

Direct mail programs work... but will health centers implement them? Findings from STOP CRC



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Key Points













- How effective is a direct-mail fecal testing program when implemented in busy community clinic practices as part of standard care?
- To report the effectiveness and level of implementation of an electronic health record (EHR)– embedded program to directly mail fecal tests to patients due for colorectal cancer screening.

Background

- The US Preventive Services Task Force recommends routine colorectal cancer screening for individuals aged 50 – 75.
- Programs that directly mail fecal tests to patients' homes have been shown to improve rates of colorectal cancer screening in various clinical settings.
 - Improvements have ranged from 6 – 40%.
- Little is known about the effectiveness of such programs when implemented in community health centers as part of standard care.

Previous direct-mail programs

Meta-Analysis of gFOBT or FIT outreach vs. usual care (n=11 studies)

| Test Offered | Study | Events/ Total | | | Risk ratio and 95%CI | | | |
|--------------|------------------|---------------|-------------|-------------|----------------------|---|---|--|
| | | Risk ratio | Mailed | Usual Care | | | | |
| FIT | Sngal 2015 | 1.98 | 1410 / 2400 | 355 / 1199 | | |  | |
| FIT | Gupta 2013 | 3.73 | 648 / 1593 | 471 / 3898 | | |  | |
| FIT | Myers2013 | 1.19 | 117 / 312 | 12 / 38 | |  | | |
| FIT | Hendren 2013 | 3.57 | 43 / 114 | 21 / 126 | | |  | |
| FIT | Levy 2013 | 4.48 | 107 / 187 | 33 / 185 | | |  | |
| FIT | Myers2007 | 1.63 | 185 / 386 | 135 / 387 | | |  | |
| FIT | | 2.10 | 2510 / 4992 | 1027 / 5833 | | |  | |
| FOBT | Green 2013 | 2.46 | 760 / 1174 | 307 / 1167 | | |  | |
| FOBT | Jean-Jacques2012 | 6.03 | 32 / 104 | 5 / 98 | | |  | |
| FOBT | Hoffman 2011 | 2.61 | 98 / 202 | 591 / 3184 | | |  | |
| FOBT | Coronado2011 | 14.40 | 44 / 168 | 3 / 165 | | |  | |
| FOBT | Goldberg 2004 | 8.14 | 24 / 59 | 3 / 60 | | |  | |
| FOBT | | 3.26 | 958 / 1707 | 909 / 4674 | | |  | |

0.01 0.1 1 10 100
Favors Usual Care Favors Intervention

Marquez E, Singh S, Gupta S. Gastroenterology, Vol. 150, Issue 4, S450; DDW 2016

Success of direct-mail programs

Kaiser Permanente Northern California

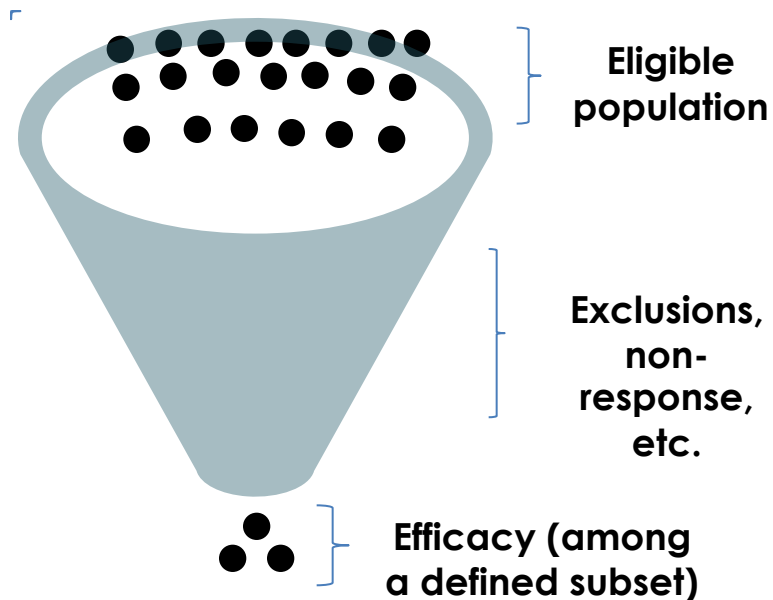
Levin TR Gastrointest Endosc. 2016
Mar;83(3):552-4.

- Over 500,000 FITs mailed annually, with >60% returned
- Major contributor to achieving screening rate over 85%

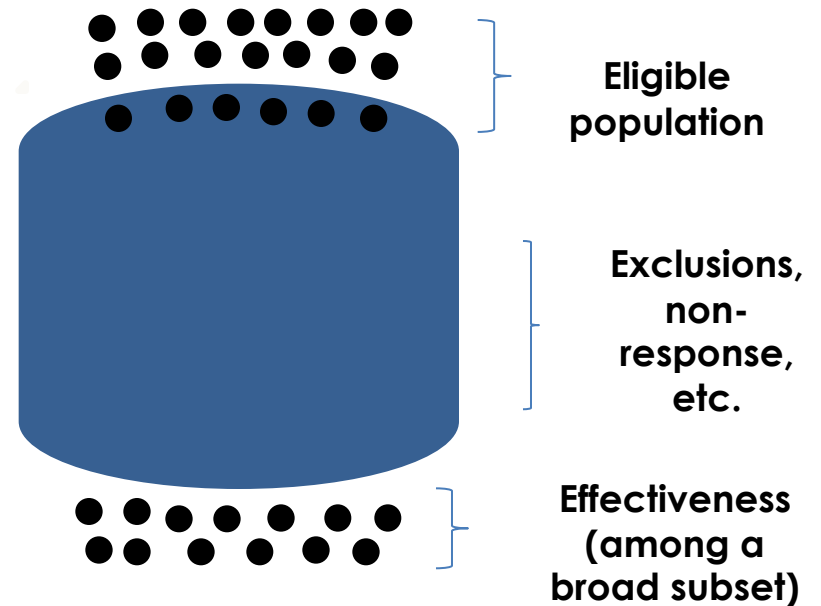


Explanatory study vs. pragmatic study

Explanatory Study



Pragmatic Study



Design, Setting, Participants

- Pragmatic cluster-randomized clinical study
 - Eligibility, 50-75, screening appropriate
 - Clinic visit in the past year
- 8 federally qualified health centers
 - 26 clinics (13 clinics randomized to each of 2 arms)
 - 41,000 patients
- Year 01 intervention interval: February 4, 2014 – February 3, 2015
- Year 01 evaluation interval: February 4, 2014 -- August 3, 2015
- Lagged data interval: June 4, 2014 – August 3, 2015

Clinic Locations

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)

*Overall: colonoscopy screening in past 10 years: 5%;
fecal testing in past year: 7.5%



Characteristics of health centers, by participation

| | % Hispanic | CRC screening rate | % uninsured | |
|-------------------|------------------|--------------------|-------------|----|
| Participating | Health Center 1 | 9 | 20 | 49 |
| | Health Center 2 | 7 | 23 | 38 |
| | Health Center 3 | 17 | 20 | 50 |
| | Health Center 4 | 14 | 39 | 33 |
| | Health Center 5 | 10 | 33 | 40 |
| | Health Center 6 | 5 | 53 | 2 |
| | Health Center 7 | 2 | 33 | 11 |
| Non-participating | Health Center 8 | 36 | 34 | 37 |
| | Health Center 9 | 4 | 16 | 23 |
| | Health Center 10 | 37 | 14 | 30 |
| | Health Center 11 | 15 | 14 | 30 |

Source: Coronado et al. 2015

STOP CRC intervention

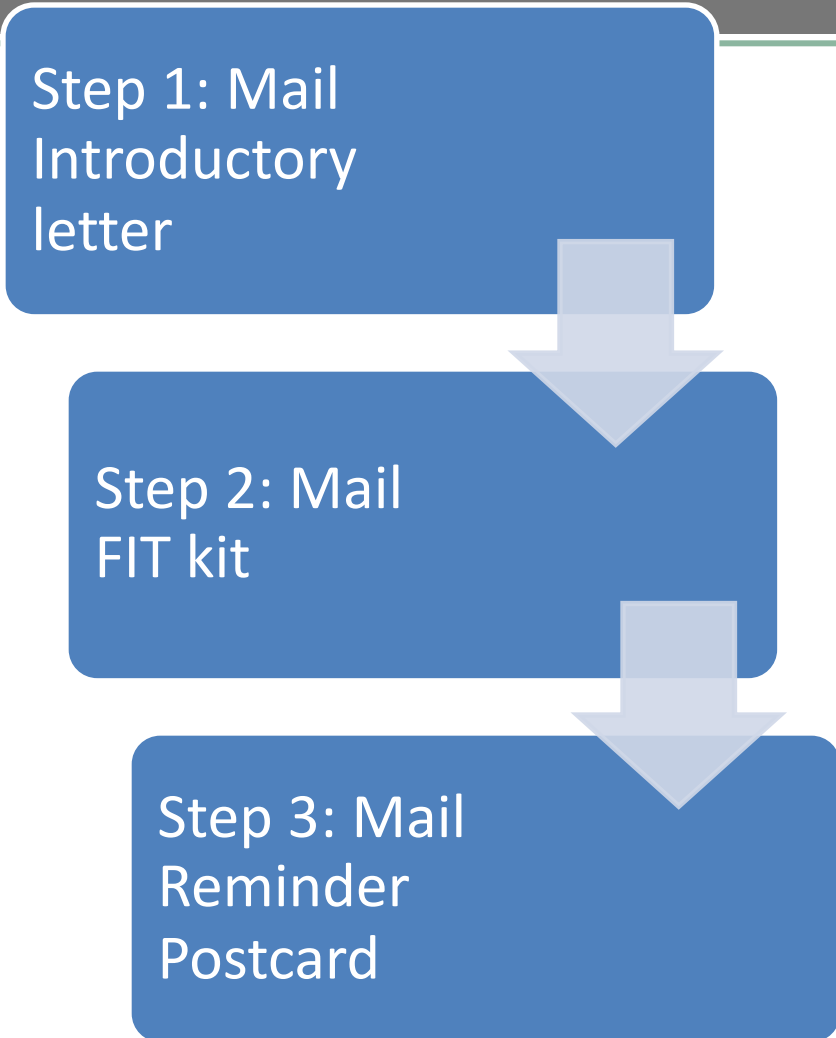
EMR tools in Reporting Workbench,
driven by Health Maintenance;

Step-wise exclusions for:

- Invalid address
- Self-reported prior screening
- Completion of CRC screening

Improvement cycle (e.g. Plan-Do-
Study-Act)

Step 1: Mail
Introductory
letter



```
graph TD; A[Step 1: Mail Introductory letter] --> B[Step 2: Mail FIT kit]; B --> C[Step 3: Mail Reminder Postcard];
```


Step 2: Mail
FIT kit



Step 3: Mail
Reminder
Postcard

Implementation support

- Real time EHR tools to identify patients eligible for each intervention step
- Training in the EHR tools
- Monthly meetings with EHR site specialists from each health center
- Leadership meeting to launch Plan-Do-Study-Act cycle
- Annual in-person meeting and quarterly webEx meetings of advisory board

Intervention materials



Dear Client,

There is an easy 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 Insure Fit test. Do the test at home and send it back to us. The test will look at 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 sticker at the time you do each test.
- Send back the test in the pre-paid yellow envelope in 3 days of finishing the test.

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

Thank you,



Marty Grasmeder, MD
Medical Director

MULTNOMAH COUNTY HEALTH DEPARTMENT #503-988-5558

Estimado(a) Cliente,

Existen análisis fáciles para encontrar señales de cáncer de colon antes de que tenga síntomas. Estos análisis pueden hacerse en casa y pueden salvar su vida. Usted recibiera este análisis si tiene entre 50 y 74 años de edad y no ha tenido una colonoscopia en los últimos 9 años.


Aquí esta su análisis Insure FIT. Haga lo en casa y devuélvanoslo. El examen verá la salud de su colon para ver si hay sangre en su popó. Encontrar estas señales de advertencia temprano le da la mejor posibilidad de un tratamiento exitoso.

Para el análisis:


- Empiece con un escusado limpio y vacío sin productos de limpieza en la agua. Jale la palanca de agua una vez antes de empezar.
- Use 2 muestras de popó diferentes. 1 para el lado A y 1 diferente para el lado B.
- Escriba la fecha en la etiqueta al momento de hacer cada lado.
- Devuelva el examen en el sobre amarillo dentro de 3 días siguientes de haber completado el análisis.


Si tiene cualquier pregunta, llame a su equipo de salud al 503-988-5558.



Gracias,



Marty Grasmeder, MD
Directora Médica





尊敬的 客戶端,

這是一個在您出現症狀前發現結腸癌徵兆的簡單測試。此測試可以在家中完成並可能挽救您的生命。如果您的年齡在 50 到 74 歲之間，並且在過去 9 年內沒有接受過結腸鏡檢查，您就可以接受該測試。


以下是您的「確保健康」測試。在家完成該測試並將其遞交給我們。本測試將查看您的結腸健康狀態，並檢視您的大便中是否有血。及早發現這些警報信號可為您提供成功治療的最佳機會。

關於測試：

- 在乾淨的空馬桶內開始測試。開始之前沖刷一次。確保馬桶水內不含任何清潔用品。
- 使用 2 個不同的大便樣本。1 個樣本用於放置在 A 槽內，另 1 個樣本用於 B 槽。
- 每次進行測試時，請在標籤上寫下日期。
- 將測試樣本於測試結束後的 3 天內裝在郵資預付的黃色信封內寄回。

如果您有任何疑問，請撥打電話 503-988-5558 聯絡您的照護團隊。

萬分感謝。



醫療副總監 Marty Grasmeder, MD

MULTNOMAH COUNTY HEALTH DEPARTMENT #503-988-5558

Уважаемый/уважаемая Клиент!

Существует очень простой тест, который может распознать признаки рака кишечника еще до появления каких-либо симптомов. Он может быть проведен в домашних условиях и может спасти вам жизнь. Вы сможете получить данный тест, если вам от 50 до 74 лет, и за последние 9 лет вы ни разу не проходили колоноскопию.


Ваш тест «Insure Fit» прилагается к данному пакету. Проведите тест дома и вышлите нам результаты. По данным результатов будет определено состояние вашего кишечника и наличие крови в вашем кале. Обнаружение этих важных признаков на ранней стадии дает вам больше шансов на успешное лечение.

Для проведения теста:


- Начните с подготовки унитаза: он должен быть пустой и чистый. Смойте его один раз перед тем, как начать. Удостоверьтесь, что вода в унитазе не содержит никаких чистящих средств.
- Используйте 2 разных образца кала. 1 для отделения «А», другой для отделения «В».
- Укажите на наклейке время проведения каждого теста.
- В течение следующих 3 дней после окончания теста вышлите его результаты в оплаченном желтом конверте.

Если у вас есть какие-либо вопросы, пожалуйста, звоните обслуживающему вас медицинскому персоналу по телефону 503-988-5558.

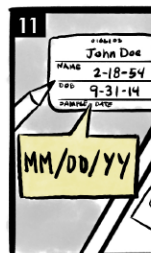
Спасибо!



Marty Grasmeder, MD
медицинского



Wordless instructions



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Funding provided by
Created by Olga

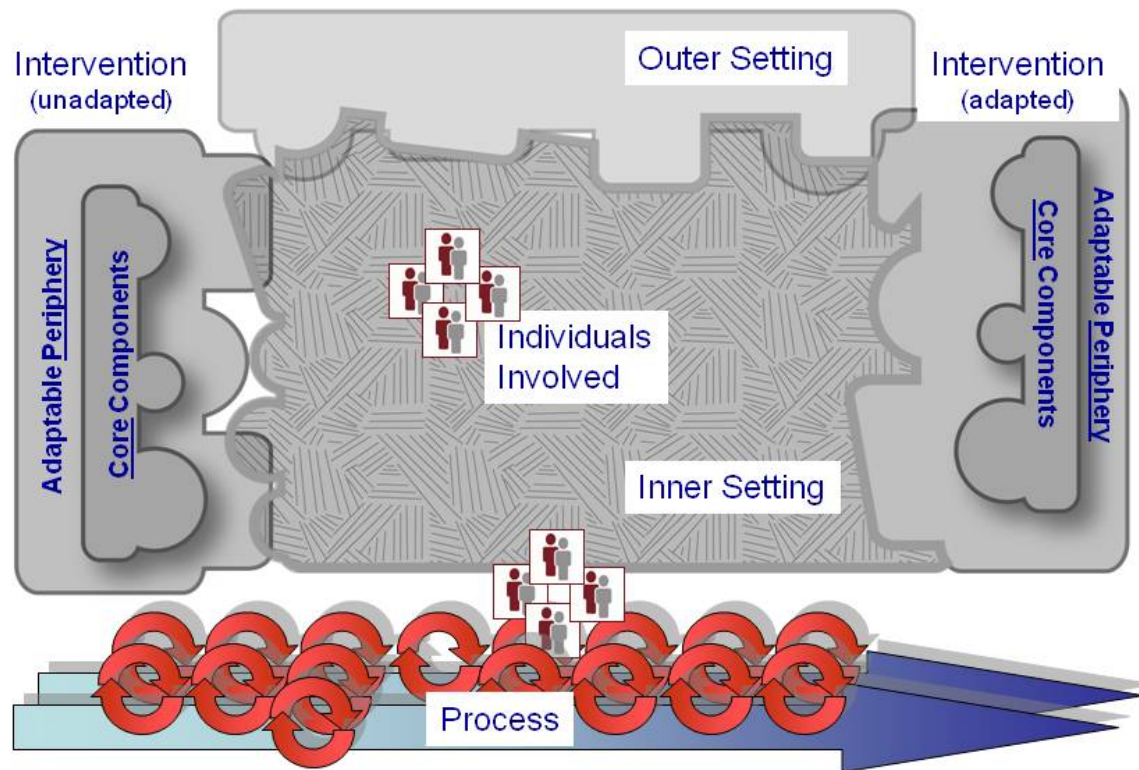


Main outcomes and measures

- **Effectiveness:** Clinic-level - proportions of adults eligible for colorectal cancer screening during the intervention interval who completed fecal testing, and secondarily any CRC screening;
- **Implementation:** Clinic-level - proportions of eligible adults who were mailed a fecal test as part of the program

Conceptual framework

Consolidated Framework for Implementation Research*



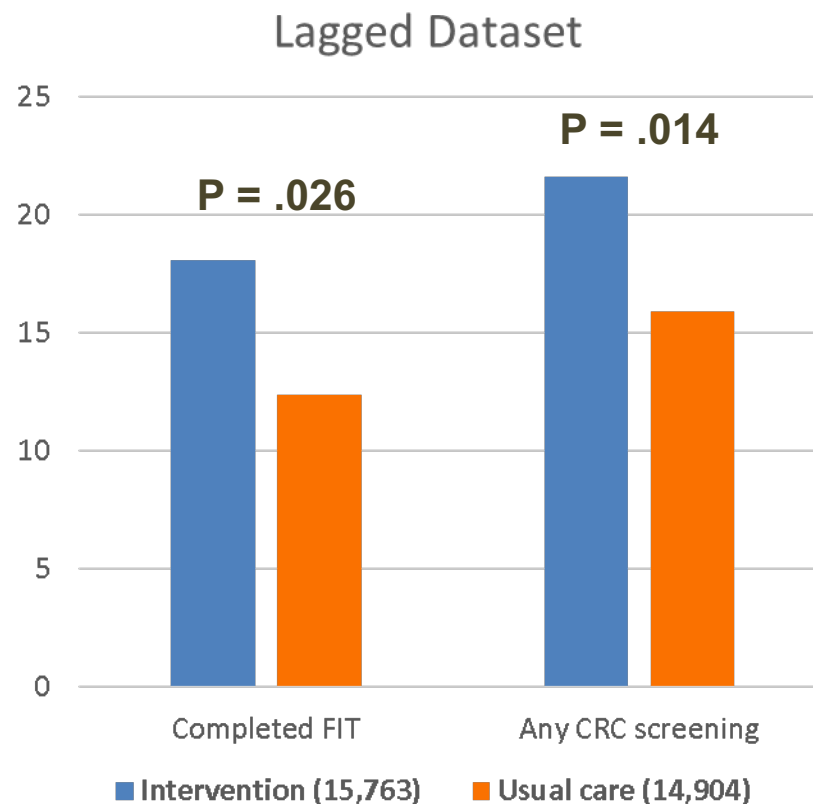
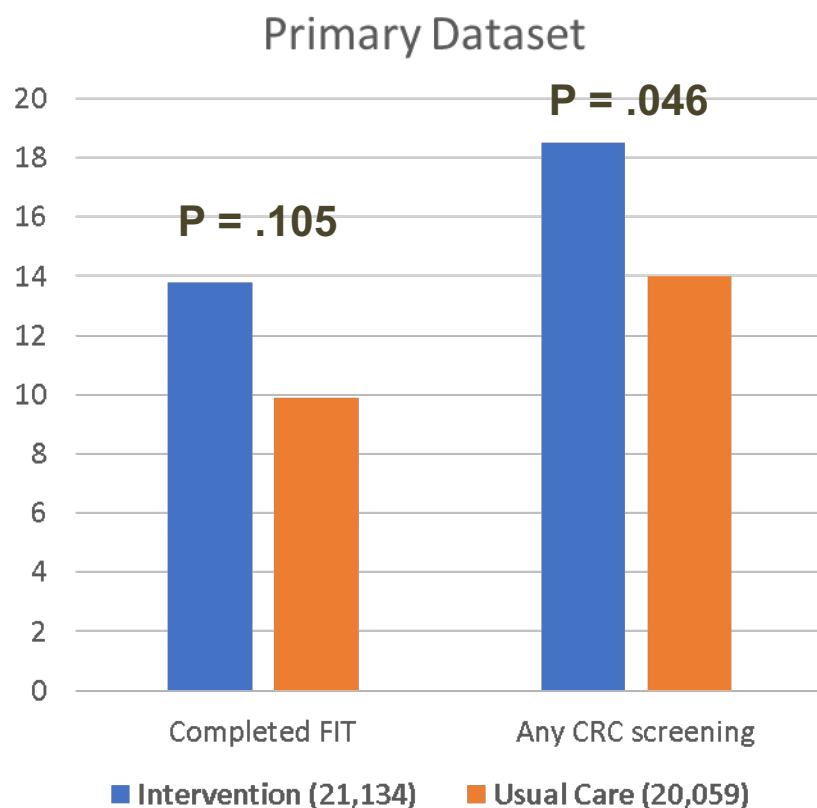
Baseline clinic-level characteristics of eligible adults in analysis sample (n = 41,193)

| | Intervention clinics | | Usual care clinics | |
|-------------------------------|------------------------------|---------|------------------------------|---------|
| | (n = 13) | | (n = 13) | |
| | Median clinic % ^a | (range) | Median clinic % ^a | (range) |
| Age (50-64) | 80 | (73-85) | 83 | (72-88) |
| Gender (Female) | 44 | (38-56) | 45 | (35-51) |
| Ethnicity (% Hispanic) | 8 | (1-33) | 15 | (2-36) |
| Language | | | | |
| English | 90 | (41-99) | 86 | (53-99) |
| Spanish | 4 | (0-26) | 12 | (1-31) |
| Other | 0 | (0-48) | 1 | (0-18) |
| Insurance status | | | | |
| Medicaid | 36 | (20-51) | 35 | (25-54) |
| Medicare | 24 | (20-37) | 23 | (15-36) |
| Uninsured | 26 | (3-40) | 27 | (2-38) |
| Commercial | 10 | (1-49) | 11 | (1-39) |
| Federal poverty level | | | | |
| <100% | 47 | (13-61) | 45 | (19-64) |
| 100-150% | 19 | (6-31) | 18 | (14-24) |
| 151 - 200% | 9 | (2-14) | 9 | (5-13) |
| 201+ | 10 | (3-26) | 10 | (2-36) |
| Unknown | 17 | (3-76) | 21 | (1-36) |

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Colorectal cancer screening completion, by intervention and usual care arm



Differences ranged from 3.8% for FIT completion in primary dataset to 5.8% for any CRC screening in lagged dataset

Per protocol analysis

| Per protocol | Return rate |
|---|-------------|
| Patients who were mailed a FIT | 21% |
| Clinics that consistently delivered reminders | 25% |
| Clinics that inconsistently delivered reminders | 14% |
| Clinics that did not deliver reminders | 6% |

FIT completion and implementation, lagged dataset

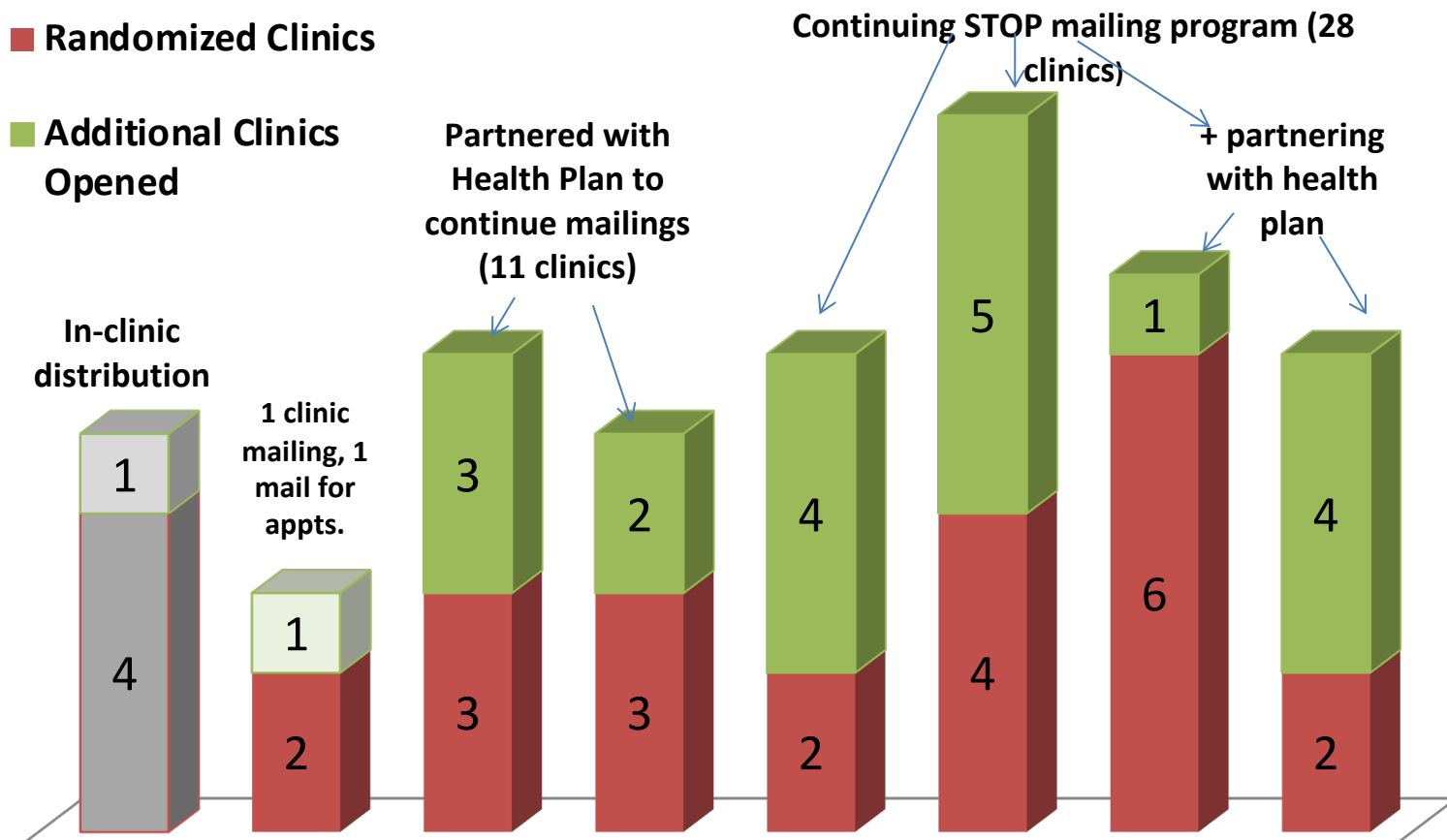
| Health Center | Differences in FIT completion* | % eligible patients mailed FIT |
|-----------------|--------------------------------|--------------------------------|
| Health Center 1 | 21.2 | 81.7 |
| Health Center 2 | 10.6 | 59.3 |
| Health Center 3 | 7.7 | 43.3 |
| Health Center 4 | 5.2 | 37.1 |
| Health Center 5 | 3.6 | 26.3 |
| Health Center 6 | -2.0 | 33.2 |
| Health Center 7 | -5.4 | 38.5 |
| Health Center 8 | -11.7 | 21.0 |
| ALL | | 42.1% |

* Comparing intervention and usual care clinics within health center

Efficacy-Effectiveness gap



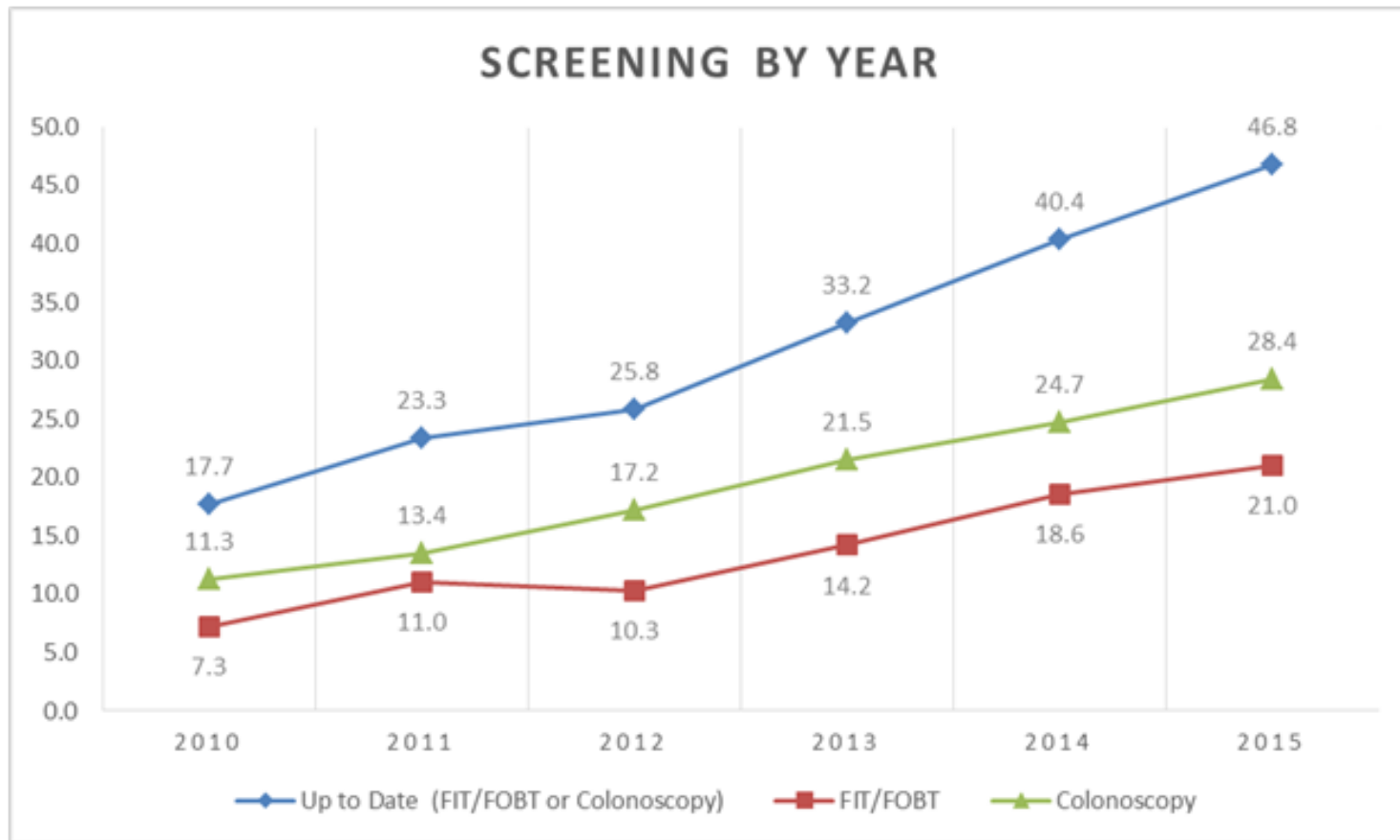
Clinic Maintenance by Health System



Maintenance

- N clinic randomized in STOP CRC: 26
- N clinics delivered STOP CRC in Year 2 (and beyond: 41 (22 randomized, 19 non-randomized))

Trends in CRC screening



Conclusion

- Implementing mailed FIT outreach can increase screening rates in "real world settings."
- Findings confirm the major challenge of bridging the gap between efficacy studies and effectiveness studies.
- Given variation in clinics in the timing and extent of intervention delivery, this work offers the potential to understand more deeply the clinic level factors that facilitate and challenge successful implementation.

A man with short brown hair, wearing a yellow t-shirt and blue shorts, is kneeling in a garden. He is wearing blue and white striped gardening gloves and is holding a small green seedling with both hands. A young child with curly blonde hair, wearing a green long-sleeved shirt, is sitting on the ground next to him, also holding the seedling. They are both looking down at the plant. The garden bed is filled with dark brown soil. In the background, there are other garden beds, a wooden fence, and some trees. The text "Future Growth" is written in a bold, dark blue font in the upper right corner of the image.

**Future
Growth**

Implementation Analysis

Data Sources:

- EHR data (mailings, phone calls, diagnoses, procedures, NQF, etc.)
- Cost data provided by clinics included program compliance and fidelity questions
- Survey's, staff and leadership interviews at baseline and follow-up
- Project participation data from meetings, EPIC Jira tickets, logs for technical assistance, and training sessions

Did They Do It?

Implementation of Key Components of the Intervention

| Health Center | Mailed FIT to Eligible Patients (%) | Also Mailed Reminder Letters (Yes/No) | Net Increase FIT Compared to Control Clinic (%) |
|---------------|-------------------------------------|---------------------------------------|---|
| 1 | 81.7% | Yes | 21.2% |
| 2 | 59.3% | Yes | 10.6% |
| 4 | 42.1% | No | 7.7% |
| 3 | 43.3% | No | 5.2% |
| 6 | 26.3% | Yes | 3.6% |
| 7 | 33.2% | No | -2.0% |
| 8 | 38.5% | No | -5.4% |
| 5 | 37.1% | No | -11.7% |

Factors Influencing Implementation (Inner Setting)

| Health Center | Lab Issues | EHR Meeting Participation | Loss of Key Providers/ Staff | PDSA Type | Planning Additional PDSA | Net Increase FIT Uptake (%) |
|---------------|------------|---------------------------|------------------------------|---------------------|--------------------------|-----------------------------|
| 1 | No | 73% | Somewhat | Phone Call | No | 21.2% |
| 2 | No | 73% | Yes | Date on Label | No | 10.6% |
| 4 | No | 60% | No | Mail Prior to Visit | Yes | 7.7% |
| 3 | No | 60% | No | Intro letter or not | Yes | 5.2% |
| 6 | No | 80% | Yes | Work Flow | Yes | 3.6% |
| 7 | No | 40% | Yes | Work Flow | No | -2.0% |
| 8 | Challenges | 27% | Yes | Pre-visit Planning | Yes | -5.4% |
| 5 | Challenges | 53% | Yes | Mail Return | No | -11.7% |

Factors Influencing Patient Completion

| Health Center | Reminder Letter | Number FIT Samples | Patient Mail/Clinic Drop off | Net Increase FIT Uptake (%) |
|---------------|-----------------|--------------------|------------------------------|-----------------------------|
| 1 | Yes | 1 | Mail | 21.2% |
| 2 | Yes | 2 | Mail | 10.6% |
| 4 | No | 1 | Mail | 7.7% |
| 3 | No | 1 | Mail | 5.2% |
| 6 | Yes | 1 | Clinic | 3.6% |
| 7 | No | 1 | Mail | -2.0% |
| 8 | No | 2 | Mail | -5.4% |
| 5 | No | 2 | Clinic | -11.7% |

Research Team

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