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



Gloria D Coronado, PhD Beverly B Green, MD, MPH



Key Question

- 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.



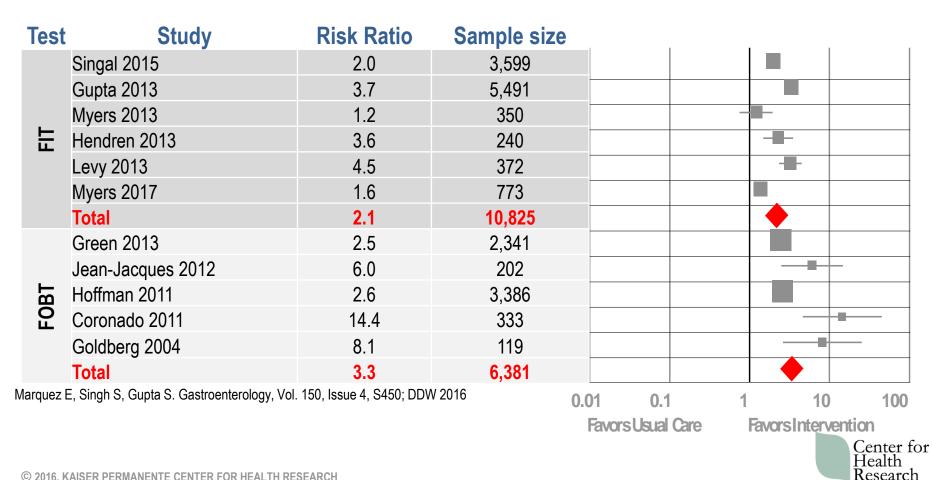
Background

- 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 11 studies



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%

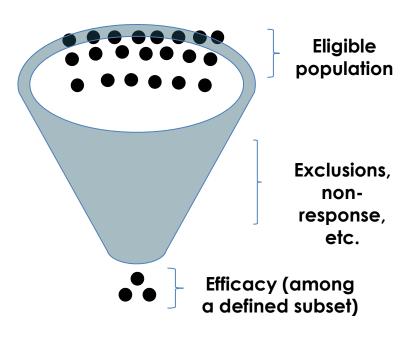




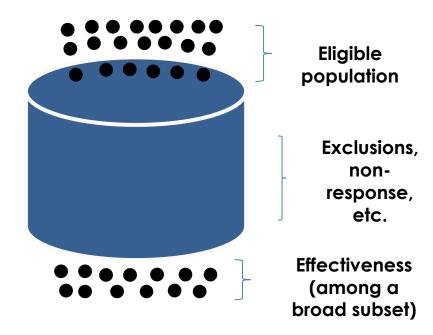


Explanatory study vs. pragmatic study

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
	Health Center 1	9	20	49
	Health Center 2	7	23	38
ating	Health Center 3	17	20	50
Participating	Health Center 4	14	39	33
Part	Health Center 5	10	33	40
	Health Center 6	5	53	2
	Health Center 7	2	33	11
D	Health Center 8	36	34	37
atin	Health Center 9	4	16	23
ricip	Health Center 10	37	14	30
Non-participating	Health Center 11	15	14	30
j	Source: Coronado et al. 20	15		Center

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

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 (4-hours)
- Monthly meetings with EHR site specialists from each health center
- Leadership meetings 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 8.
- 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 stop screen in prevent colon concer



Estimado(a) Cliente,

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

Aquí esta su análisis Insure RIT. Haga lo en casa y devuelvanoslo. 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
 a
- Escriba la fecha en la efiqueta al momento de hacer cada lado.
- Devuelva el examen en el sobre amarillo dentro de 3 días siguientes de haber completado el análisis.

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

Gracias,



Marty Grasmeder, MD Directora Médica

MULTNOMAH COUNTY HEALTH DEPARTMENT #503-988-5558



尊貴的 客户端。

這是一個在您出現症狀態提前發現結腸循微系的鞭單 測試。此期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,並且在總去9 年內沒有接受總結腸機檢查,您就可以接受該測試。

以下是您的「確保健康」測試。在客完成級測試並將 其機交給我們。本測試將客當您的結構健康狀態。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。

解於30成:

- 在乾淨的空馬桶內開始測試。開始之前沖劃一次。確保馬桶水內不合任何清潔用品。
- 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 8 槽。
- 每次進行測試時,請在標業上寫下目期。
- 將測驗樣本於測驗結束後的3
 天內裝在郵資預付的黃色信封內等回。

如果您存有任何疑問。請撥打電話 503-988-5558 聯絡您的閱購票隊

萬分城湖:



醫療訓練影Marty Grasmeder, MD





Уважаемый/уважаемая Клиент!

Существует очень простой тест, который может распознать признаки рако кишенняка еще до повъления какик-либо симптомов. Он может быть проведен в домащник условики и может спастн вам хиснь. Вы сможете получить данный тест, если вам от 50 до 74 лет, и за последние 9 лет вы ни разу не проходили колоноскотью.

Ваш тест кіпкигея примагается к данному пакету. Проведите тест дома и вышмите нам резумататы. По данным резумататам будет определено состовние вашието кициновкий и налиние крови в вашем кале. Обнаружение этих важных признаков на ранней стадин дает вам больше шансов на успешное личение.

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 никазих чистящих средств.
- Используйте 2 разных образца кала. 1 для отделення кАх. другой для отделення кВх.
- Укажите на наклейке время проведения кажеми теста.
- В течение следующих 3 дней после окончания теста вышлите его результаты в оплаченном желтом конверте.

Если у вас есть какне-либо вопросы, пожалуйста, звоните обслуживающему вас медицинскому персоналу по телефону\$03-988-5558

Спасибо!



Marty Grasmeder, MD медицинского

MULTNOMAH COUNTY HEALTH DEPARTMENT #503-988-5558

Wordless instructions







9 Poop Two Popó Dos Второй образец кала 大便二









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Coronado et al. 2014



Main outcomes and measures

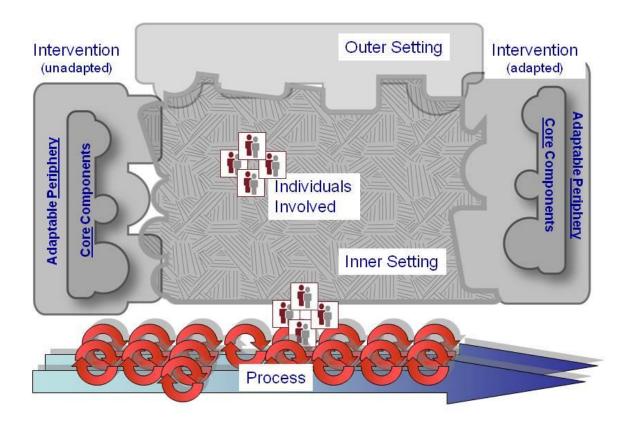
 Effectiveness: Clinic-level - proportions of adults eligible for colorectal cancer screening during the intervention interval who completed fecal testing, and secondarily any CRC screening;

 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*





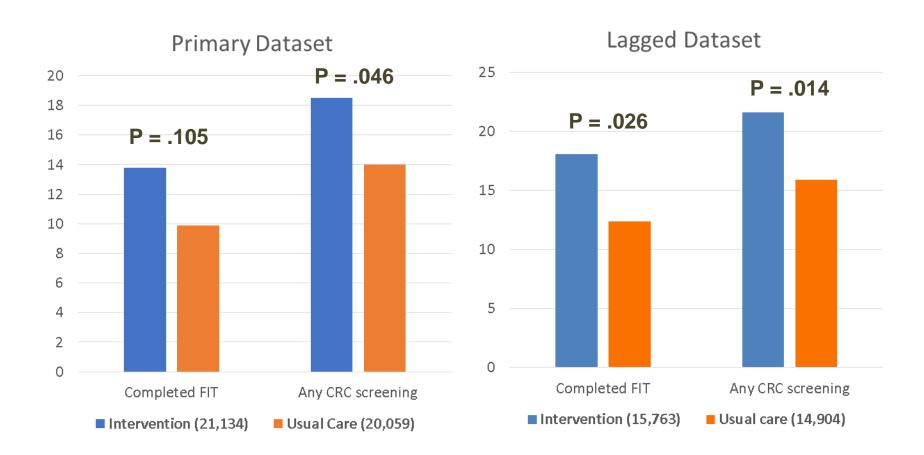
Baseline clinic-level characteristics of eligible adults in analysis sample (n = 41,193)

	Intervention clinics		Usual care clinics	
	(n = 13)		(n = 13)	
			Median clinic %	
	Median clinic % a	(range)	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)
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)

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Colorectal cancer screening completion, by intervention and usual care arm



FIT completion differences were 3.8% in primary dataset and 5.6% in lagged dataset, adjusted for health center, age, and gender



Per-protocol analysis

Per-protocol analysis	FIT return rate	
Patients who were mailed a FIT (OVERALL)	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	4.8	42.1

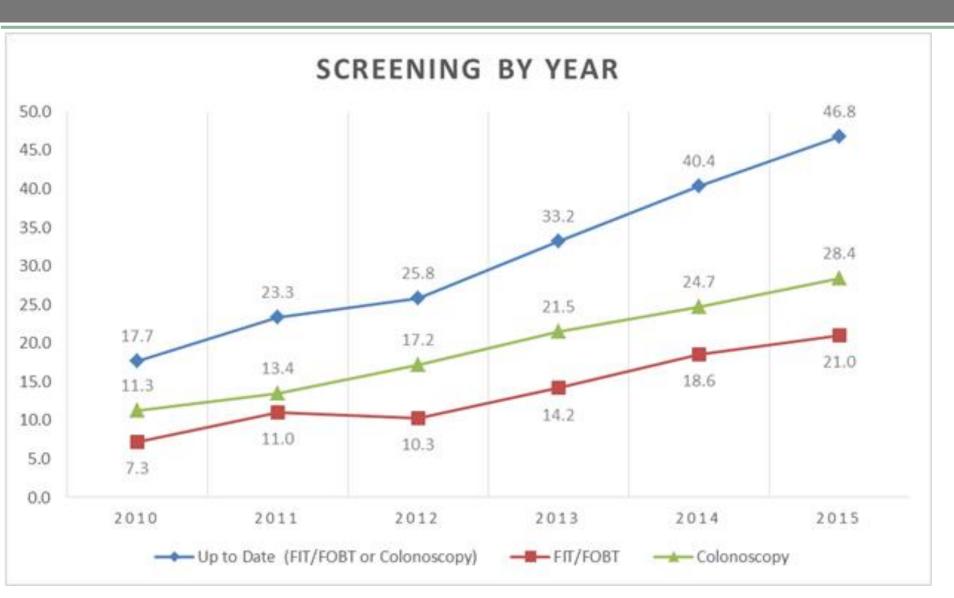
^{*}Comparing intervention and usual care clinics within health center; unadjusted primary dataset correlation = .89; lagged dataset correlation = .87



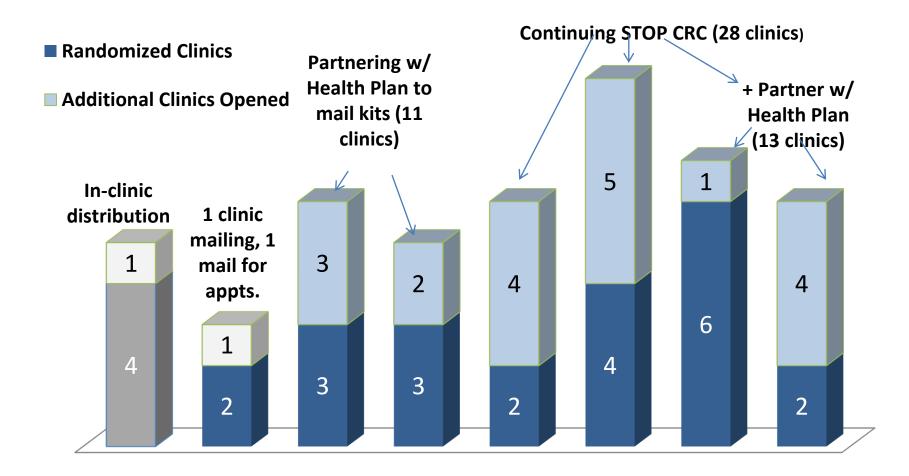
Efficacy-Effectiveness gap



Trends in CRC screening



STOP CRC Maintenance, by Health Center





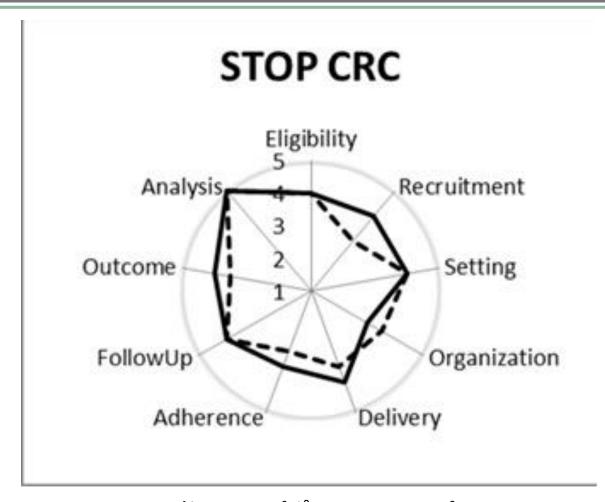
Maintenance

N clinic randomized in STOP CRC: 26

 N clinics delivered STOP CRC in Year 2 (and beyond: 41 (22 randomized, 19 nonrandomized)



Implementation STOP CRC Precis Diagram



Flexibility of intervention delivery:

Dashed line: UH2

Solid line: UH3

Authors: Karin E. Johnson^{1*}, Gila Neta^{2a*§}, Laura M. Dember³, Gloria D. Coronado^{4a}

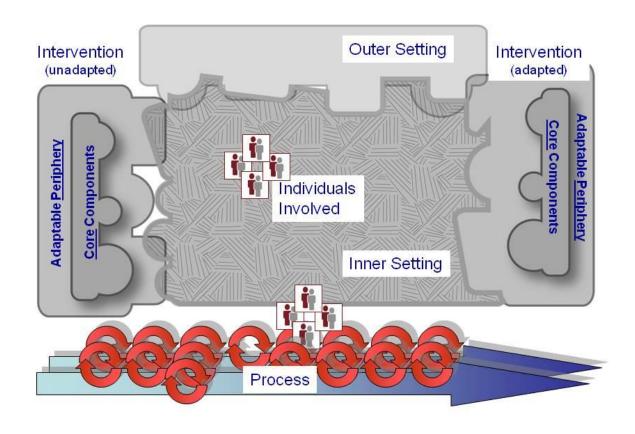
Use of PRECIS Ratings in the NIH Healthcare Systems Research Collaboratory; Trials 2016

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Conceptual framework

Consolidated Framework for Implementation Research*





Implementation Analysis Guided by the CFIR Framework

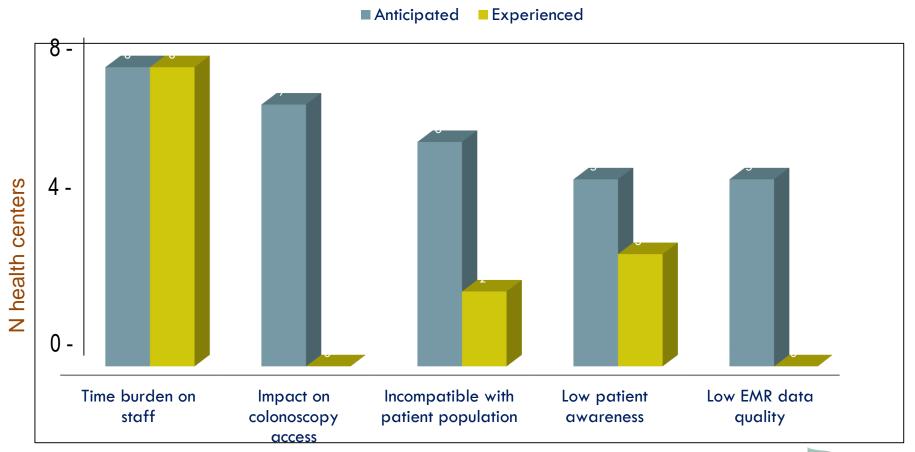
Data Sources:

- EHR data (mailings, phone calls)
- Staff and leadership surveys and interviews at baseline and follow-up
- Cost data provided by clinics included questions about implementation processes (e.g. project staff)
- Project participation data from training sessions, EHR specialist meetings



Primary challenge to implementation

Challenges to Direct-Mail Fecal Testing Program





Did they do it? Implementation of key components

Health Center	Mailed FIT (%)	Mailed FIT plus Reminder Letters (Yes/No)	Difference in FIT completion (%)
1	59.3	Y	21.2
2	43.3	Y	10.6
3	37.1	N	7.7
4	26.3	N	5.2
5	33.2	Y	3.6
6	38.5	N	-2.0
7	21.0	N	-5.4
8	42.1	N	-11.7



Factors influencing implementation

Health Center	Lab issues	EMR meeting attendance (%)	Loss of key staff	Plan additional PDSAs	Difference in FIT completion (%)
1	N	73	SOMEWHAT	N	21.2
2	N	73	Υ	N	10.6
3	N	60	N	Υ	7.7
4	N	60	N	Y	5.2
5	N	80	Υ	Y	3.6
6	N	40	Υ	N	-2.0
7	Y	27	Υ	Y	-5.4
8	Y	53	Υ	N	-11.7



Factors influencing patient completion

Health Center	FIT samples (1 vs. 2)	Mailed return vs. drop off	Difference in FIT completion (%)
1*	1	Mail	21.2
2	2	Mail	10.6
3	1	Mail	7.7
4	1	Mail	5.2
5	1	Drop off	3.6
6	1	Mail	-2.0
7	2	Mail	-5.4
8	2	Drop off	-11.7

^{*} PDSA included phone reminders



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.





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