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## Effectiveness and implementation of a colorectal cancer screening program



**Kaiser Permanente Center for Health Research**

# Presentation outline

The need for more research in safety net settings

Unique aspects of safety net practices

How my research practice-based began: Sea Mar Community Health Centers

How it expanded: STOP Colon Cancer

How it is being sustained: BENEFIT

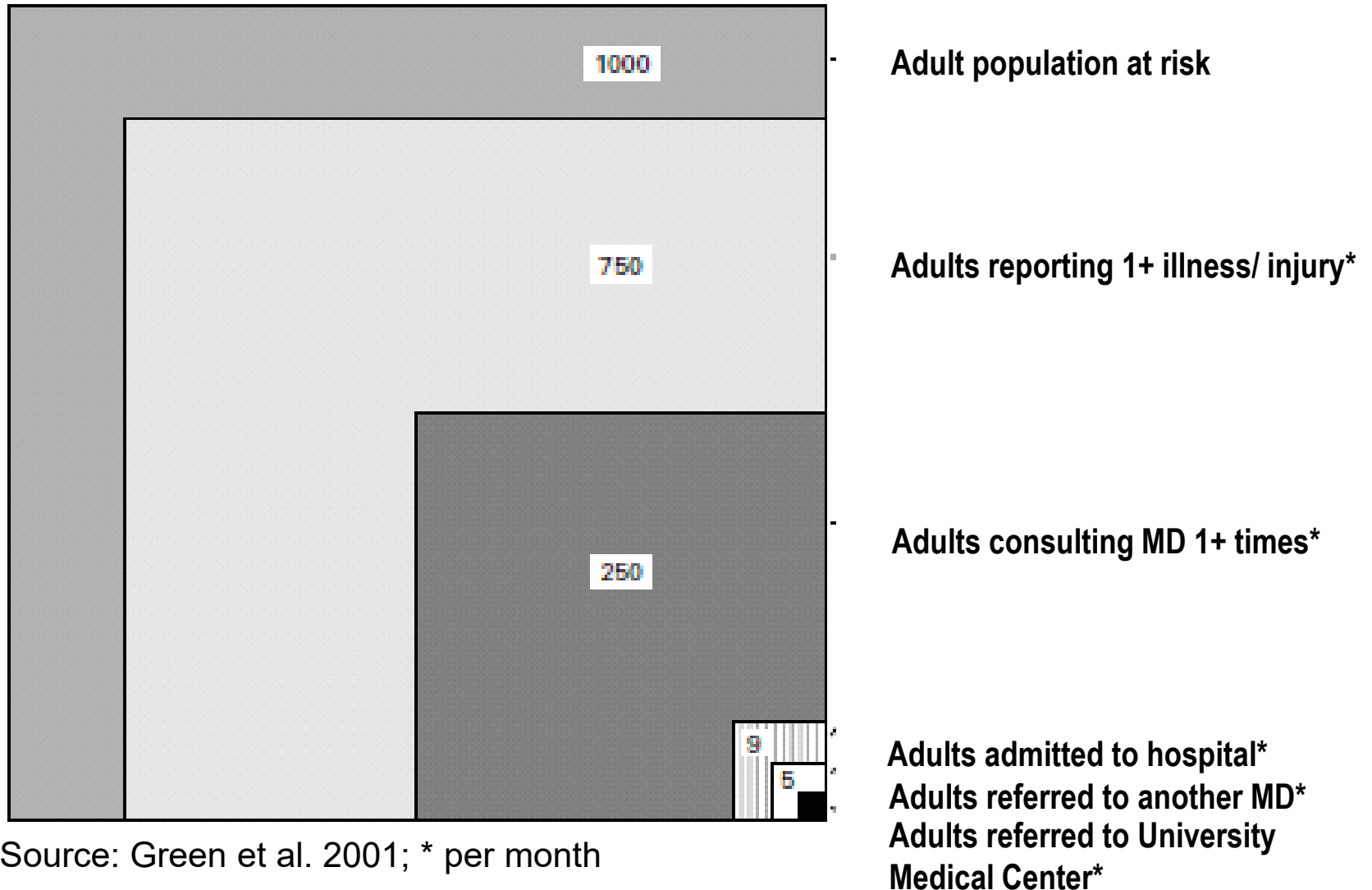
What's next?

# Topic 1

## The need for more research in safety net practices

- Most research is conducted in academic medical centers
- Patients in academic medical center do not represent the community at large
- Safety net - practice data are needed to inform patient care and policy

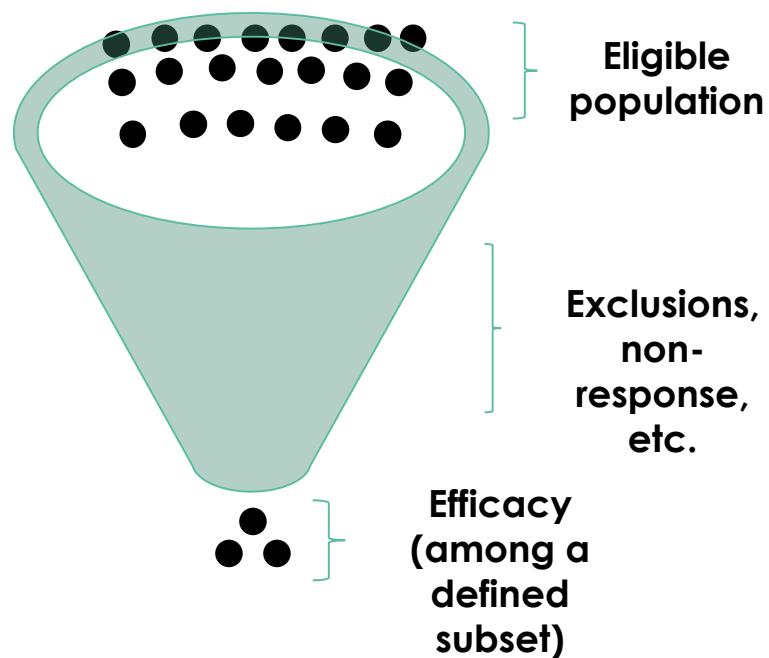
# Community poorly represented in most research



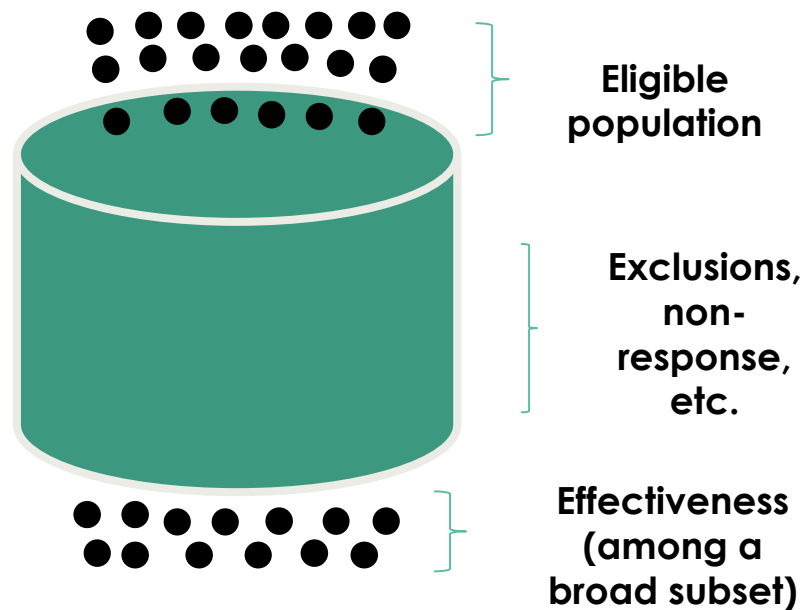
Source: Green et al. 2001; \* per month

# Explanatory study vs. pragmatic study

## Explanatory Study



## Pragmatic Study

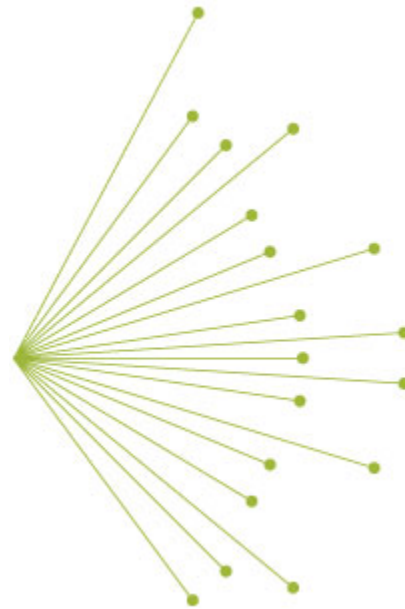


# Topic 2

## Unique aspects of safety net practices

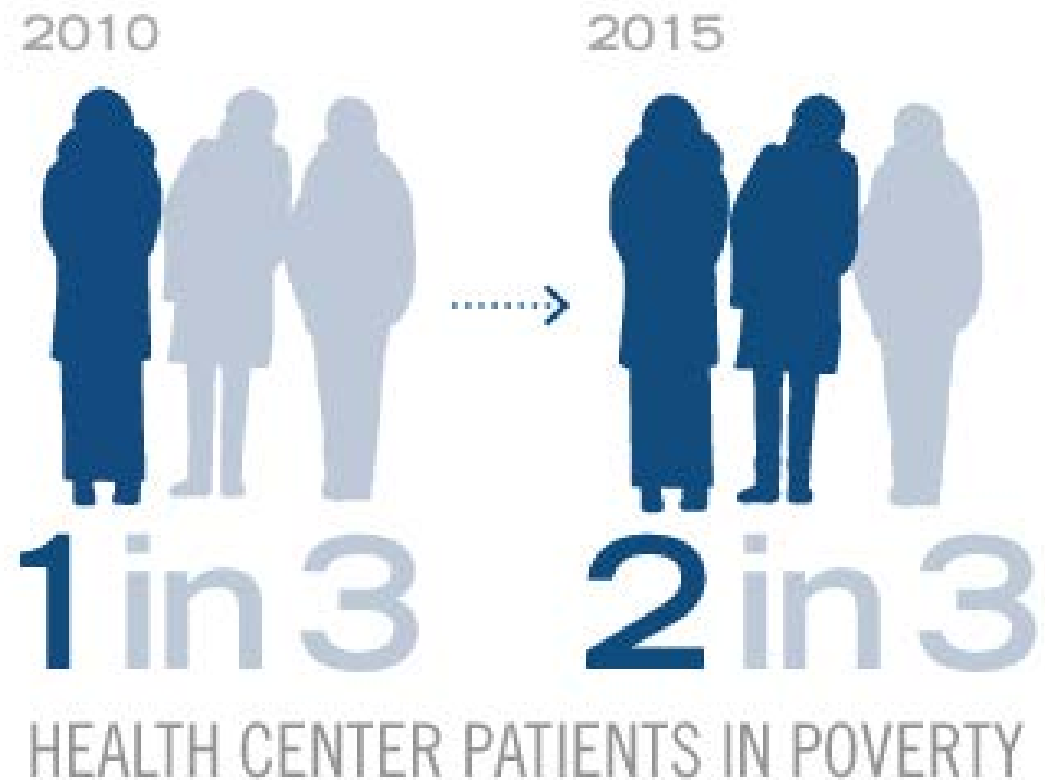
- Many delivery sites
- Young, low-income populations with multiple chronic conditions
- Lower per-patient costs, fewer ER visits

# What we know about health centers ...



Source: <https://avanzastrategies.com/hospital-fqhc-partnerships-make-sense/>

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Source: <https://avanzastrategies.com/hospital-fqhc-partnerships-make-sense/>



# What we know about health centers ...

MEDICAID BENEFICIARIES RECEIVING  
CARE FROM HEALTH CENTERS ARE



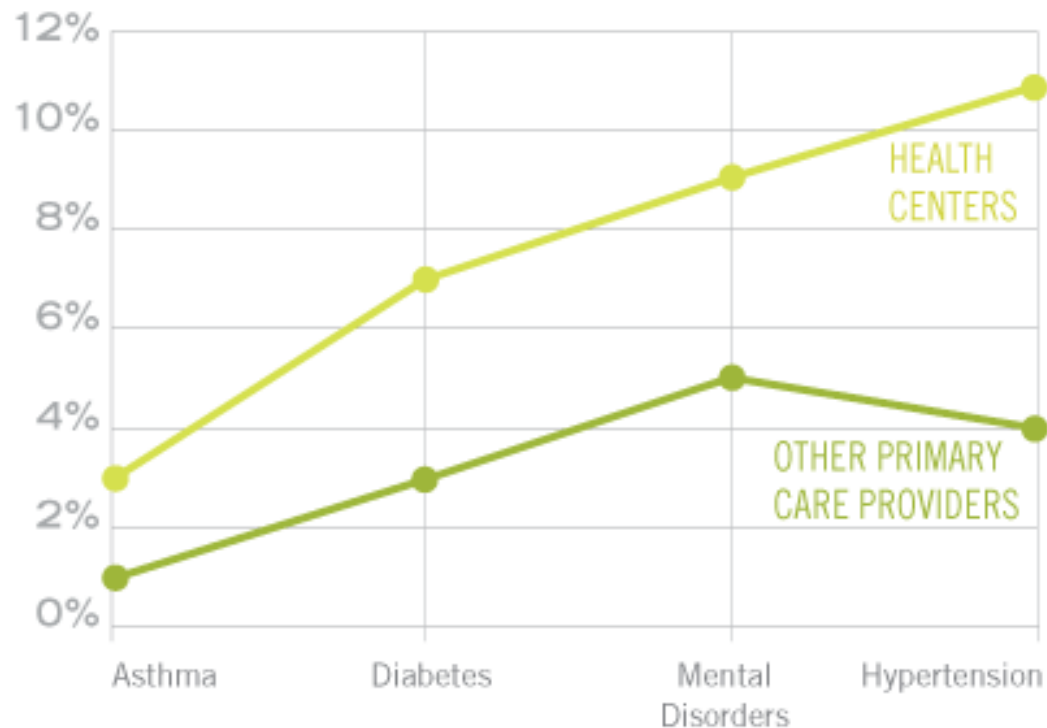
**19%**

LESS LIKELY  
TO USE AN  
EMERGENCY  
DEPARTMENT

Source: <https://avanzastrategies.com/hospital-fqhc-partnerships-make-sense/>

# What we know about health centers ...

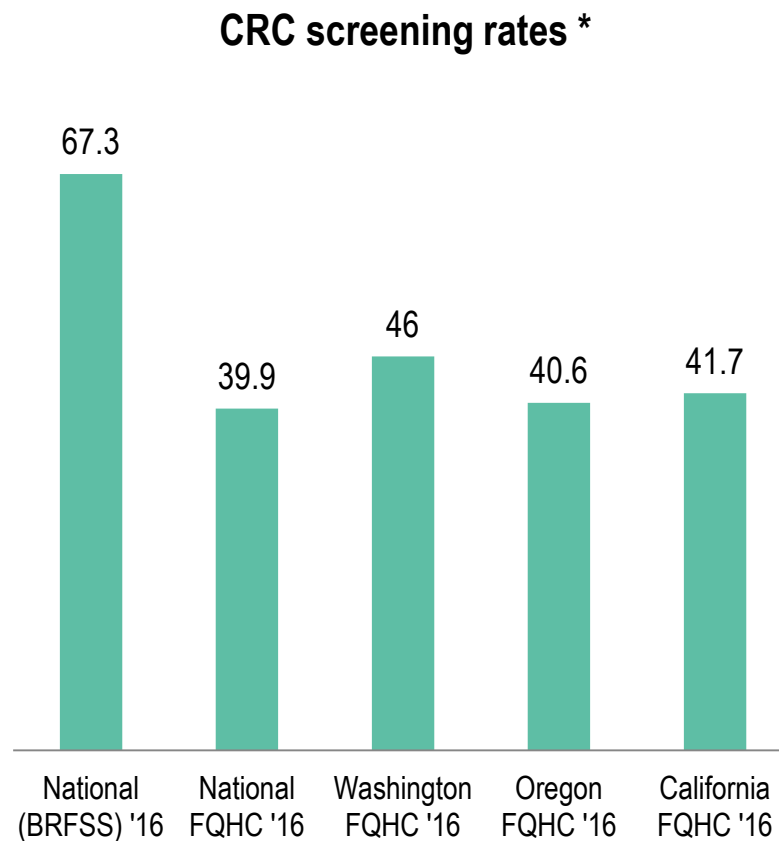
HEALTH CENTER PATIENTS ARE MORE LIKELY TO HAVE SERIOUS AND CHRONIC CONDITIONS



Source: <https://avanzastrategies.com/hospital-fqhc-partnerships-make-sense/>

# What we know about health centers ...

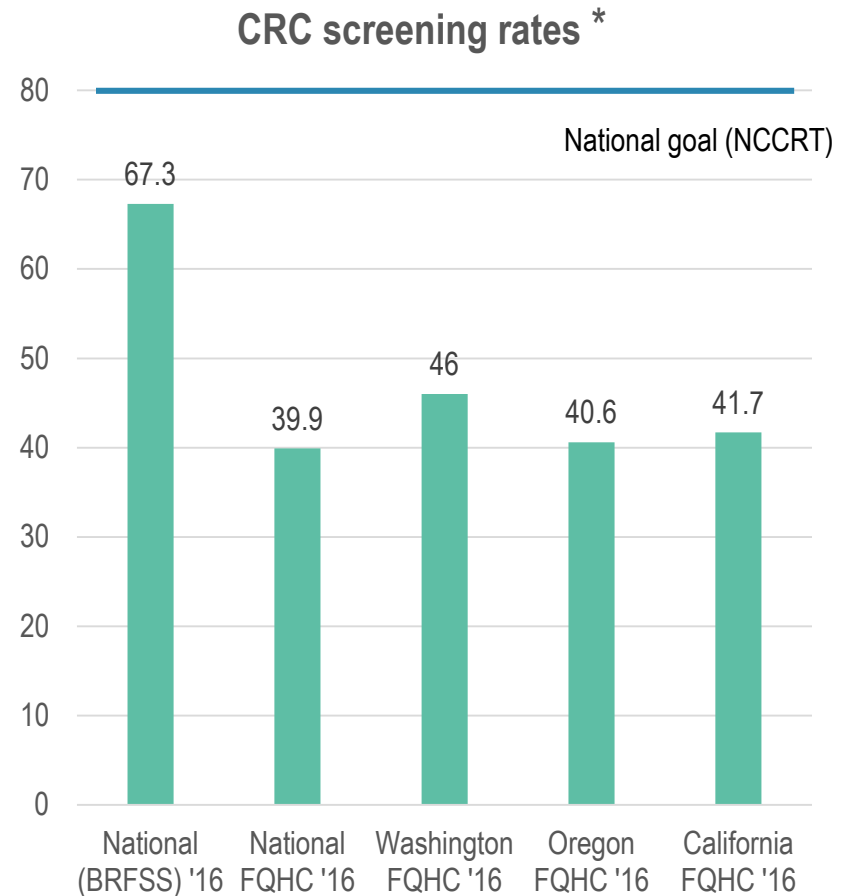
- Colon cancer is a leading cause of cancer death
- Nearly 1/3 of age-eligible adults in the US are not up-to-date, many are in community clinics
- Colon cancer can be prevented; survival is:
  - 93% for Stage 1
  - 8% for Stage IV



\*Centers for Disease Control. *MMWR Morb Mortal Wkly Rep*, 2017  
National program grantee data. 2016 Health Center Data Website.  
<http://bphc.hrsa.gov/uds/datacenter.aspx?year=2016>. Accessed April 8, 2018.

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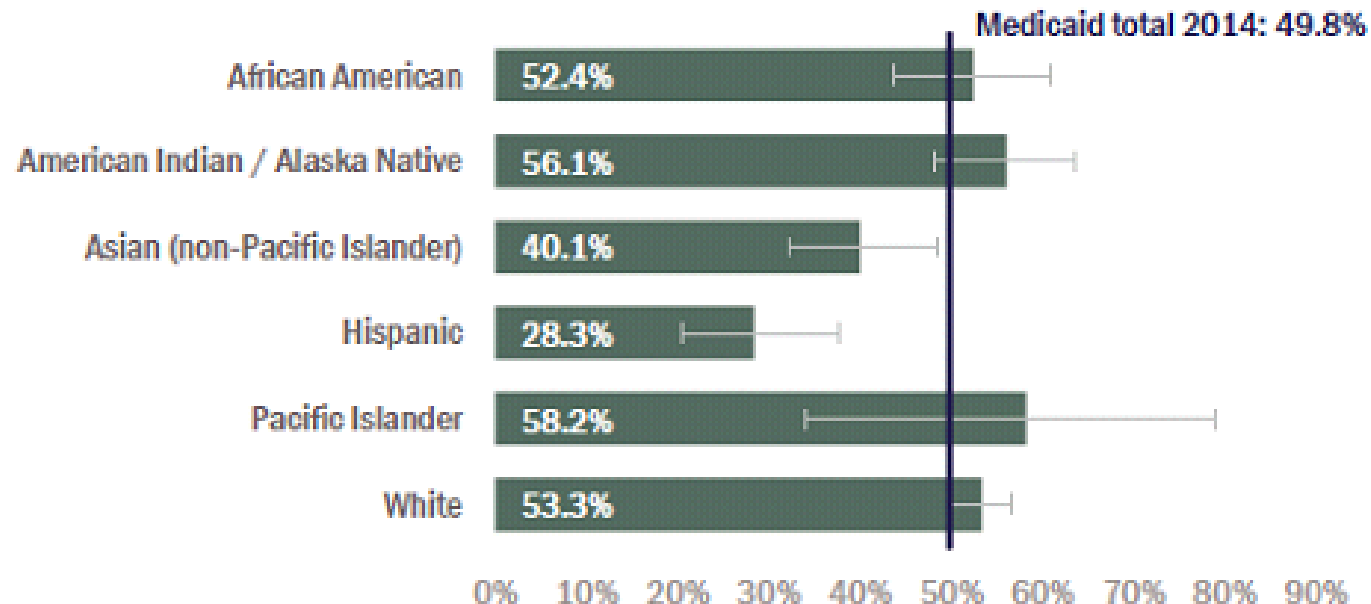


\*Centers for Disease Control. *MMWR Morb Mortal Wkly Rep*, 2017  
National program grantee data. 2016 Health Center Data Website.  
<http://bphc.hrsa.gov/uds/datacenter.aspx?year=2016>. Accessed April 8, 2018.

# Oregon Medicaid CRC screening rates suboptimal and marked by pronounced health disparity

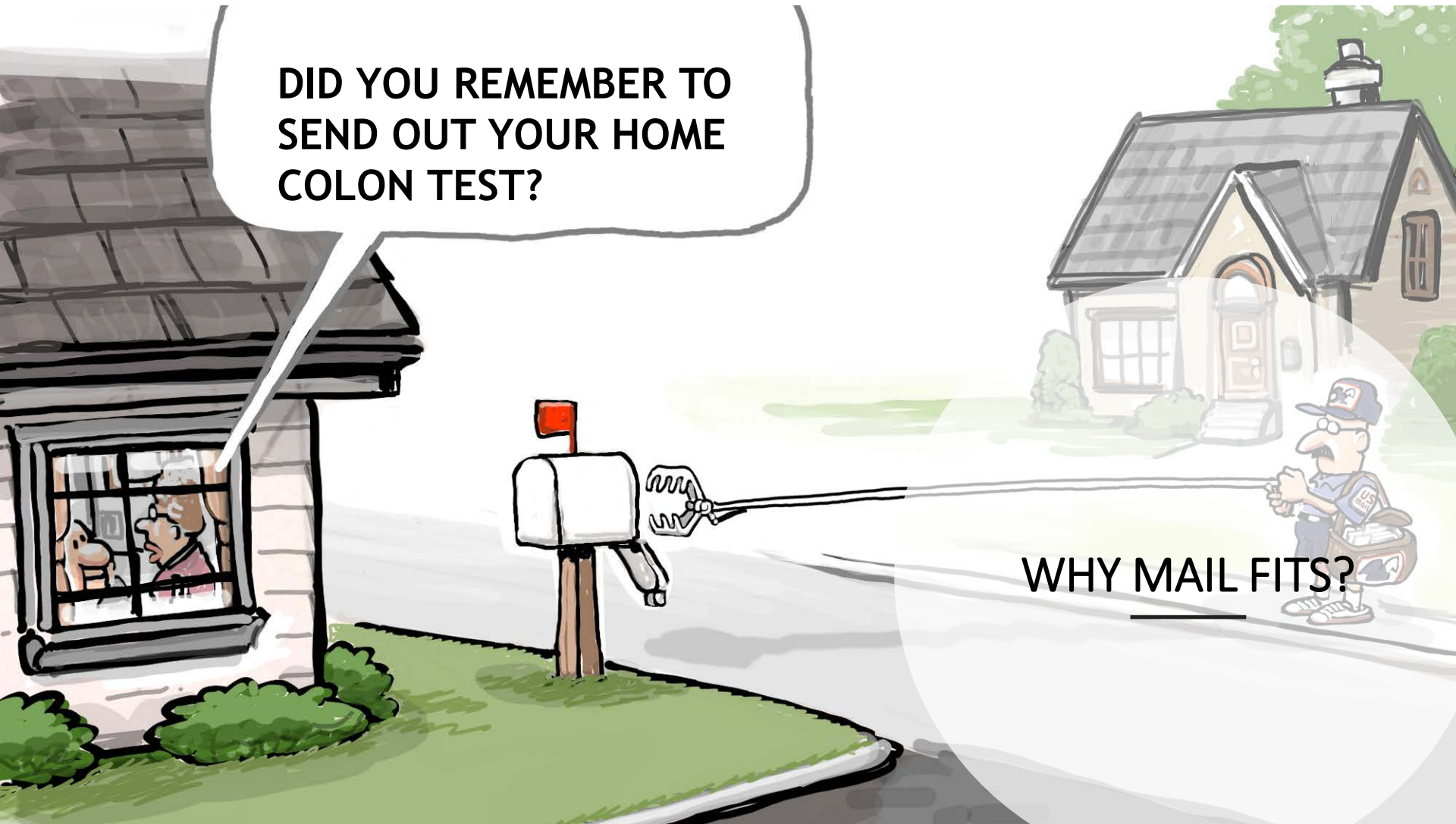
Percent of members who had recommended colorectal cancer screening, by race and ethnicity.

Bars show average rates. Gray lines represent confidence intervals.



**DID YOU REMEMBER TO  
SEND OUT YOUR HOME  
COLON TEST?**

**WHY MAIL FITS?**

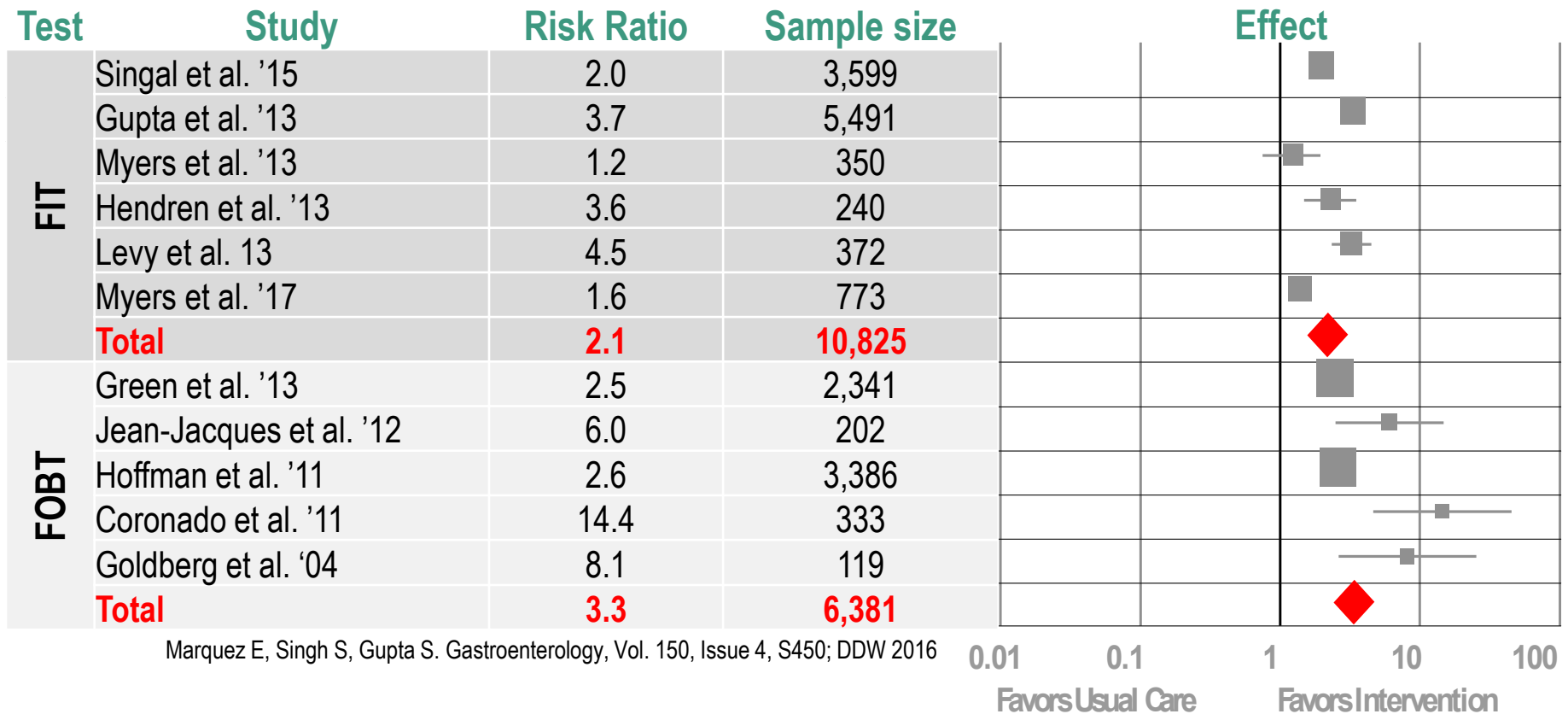


# Promising interventions in vulnerable populations

	N studies	Improves fecal testing?	Evidence strength
Direct Mail	9	Yes	High
Flu-FOBT/FIT	2	Yes	High
Clinic processes	2	Mixed	Moderate
Patient Navigator	2	Yes (overall screening) Mixed (FOBT only)	Moderate
Education at clinic / community	12	Mixed/ Unclear	Low/ Insufficient

Source: Davis et al. (2018)

# Previous direct-mail programs





# Success of direct-mail programs

## Kaiser Permanente Northern California

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



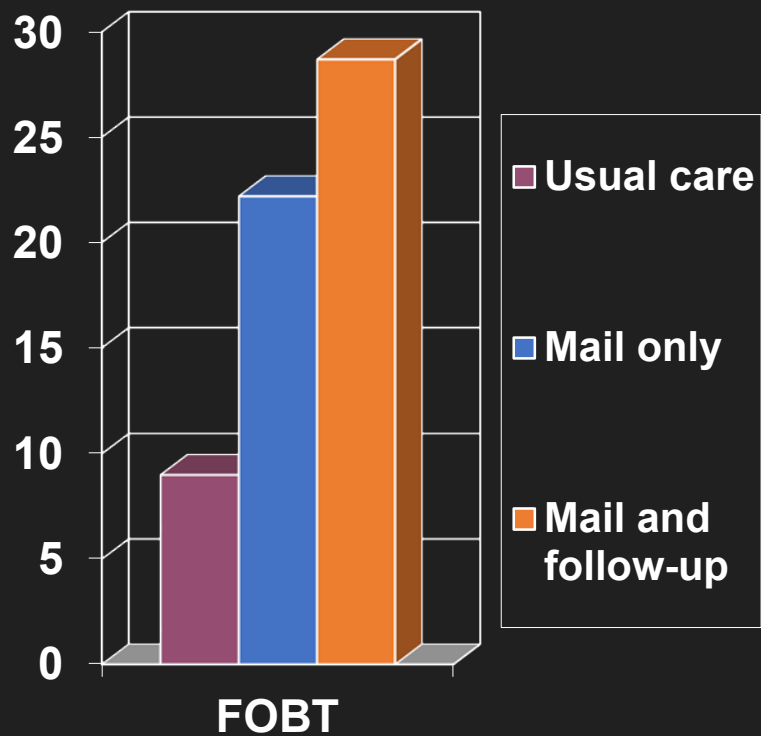
Levin TR Gastrointest Endosc. 2016 Mar;83(3):552-4.

# Topic 3

## How my research in safety net practices began?

- Sea Mar Community Health Centers pilot study

## Sea Mar pilot study demonstrated success



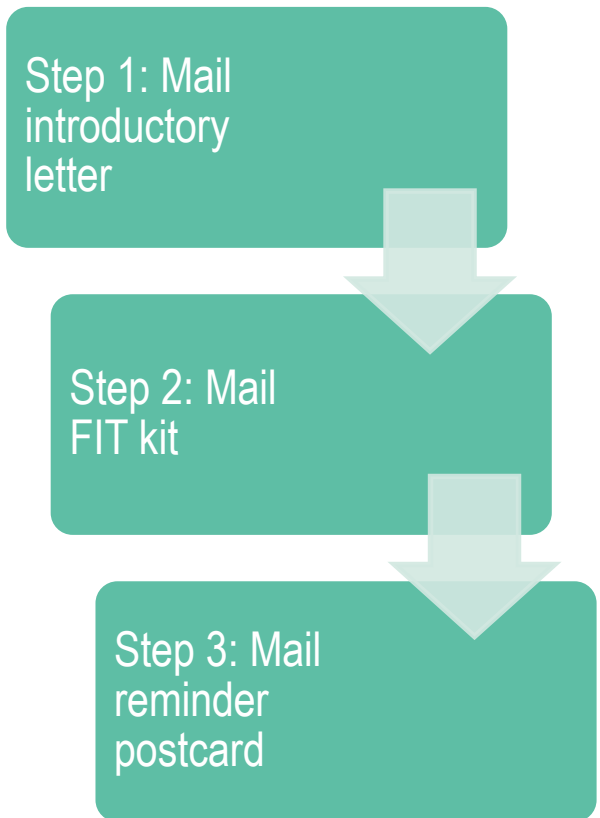
# Topic 4

## How the research expanded

- STOP Colon Cancer study
- Clinic partnership
- Application of Plan-Do-Study Act cycles

# STOP CRC study design

- Large pragmatic study involving 26 health center clinics
- Tested a direct-mail FIT program
  - Clinics randomized to receive direct-mail FIT program vs. usual care
- 5-year study funded by the NIH Common Fund



# STOP CRC pilot findings

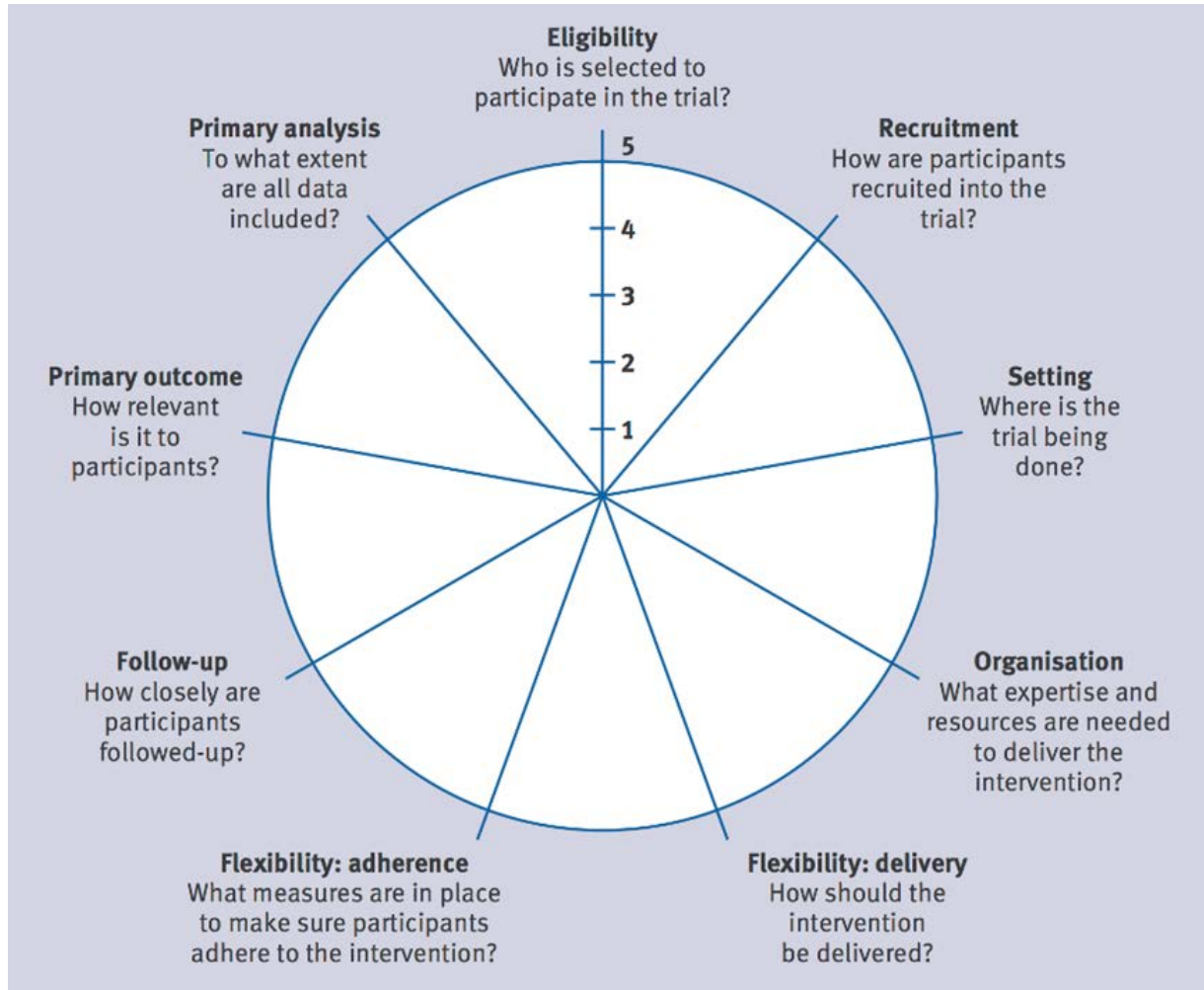
Auto Intervention      Auto Plus Intervention

	Auto Intervention	Auto Plus Intervention
Letters mailed	112	101
FIT kits mailed	109	97
Reminder postcards mailed	95	84
Reminder call delivered	NA	30*
FIT kits complete	44 (39.3%)	37 (36.6%)
Positive FIT result	5 (12.5%)	2 (5.7%)



Source: Virginia Garcia Memorial Health Center

# Pragmatic-Explanatory Continuum Index Summary 2 (PRECIS-2) wheel



## Scale:

1 = very explanatory

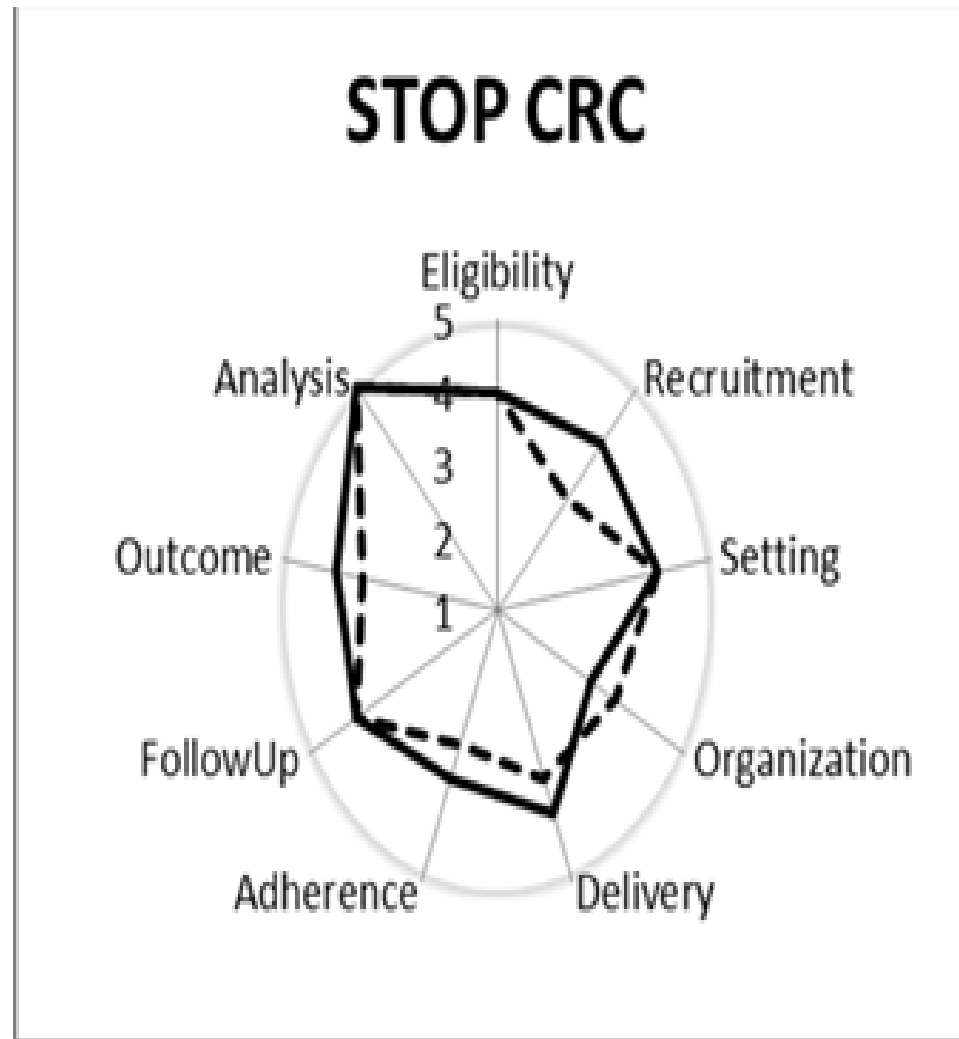
3 = equally  
pragmatic and  
explanatory

5 = very pragmatic

Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. 2015;350:h2147.

# Applying PRECIS to STOP CRC

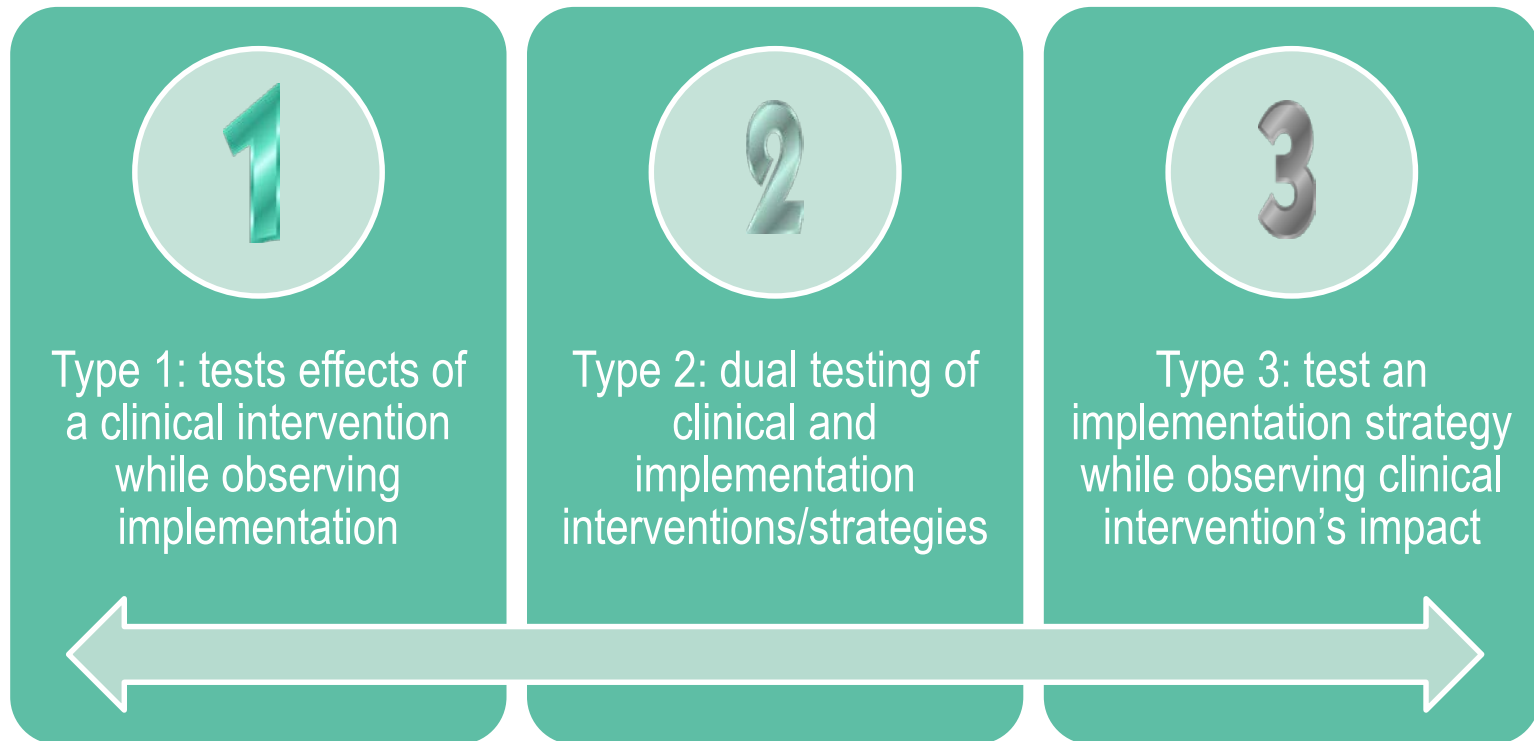
Dashed line:  
UH2  
Solid line: UH3



Authors: Karin E. Johnson<sup>1\*</sup>, Gila Neta<sup>2a\*§</sup>, Laura M. Dember<sup>3</sup>, Gloria D. Coronado<sup>4a</sup>  
Use of PRECIS Ratings in the NIH Healthcare Systems Research Collaboratory; *Trials* 2016



# Effectiveness – Implementation hybrid designs

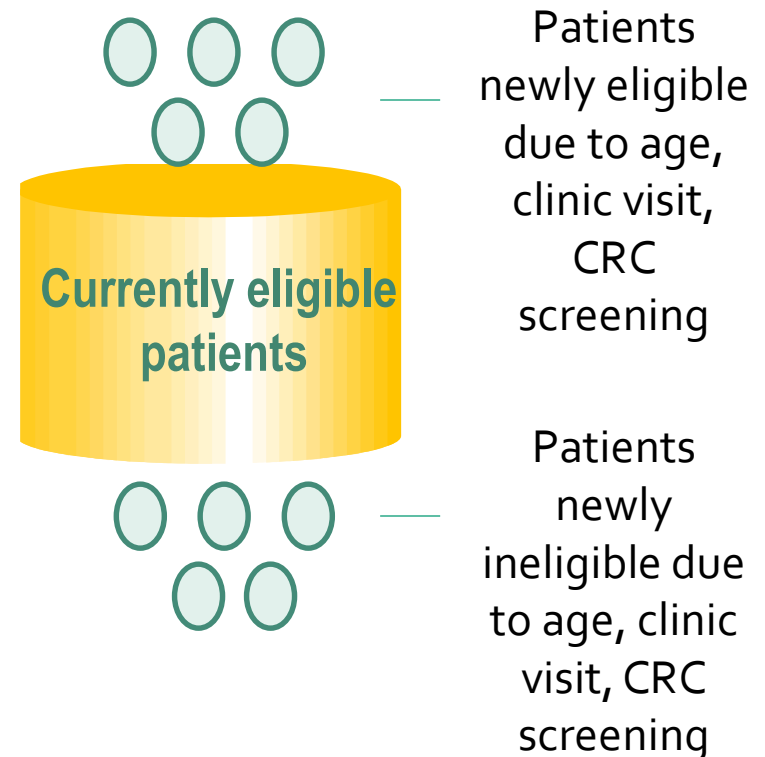


**Effectiveness**

**Implementation**

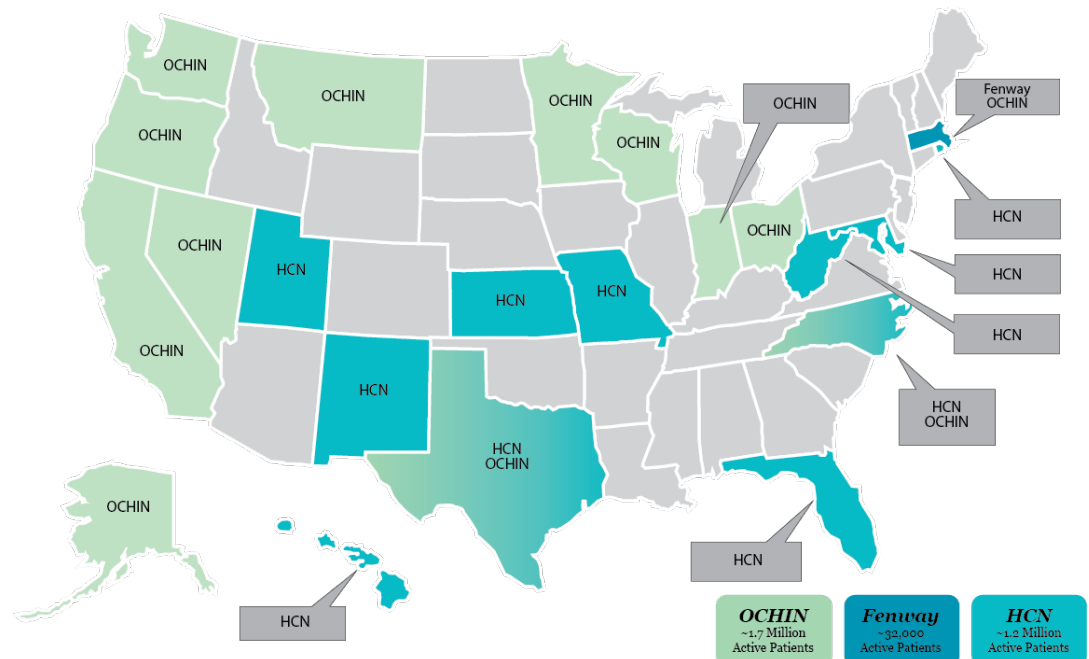
# STOP CRC EMR Tools

- Real-time tools, designed in Reporting Workbench, updated daily;
- Use EMR codes, and Health Maintenance (incorporates provider input);
- Define 'active patients' as those with clinic visit in past year;
- Can order FIT tests for all patients on list (bulk order).



# OCHIN network

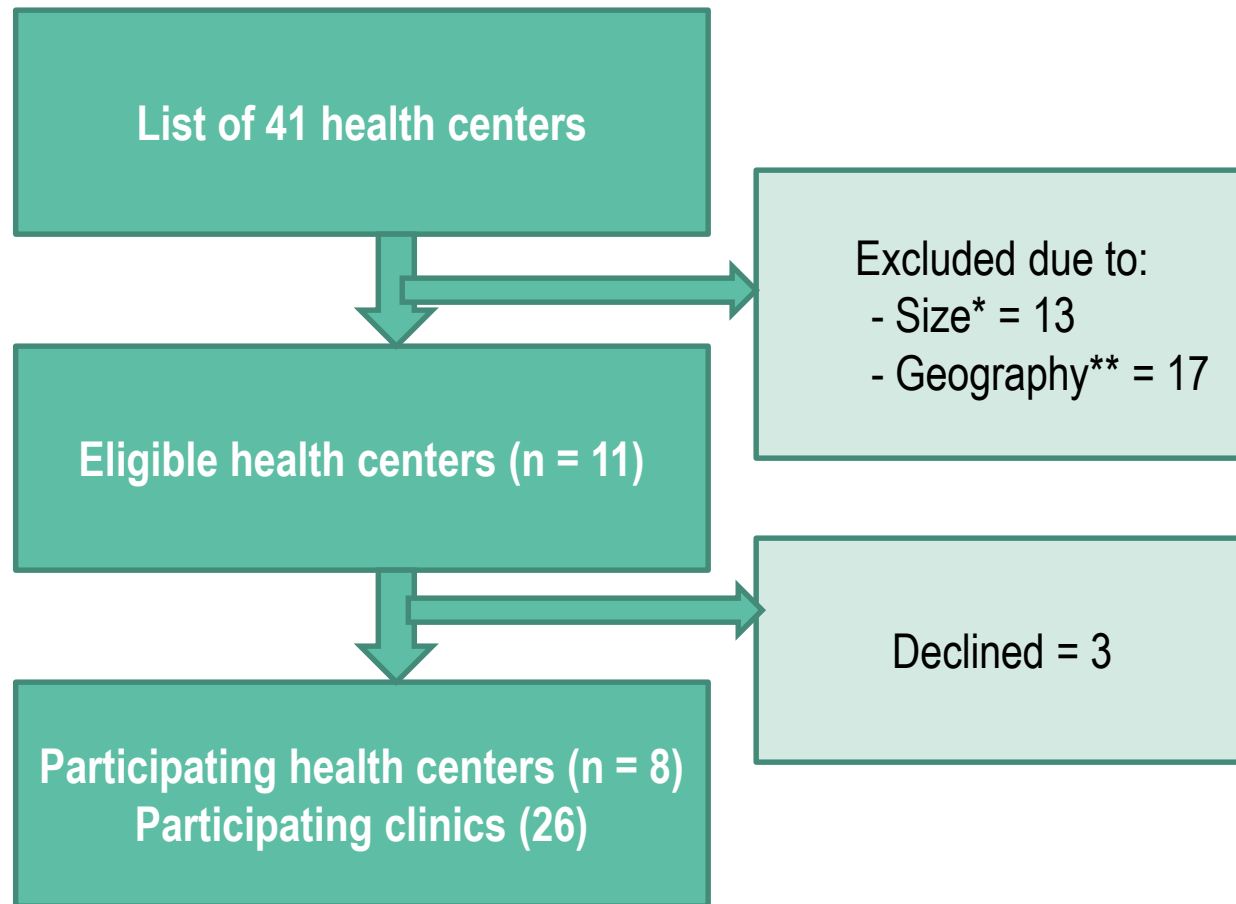
- Formerly the Oregon Community Health Information Network
- OCHIN Epic – 95 total members, primarily safety net clinics, serving 1.7 million patients
- OCHIN now also supports clinics that use Next Gen



# Recruiting clinics for pragmatic research

- Partnered with OCHIN to recruit health centers
  - 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
- Assessed recruitment using systematic approach (Gaglio et al.)
  - % of approached sites that agreed to participate, characteristics of participating and non-participating sites,
  - Qualitative summaries of notes taken during “recruitment” meetings with leadership teams (both participating and non-participating)

# Recruitment flow diagram



\* < 2 clinics with 450+ patients

\*\* Outside of Oregon, N California or Washington

# 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
	Health Center 8	36	34	37
Non-participating	Health Center 9	4	16	23
	Health Center 10	37	14	30
	Health Center 11	15	14	30



Source: Coronado et al. 2015

## 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%



# Reasons for participation

External environment	Internal environment	Intervention attributes
<ul style="list-style-type: none"><li>■ Colon cancer screening is a high priority</li></ul>	<ul style="list-style-type: none"><li>■ STOP CRC supports/catalyzes needed change</li></ul>	<ul style="list-style-type: none"><li>■ Choice &amp; flexibility in how implemented</li><li>■ Pilot success supports efficacy</li></ul>



# Reasons for participation

## External environment: Colon cancer screening is a high priority

*“I think national reporting requirements have been influential. However ... the local and regional reporting requirements have been a little more influential, specifically the CCO reporting requirements ... with colorectal cancer screening as one of the CCO measures it’s on everybody’s radar.”*

— Operations Director



Source: Coronado et al. 2015

# Reasons for non-participation

External environment	Internal environment	Intervention attributes
<ul style="list-style-type: none"><li data-bbox="162 572 531 736">■ Cost of testing &amp; follow-up for uninsured</li></ul>	<ul style="list-style-type: none"><li data-bbox="736 572 1064 625">■ Clinic capacity</li><li data-bbox="736 668 1174 721">■ Competing priorities</li></ul>	<ul style="list-style-type: none"><li data-bbox="1307 572 1669 676">■ Concerns about randomization</li><li data-bbox="1307 725 1721 829">■ Concerns program will not work</li></ul>

# Reasons for non-participation

Intervention attributes: Randomization; concerns program will not work

*“And I think I expressed some disagreement with that part of the design...The reason I said that is because I have a difficult time having a tool I have access to for one clinic, and not be able to offer it to the other clinic.”*

— Medical Director



Source: Coronado et al. 2015

# Traditional clinical research

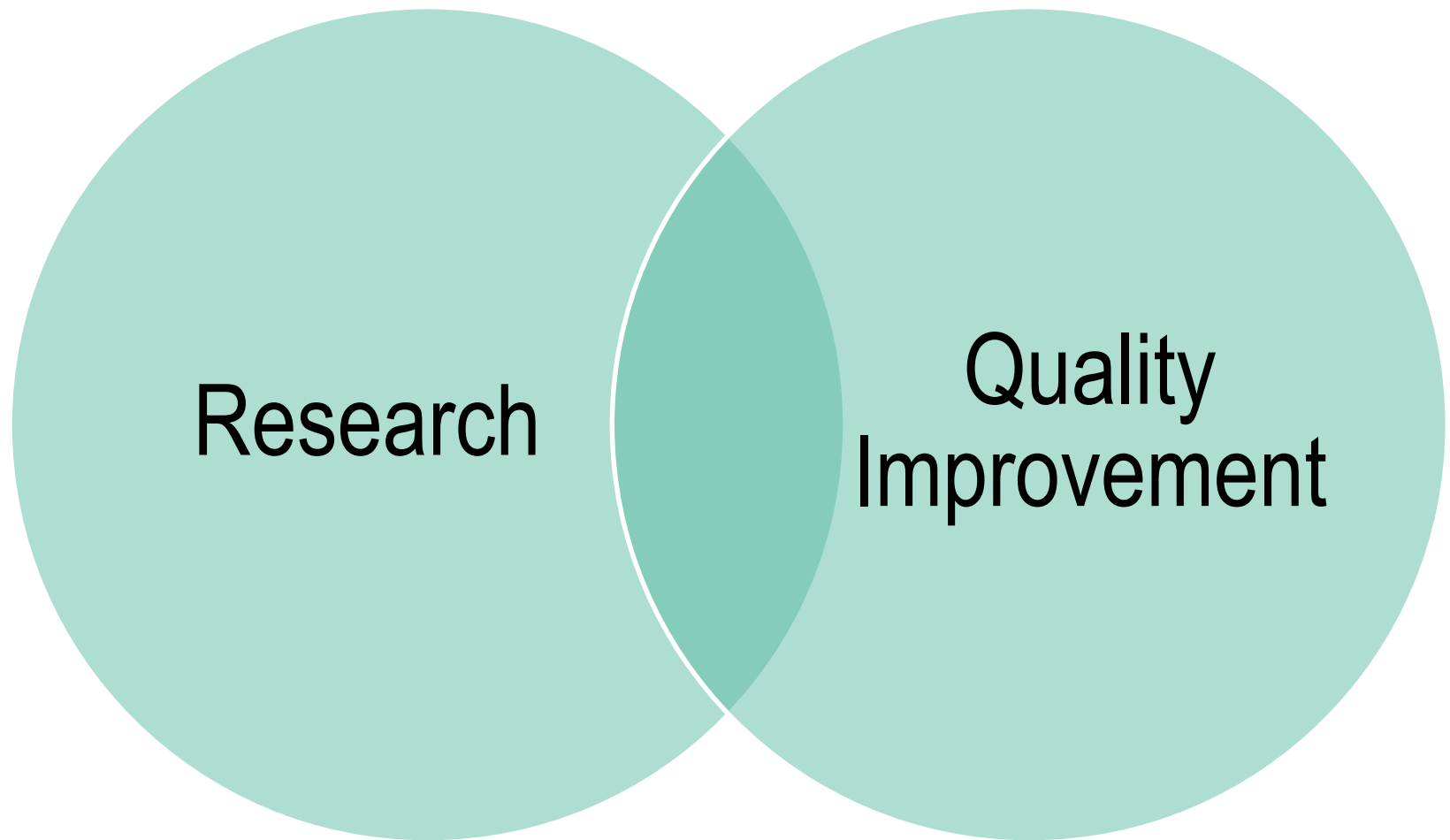


Research

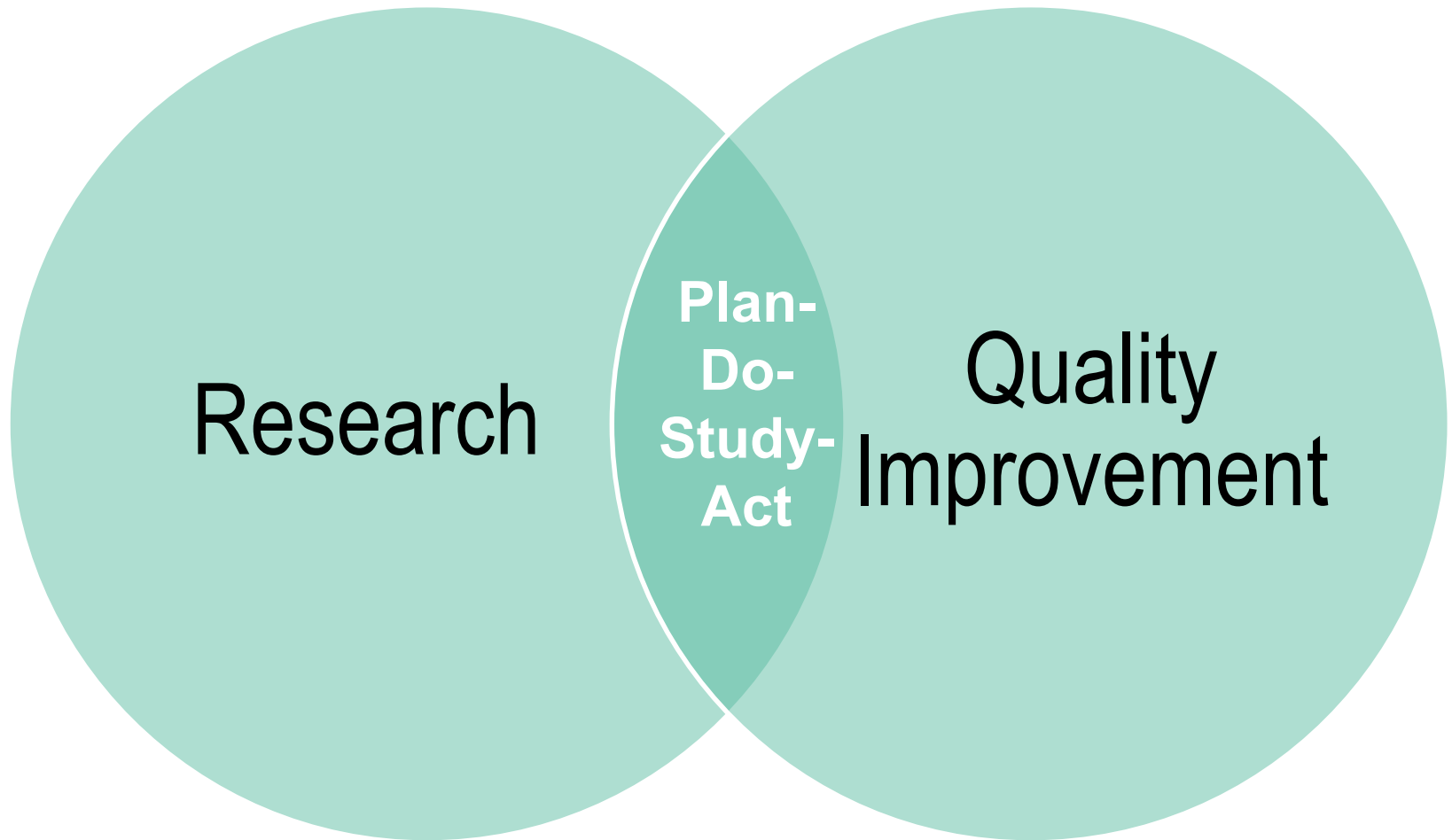


Quality  
Improvement

# Pragmatic research



# Pragmatic research

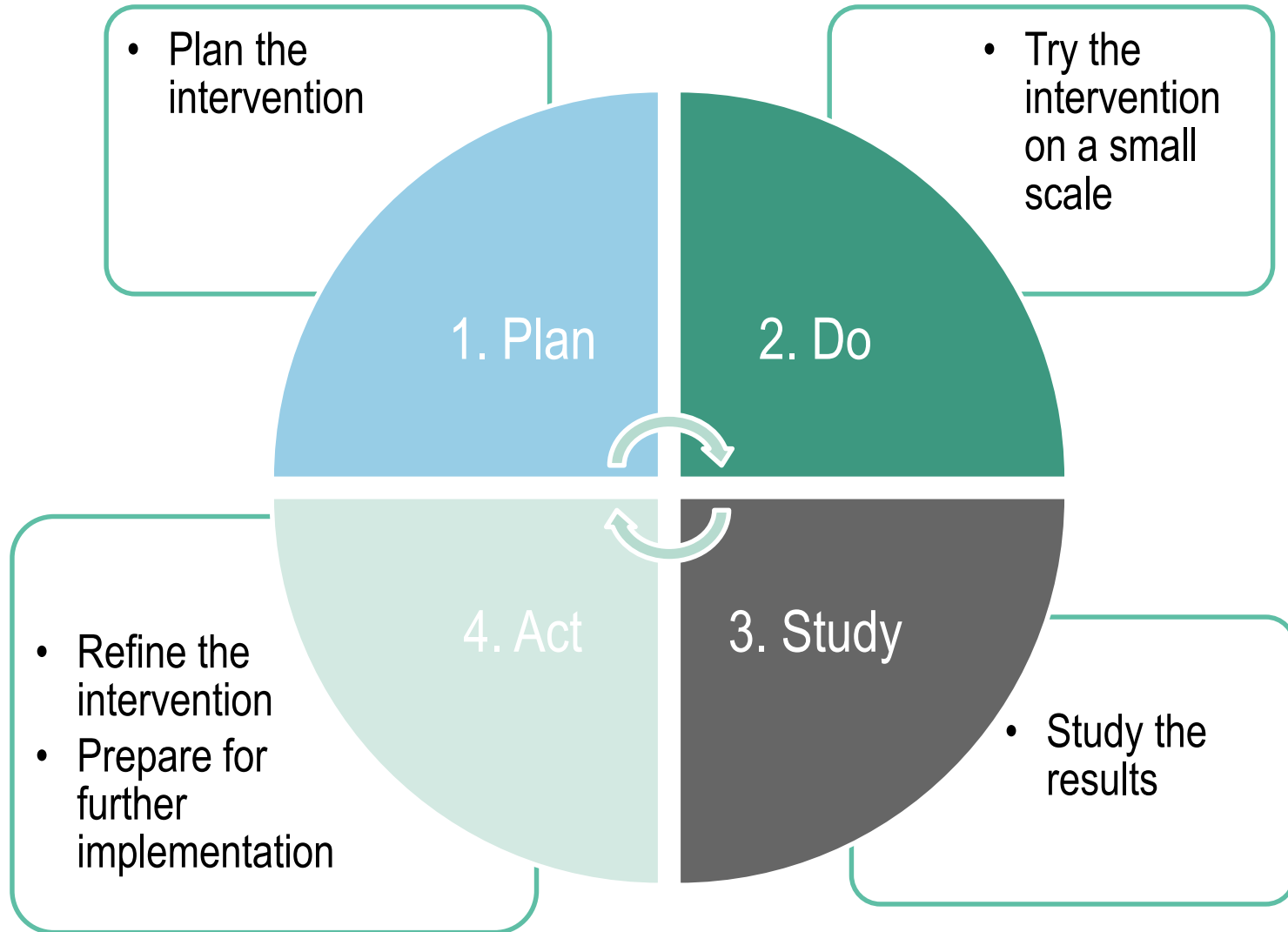


Research

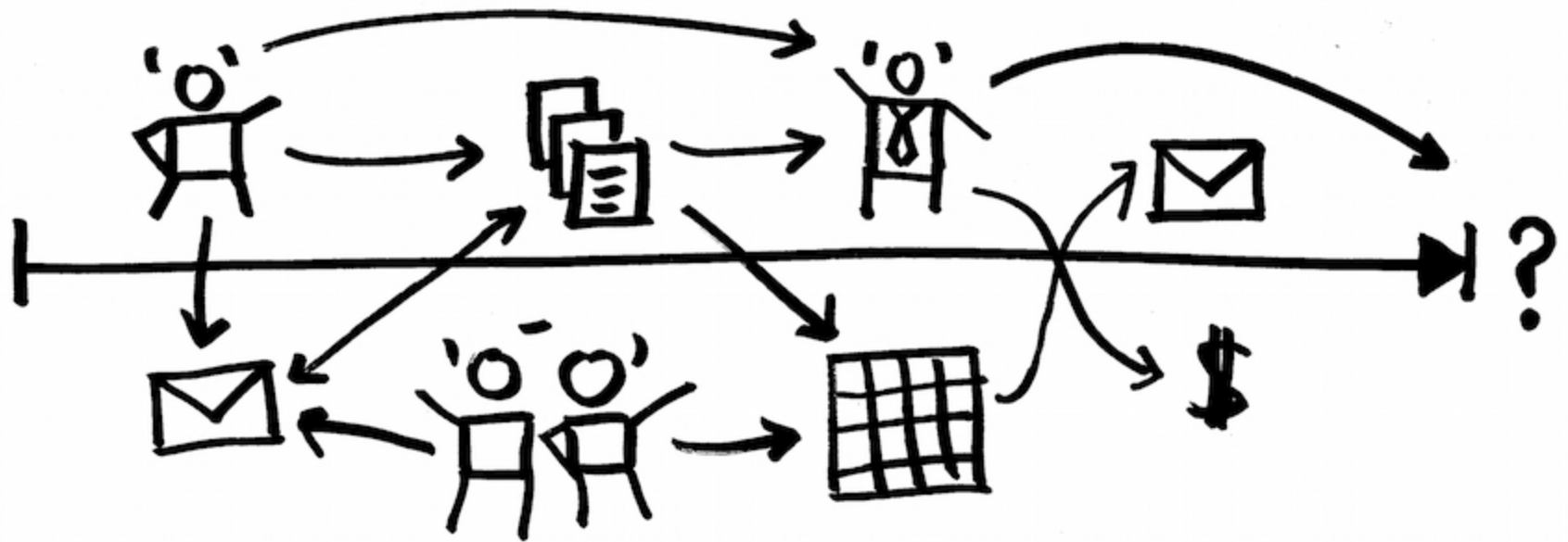
Plan-  
Do-  
Study-  
Act

Quality  
Improvement

# Process Improvement: Plan–Do–Study–Act



# Example of clinic process



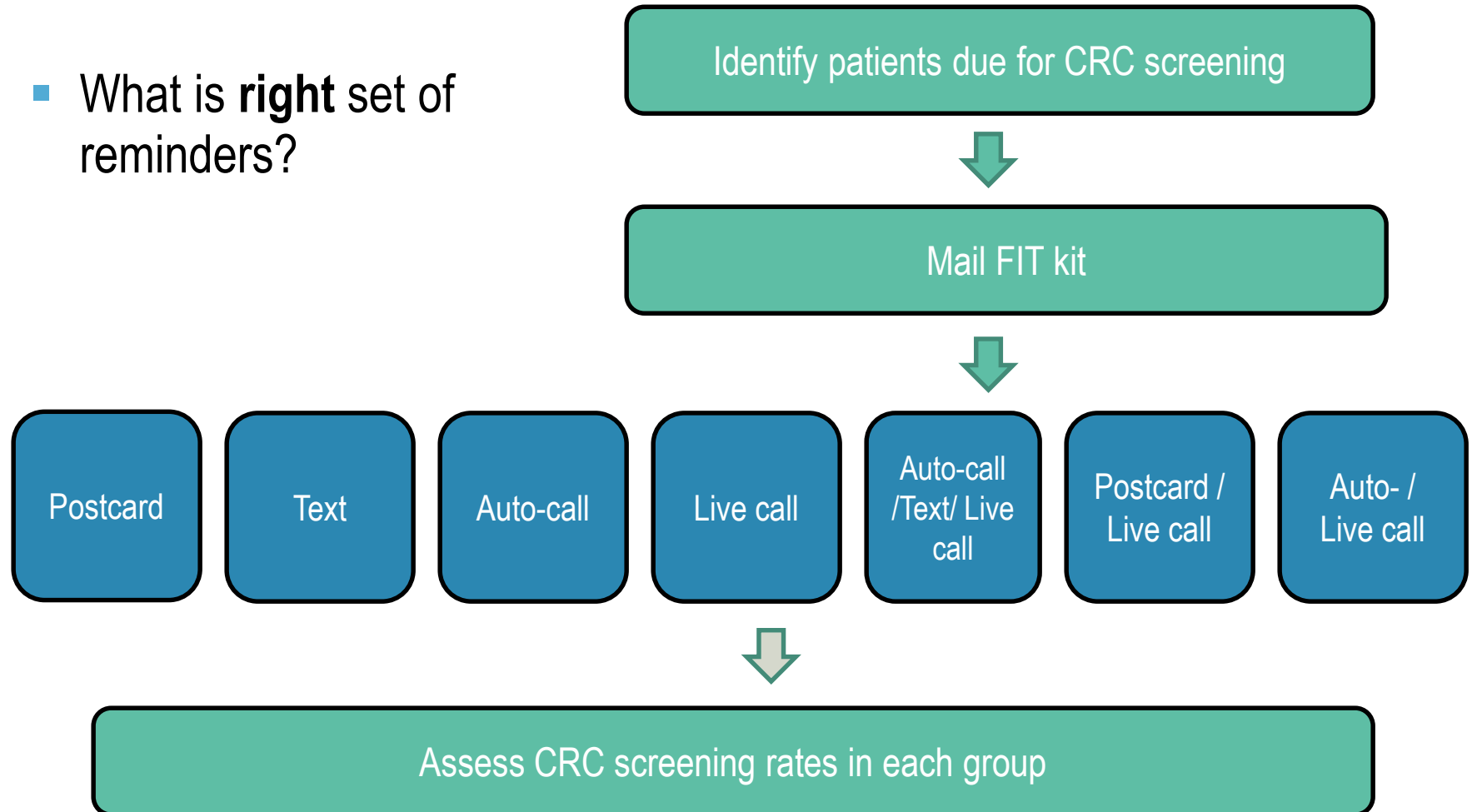


# STOP CRC approach to using PDSA cycles

- Partnered with a Quality Improvement facilitator, trained in PDSA
- Met with the leadership teams of all 8 participating health centers
  - Prepared a PowerPoint; reviewed PDSA approach
  - Shared local data, EMR data on screening rates, and provider surveys
- Asked for submission of a PDSA plan (within 1 month)
- Asked for submission of PDSA results (in 3 – 6 months)
- All sites presented findings at Advisory Board meeting

# PDSA #1: Reminders for direct-mail program

- What is **right** set of reminders?



# Success of reminders for a mailed FIT program

	English	Spanish	Other
Reminder letter	19%	33%	43%
Automated phone call	23%	25%	26%
Text message	14%	23%	29%
Live phone call	30%	38%	35%
Automated phone call + live phone call	24%	49%	39%
Text message + live phone call	24%	40%	13%
Reminder letter + live phone call	24%	35%	44%
Email (patient portal)	19%	29%	46%

Source: Sea Mar Community Health Center; English = 1467, Spanish = 384; Other = 159

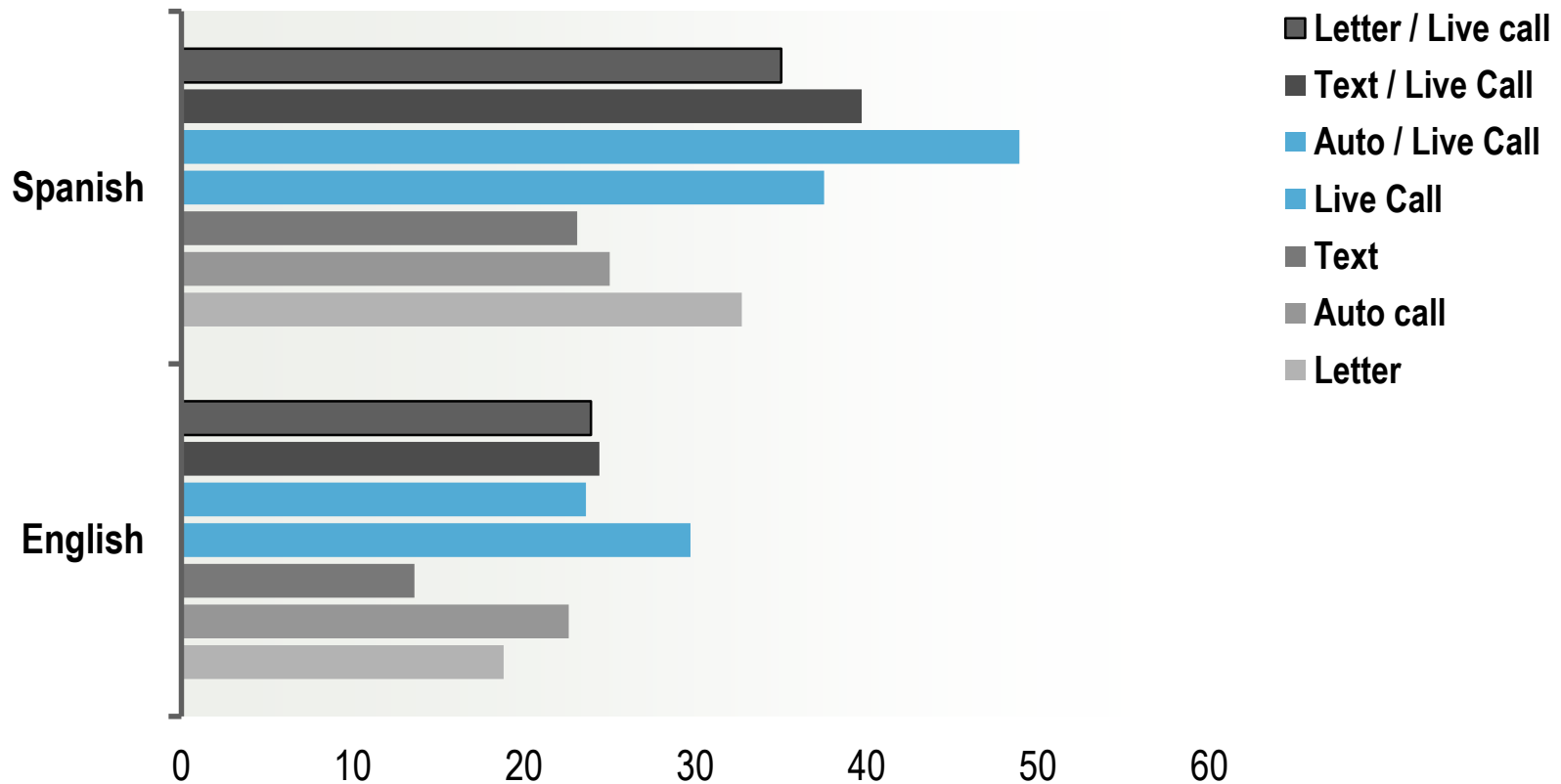
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# Success of reminders for a mailed FIT program

FIT return rates among patients who prefer Spanish versus English



Source: Sea Mar Community Health Center

# Automated phone call sample

“This is Sea Mar Community Health Center calling to remind [patient’s first name] about a simple colon test kit your doctor recommended for you....”

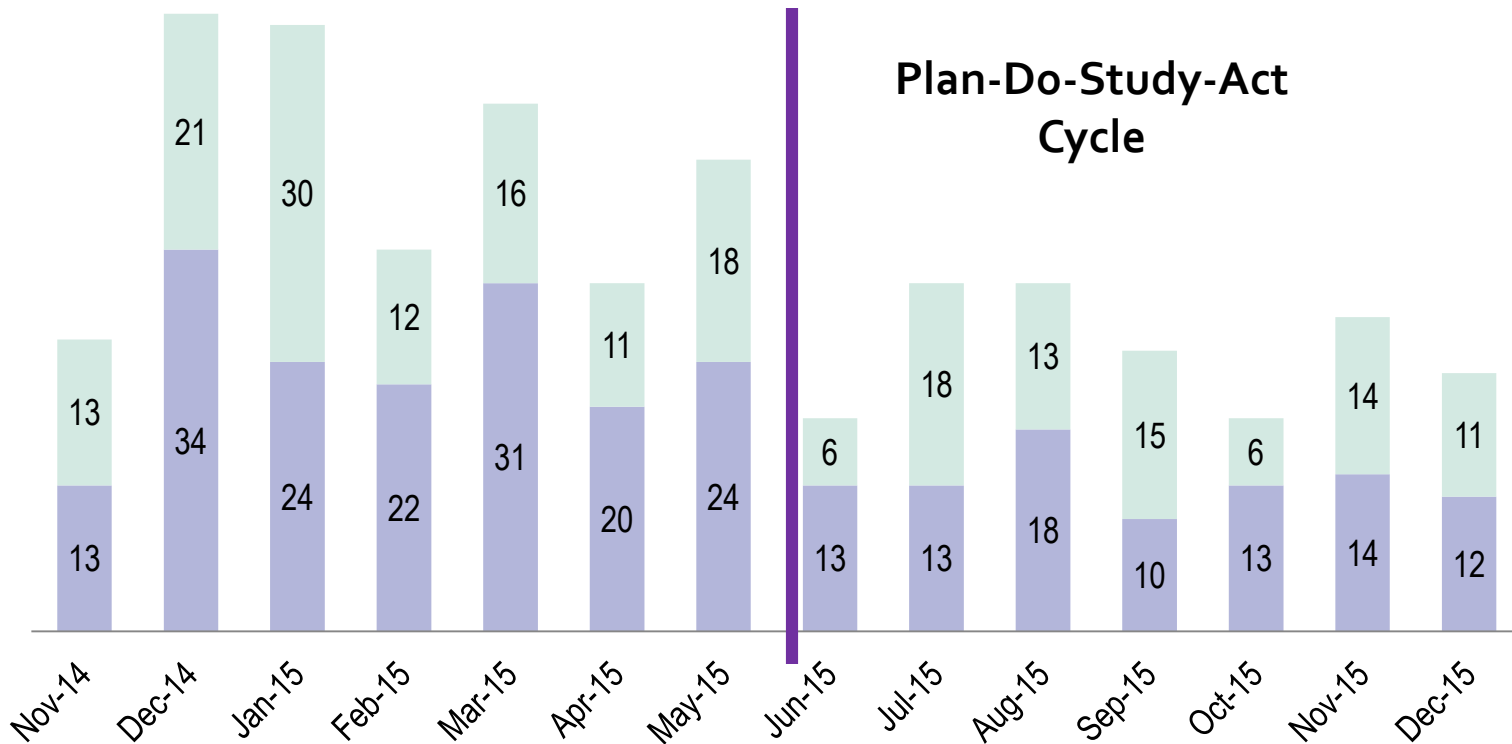
— English and Spanish




# PDSA #2: Improving FIT sample collection

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

■ N collection date missing    ■ N improperly collected - other



# Action taken: Highlighted instruction on letter



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

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

MULTNOMAH COUNTY HEALTH DEPARTMENT #503-988-5558



尊敬的 客戶端,

這是一個在您出現症狀前便能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。本測試將察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。開始之前沖廁一次。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。

如果您存有任何疑問，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




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 результатам 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 A, другой для отделения B.
- 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

MULTNOMAH 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日期。
- Не забудьте указать дату, когда вы собрали анализ кала

Last Name, First Name  
DOB: 01/01/1980  
MRN: 1234567  
Date: \_\_\_\_\_

Last Name, First Name  
DOB: 01/01/1980  
MRN: 1234567  
Date: \_\_\_\_\_



# Reactions to PDSA used in research

## Providers and clinic staff had favorable reactions

“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

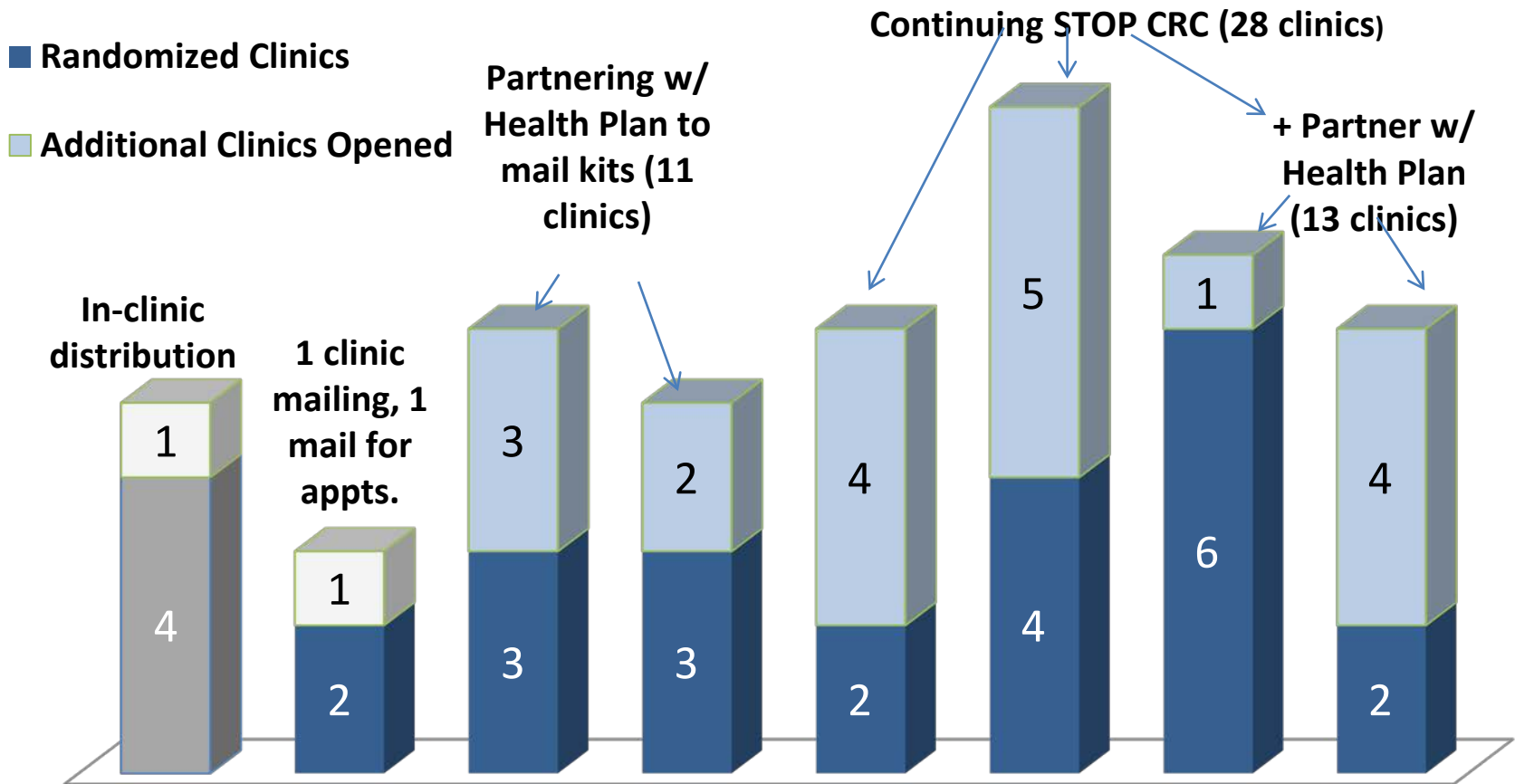


# Topic 5

## How the research is being sustained

- CRC screening incentive and reimbursement policy
- BENEFIT study

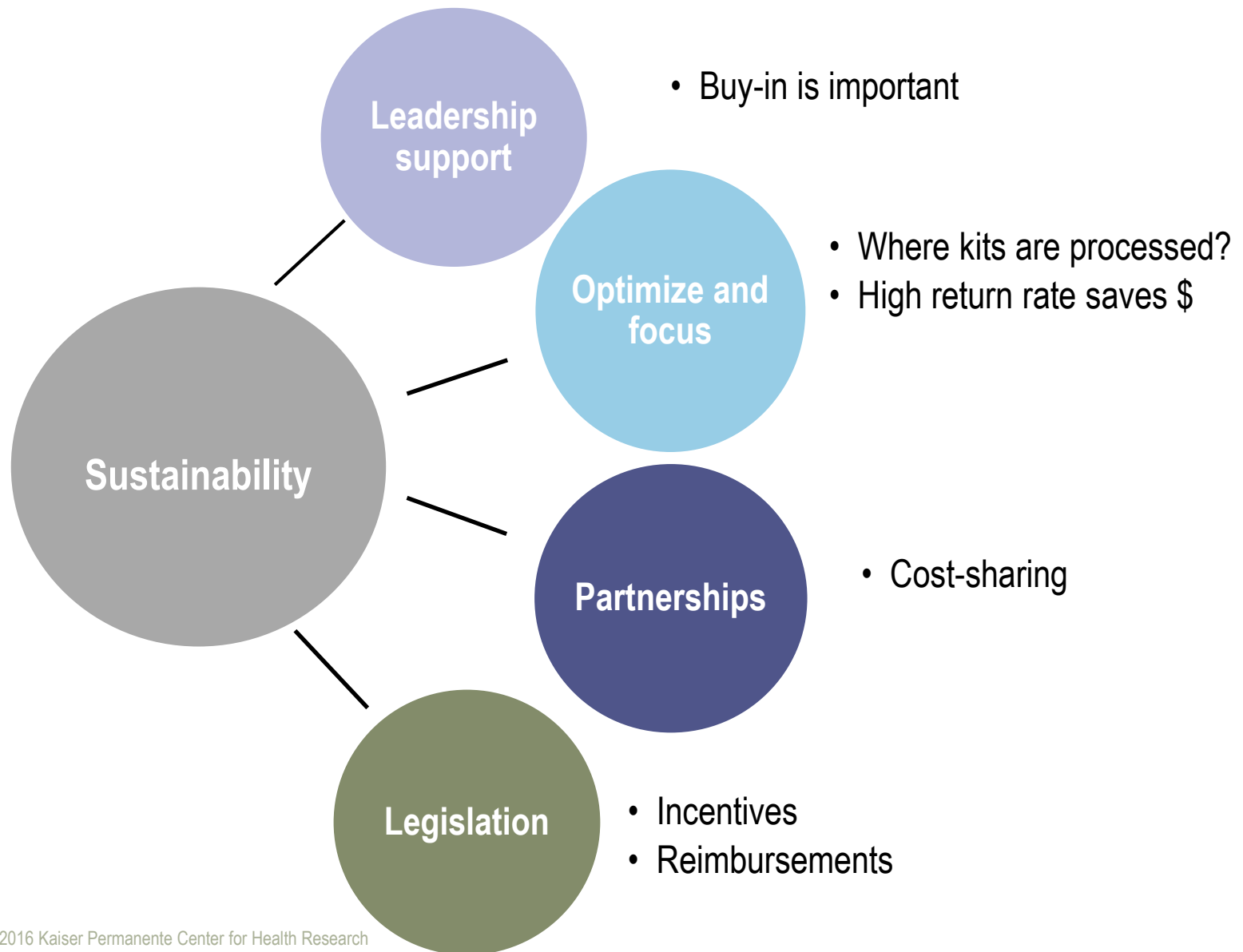
# STOP CRC Maintenance, by Health Center



# Maintenance

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

# Ways to sustain program/impacts



# Medicaid expansion's impact

State	Pre-ACA average monthly enrollment	Total Monthly Medicaid/CHIP enrollment	Percent change
Alaska	122,334	125,616	3%
California	9,157,000	12,636,680	38%
Oregon	626,356	1,055,198	69%
Texas	4,441,605	4,666,144	5%
Washington	1,117,576	1,735,511	55%
Wyoming	67,518	64,462	-5%

Washington increase: 625,847 (21% adults)

Oregon increase: 429,651 (29% adults)

Source: Centers for Medicare and Medicaid, 2015

# Medicaid expansion in adults age 51 – 64

	Before Medicaid Expansion Dec 2013	After Medicaid Expansion June 2014	% change
All ages	659,114	971,095	47.3
< 19	372,639	426,130	14.4
19 – 21	20,996	41,625	98.3
22 – 35	90,356	193,078	113.7
36 – 50	70,203	147,184	109.7
51 – 64	57,295	124,418	117.2
65 +	47,625	38,660	-18.8

Source: Oregon Health Authority 2014



# Consider policy as a way to align priorities

- Colon cancer screening legislation
  - In 2012, CRC screening became an incentivized metric for state's Coordinated Care Organizations
  - In 2013, Oregon passed legislation to make a screening colonoscopy remain a screening exam, even when polyps are removed
  - In 2014, Oregon passed legislation to require insurance companies to cover the cost of a follow-up colonoscopy among patients who screen positive on FIT
- Impact of national legislation
  - Pre-ACA (2007 – 2010): On average, traditional Medicare paid all but \$275 for a screening colonoscopy\*
  - Post-ACA (2011 – 2013): Traditional Medicare paid in full for a screening colonoscopy\*
  - ACA resulted in an 8% increase in early stage colon cancer detection.

# BENEFIT study design

- **Pragmatic study involving two Medicaid/Medicare Health Plans**
- **Tests a direct-mail FIT program**
  - Uses a pre- post- design
- **Funded by the Centers for Disease Control**



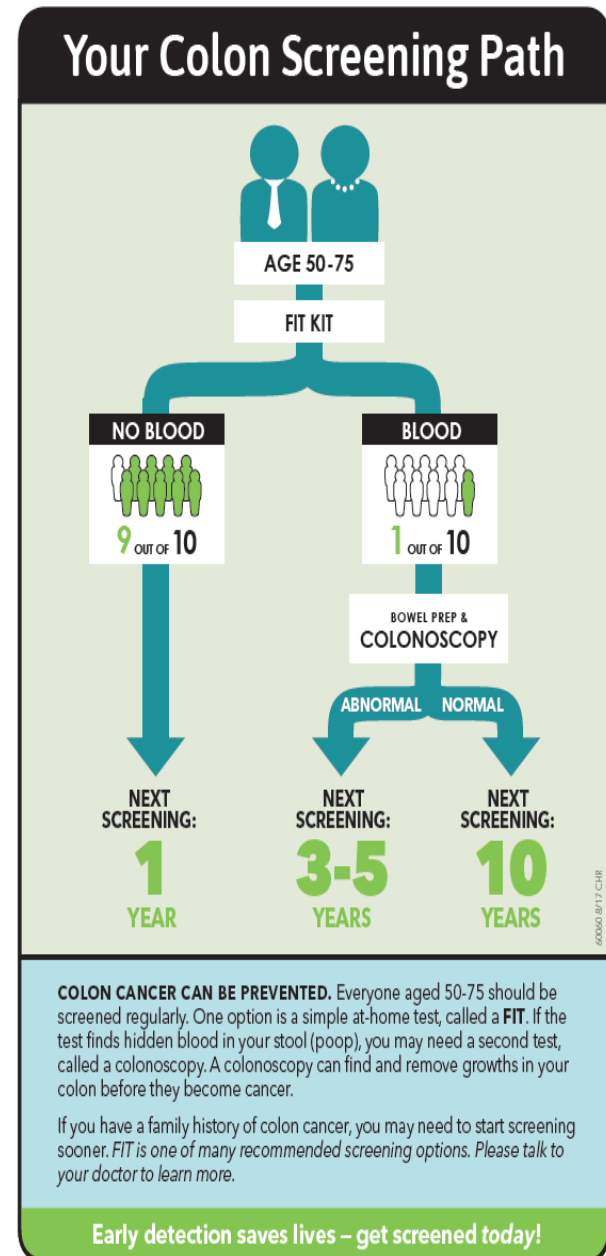
# Topic 6

## What's next

- Achieving higher rates of follow-up colonoscopy
- Using risk prediction models to identify high-risk patients

# The problem

- An estimated 8.7 million individuals complete a fecal test each year.
- Yet, not all individuals who test positive get a follow-up colonoscopy.
- For these patients, the benefit of fecal testing is nullified!

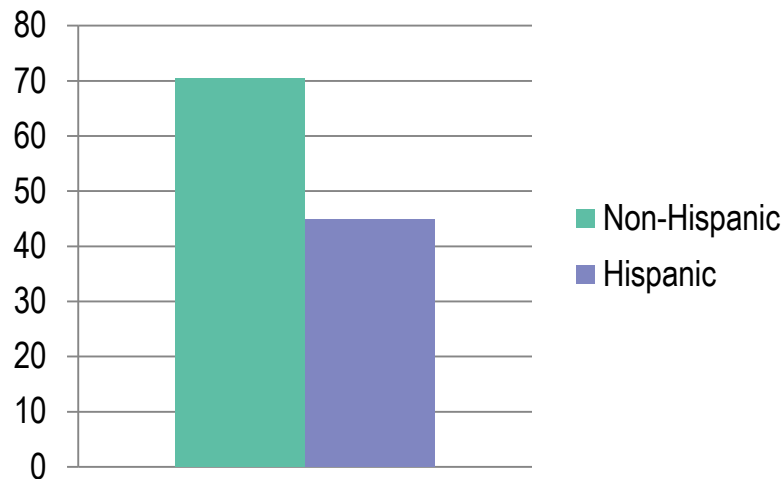


In safety net practices, only **52% - 54%\*** of individuals who screen positive on FIT obtain a follow-up colonoscopy.

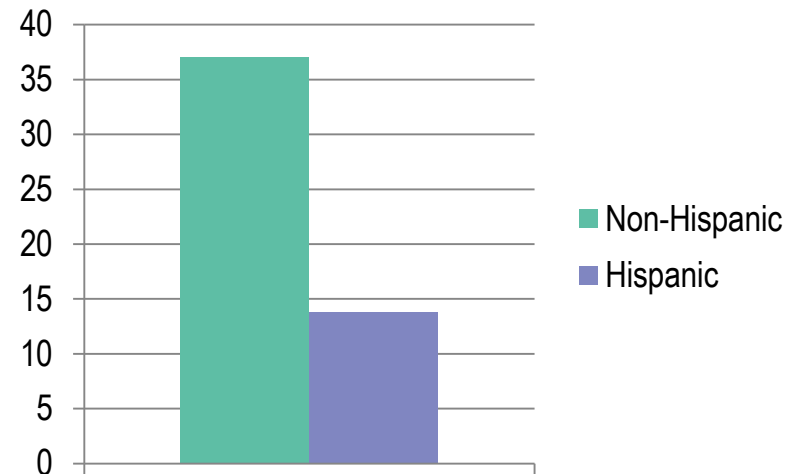
\* Liss et al. 2016; STOP CRC study

# Health disparities persist in follow-up colonoscopy rates

Colonoscopy receipt w/i 18 mo. (n = 32)



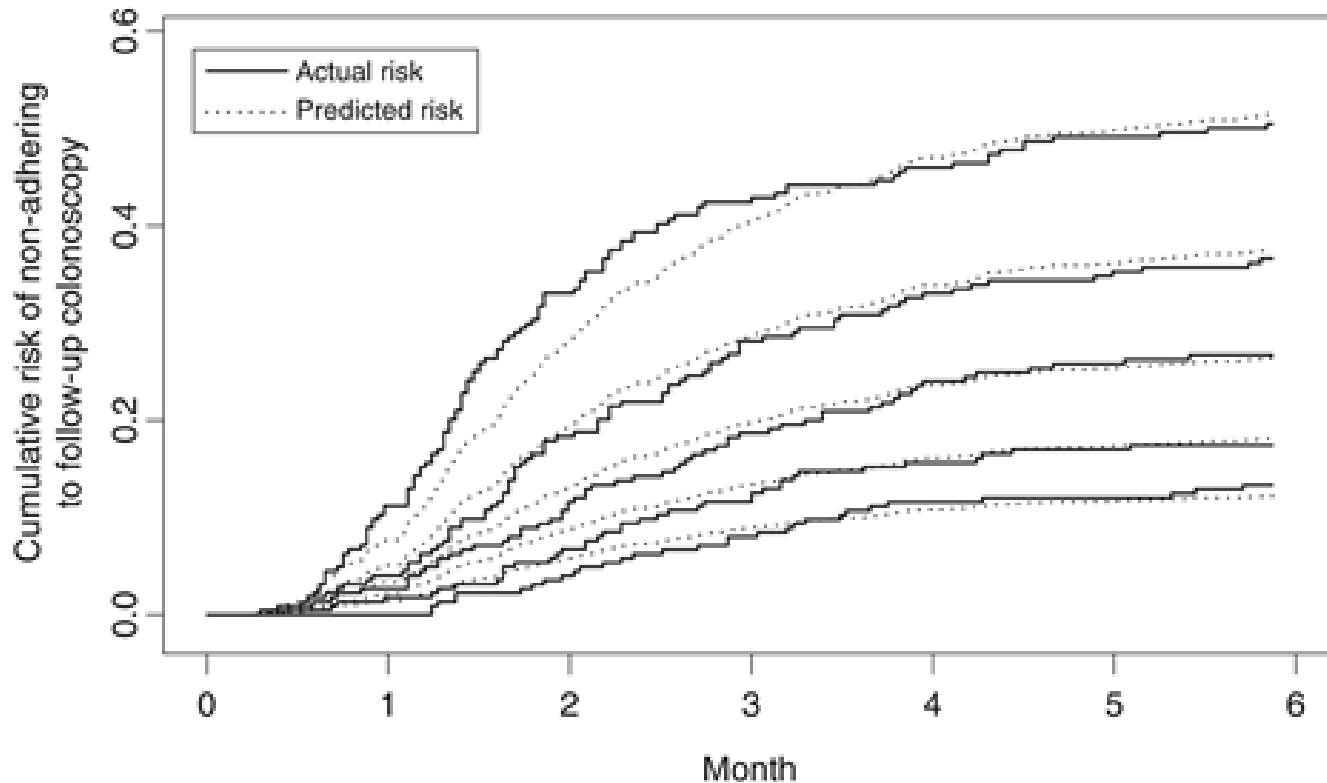
Colonoscopy receipt w/i 60 days (n = 14)



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

# Targeted patient navigation efforts

- PRECISE – Predicting and Assessing Follow-up Colonoscopy in the Safety Net



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## Mailed FIT – Resources to Optimize Colorectal Cancer Screening



- Mailed FIT
- Why Do It?
- Research Projects
- Program Materials
- Mailed FIT News
- Workflows

**Contact**  
Gloria Coronado, PhD

We, at the Center for Health Research, and with our partners, are trying to understand how to

75%



# Acknowledgements

## It takes a village...

- CHR research team:
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# Trends in CRC screening

## SCREENING BY YEAR



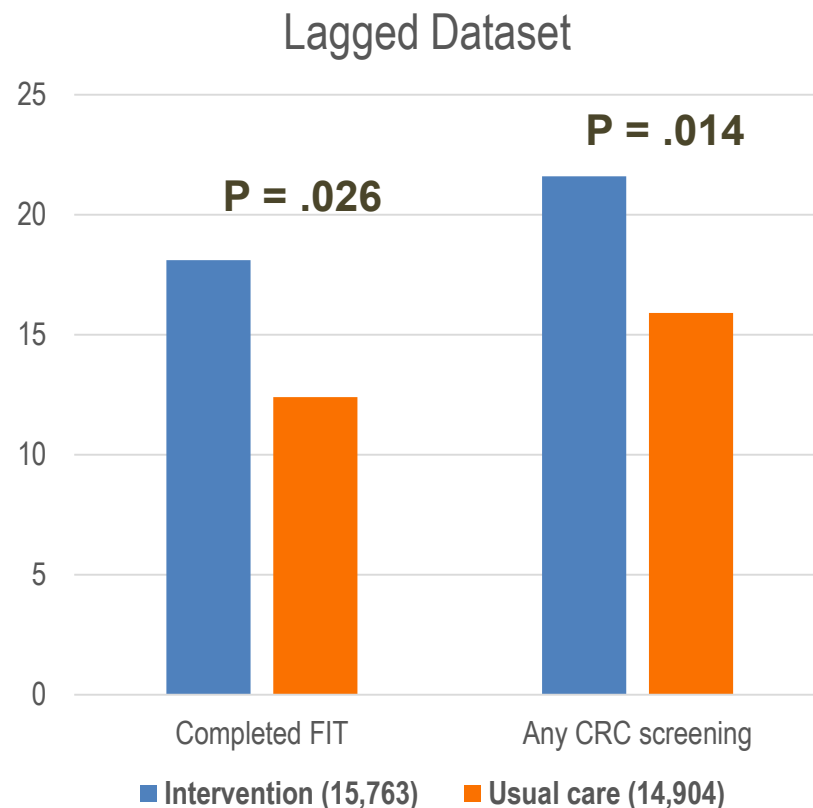
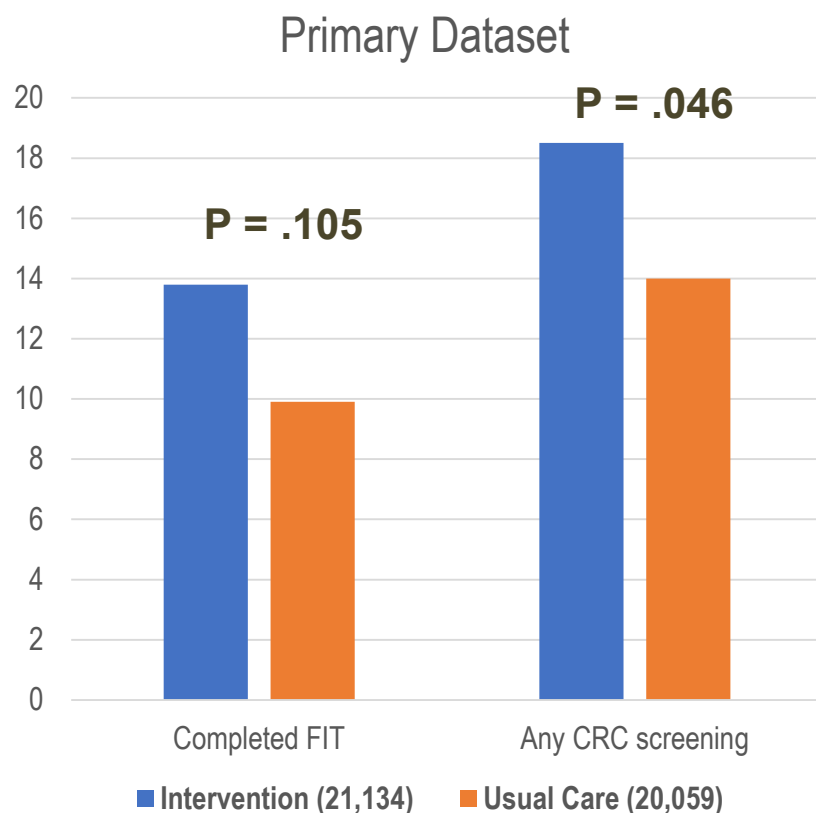
# Baseline clinic-level characteristics of eligible adults in analysis sample (n = 41,193)

	Intervention clinics (n = 13)		Usual care clinics (n = 13)	
	Median clinic % <sup>a</sup>	(range)	Median clinic % <sup>a</sup>	(range)
<b>Age (50-64)</b>	80	(73-85)	83	(72-88)
<b>Gender (Female)</b>	44	(38-56)	45	(35-51)
<b>Ethnicity (% Hispanic)</b>	8	(1-33)	15	(2-36)
<b>Language</b>				
<b>English</b>	90	(41-99)	86	(53-99)
<b>Spanish</b>	4	(0-26)	12	(1-31)
<b>Insurance status</b>				
<b>Medicaid</b>	36	(20-51)	35	(25-54)
<b>Medicare</b>	24	(20-37)	23	(15-36)
<b>Uninsured</b>	26	(3-40)	27	(2-38)
<b>Commercial</b>	10	(1-49)	11	(1-39)
<b>Federal poverty level</b>				
<b>&lt;100%</b>	47	(13-61)	45	(19-64)

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# Colorectal cancer screening completion intervention and usual care arm

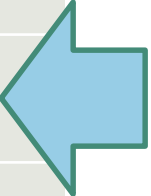


FIT completion differences were 3.8% in primary dataset and 5.6% in lagged dataset, adjusted for health center, age, and gender

# Per-protocol analysis

Per-protocol analysis

FIT return rate

<b>Patients who were mailed a FIT (OVERALL)</b>	<b>21%</b>	
<b>Clinics that consistently delivered reminders</b>	<b>25%</b>	
<b>Clinics that inconsistently delivered reminders</b>	<b>14%</b>	
<b>Clinics that did not deliver reminders</b>	<b>6%</b>	

# 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