancer screening rates by offering home FOBT to eligible patients during annual flu shot activities

**Core Functional Component:** Stating orders to allow non-physician clinic staff to offer flu shots and FOBT together to any clinic patient or health care client aged 50-75 who is seen during flu shot season.

**Target Clinical Settings:** Community health centers, pharmacies, managed care organizations, and other health care settings where flu shots are provided and where FOBT is offered for average risk colorectal cancer screening.

### Program Planning & Advertising
- Designated clinic leader for the FLU-FOBT Program
- Program leader completes formal training online
- Program leader assigns clinic staff members to participate
- Clinic staff members complete formal training
- Clinic team approves implementation work plan
- Advertise program to patients with postcards and posters

### Daily Implementation
- Daily supervision by program leader
- Trained staff offers program every day during flu shot season
- EHR used to assess FOBT eligibility when possible
- FOBT given to eligible patients before flu shot is given
- FOBT kits pre-packaged with all selected program materials to facilitate patient understanding, test completion, and return of completed tests to the laboratory.

### Tracking
- Flu shots and FOBT dispensed are recorded together and at the same time for tracking purposes

### FOBT Completion
- **FOBT not Completed**
  - Postcards and phone call reminders as needed
- **FOBT Completed**
  - FOBT kit mailed by patients to lab with addressed, stamped mailing pouch
  - Check results

### Results Follow-up
- **Normal Test Results**
  - Notify patient and primary care provider
  - Remind patient to repeat test in a year
- **Abnormal Test Results**
  - Notify patient and primary care provider
  - Arrange for follow-up appointment and colonoscopy

### Sample Program Implementation Materials
- Mailed FLU-FOBT Program announcements
- Clinic posters to advertise FLU-FOBT Program
- Algorithm for FLU-FOBT Program patient flow
- Algorithm to use EHR to assess FOBT eligibility
- Script to introduce/explain FOBT with flu shots to patients
- Visual aids to use when offering FOBT to patients

- Multilingual materials to explain why FOBT is important
- Multilingual FOBT completion instructions
- Multilingual video instructions
- Pre-addressed FOBT mailing pouches
- Pre-stamped FOBT mailing pouches
- FLU-FOBT log-sheet to record flu shots and FOBT dispensed
Beginning the Dissemination Process

See how it works in community clinics

What are FLU–FIT & FLU–FOBT Programs?

FLU–FIT and FLU–FOBT Programs allow healthcare providers to increase access to colorectal cancer screening by offering home tests to patients at the time of their annual flu shots. Successful FLU–FIT and FLU–FOBT Programs have been implemented in community health centers, in a public hospital, and in a large health maintenance organization. They have also been pilot tested in commercial pharmacies.

On this website, you will find information to develop your own successful FLU–FIT or FLU–FOBT Program.

Public Website with Sample Program Materials:  http://flufobt.org
The FLU-FIT Program is an innovative approach to increase colorectal cancer screening rates above what can typically be achieved in routine clinical practice.

In the FLU-FIT program, non-physician medical staff are provided with the training and resources to offer annual fecal immunochemical test (FIT) to patients during the time of their annual influenza vaccination (FLU).

Kaiser-specific FLU-FIT Website now posted on their national intranet
Stages in Translational Research

Exploration of New Settings

Adoption / Program Planning

Implementation Processes

Dissemination and Implementation Studies

Sustainment / Scaling Up

Effectiveness Studies

Efficacy Studies

Preintervention

adapted from Chapter 12, Figure 12-1
Dissemination and Implementation Research in Health
Remaining Questions

• Are we done yet?
  – To what extent will our program continue to diffuse into clinical practice on its own? How effective will it be?

• Where end-users might still need help
  – How to design a program that will work for them
  – How to implement to achieve optimal outcomes
  – How to sustain or scale up the program in their organization if it is initially successful

• What is the role for researchers in helping to address these questions?
Searching for Answers in the study of Fidelity and Adaptation

**Program Planning**
- Program components selected
- Implementation plan completed

**Implementation Process**
- Implementation processes adopted
- Evaluate with RE-AIM and clinical outcomes

**Sustainment/Scaling Up**
- Sustain effective processes and correct ineffective processes
- Scale up within local settings
- National dissemination

**Fidelity**
- Try to enforce evidence-based program package as conceived by developers
- Discourage deviation from research-tested form

**Adaptation**
- Try to identify/enforce core component(s)
- Adapt or select non-core components based on local resources, capabilities, and contextual considerations

Adapted from Chapter 14, Figure 14-1

*Dissemination and Implementation Research in Health*
Stages in Translational Research

Preintervention
Efficacy Studies
Effectiveness Studies
Exploration of New Settings
Adoption / Program Planning
Implementation Processes
Sustainment / Scaling Up
Dissemination and Implementation Studies

adapted from Chapter 12, Figure 12-1
Dissemination and Implementation Research in Health

Health Educ Res, 2012
J Healthcare Poor Underserved, 2011
Am J Managed Care, 2011
J Am Pharm Association, 2010
Ann Fam Med, 2009
BACR, 2006
Questions for discussion

• What does *implementation with fidelity and adaptation* look like?

• How do we best *help end-users* of evidence-based interventions to *achieve the right balance* of fidelity and adaptation?

• How would you design a research program to address these questions?
Partners in FLU-FOBT Program work

Too many collaborators to mention individuals by name...
THANK YOU!

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