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

Screening test	Mortality reduction*
Colonoscopy every 10 years	65%
FIT every year	64%
Flex sigmoidoscopy every 5 years	59%
Flex sigmoidoscopy every 5 years plus FIT every 3 years	66%

Promising Interventions in Vulnerable Populations (N = 27)

Intervention Classification	N studies	Does Intervention Improve FOBT/FIT Screening?	Strength of evidence
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 visit	5	Mixed	Low
Education with lay health advisors	4	Unclear	Low
Education with media (community)	1	Unclear	Insufficient
Education with media (clinic + community)	2	Mixed	Low

Davis et al. 2015 Systematic Review

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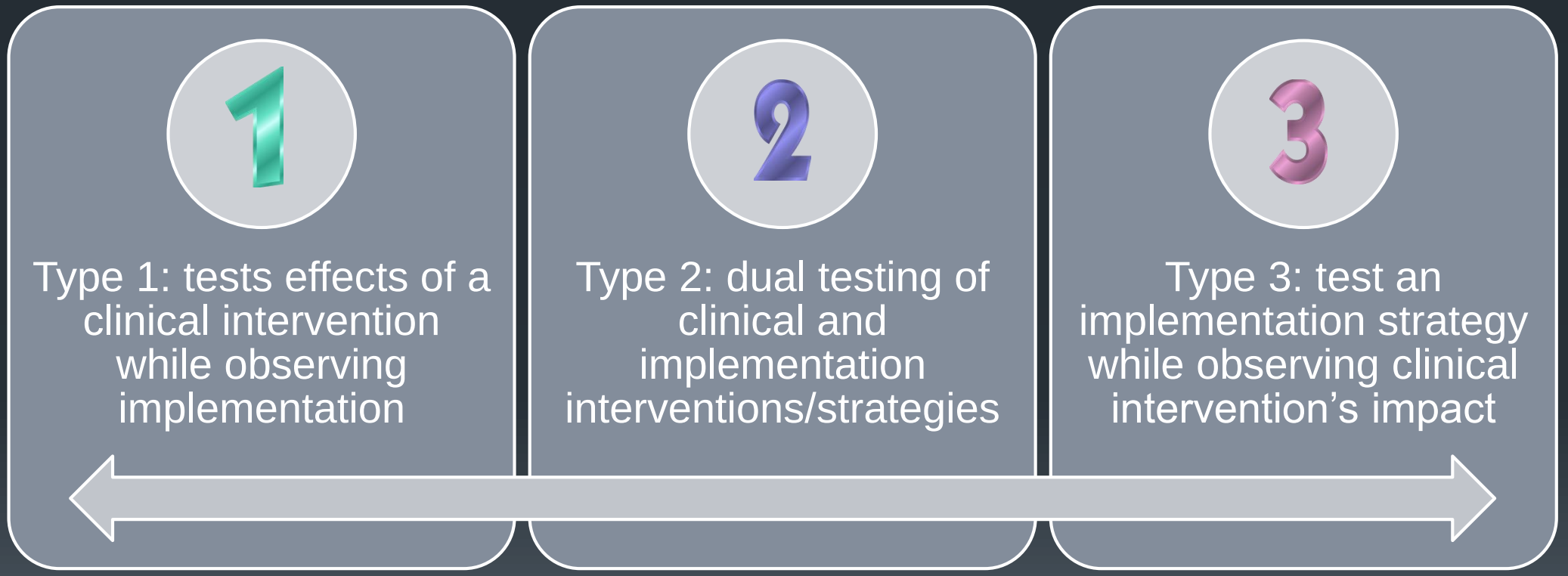
Background on STOP CRC

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.

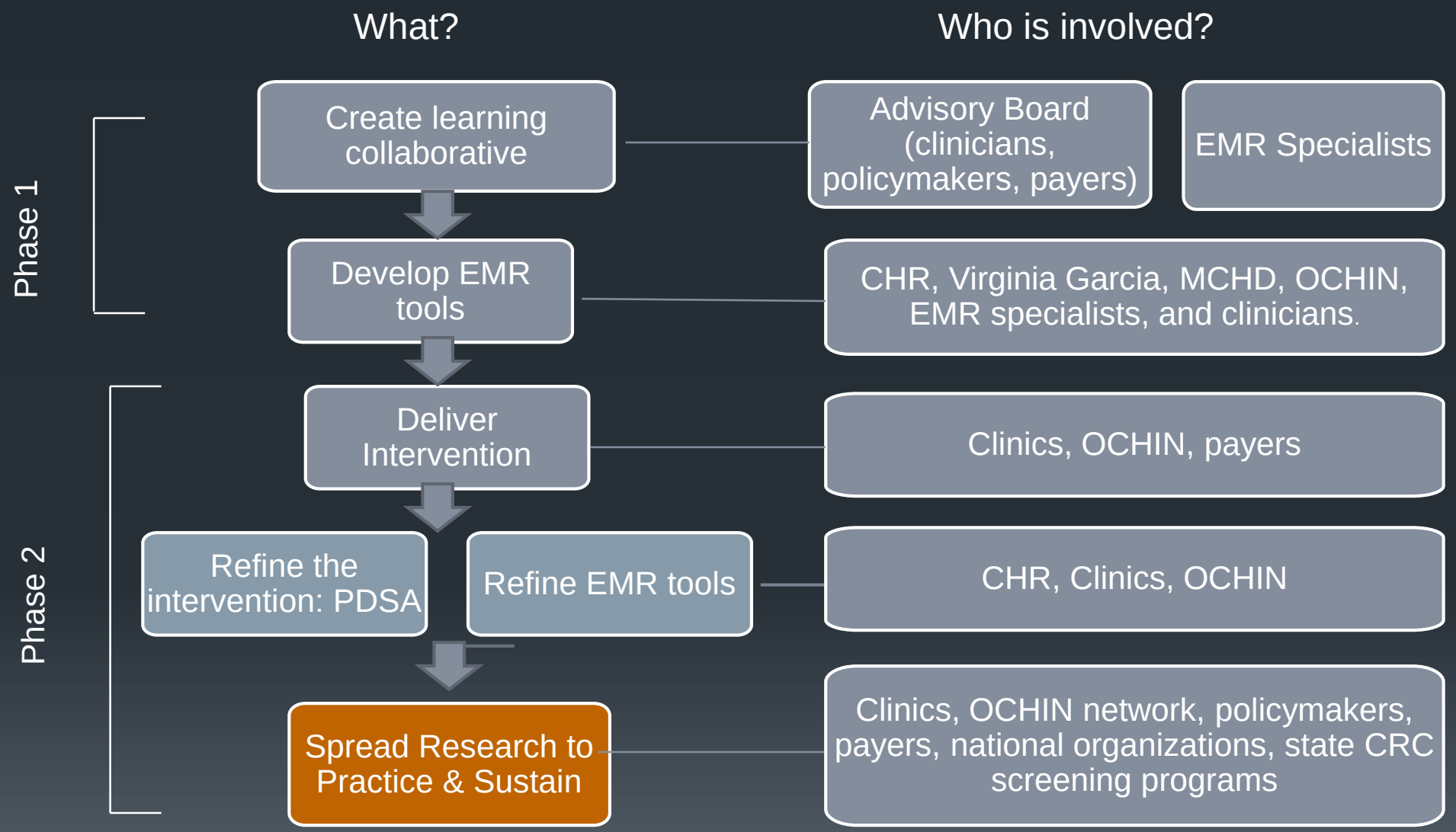
- Evaluation is guided by RE-AIM framework.

Effectiveness – Implementation hybrid designs



Curran, Mittman, 2015

STOP CRC Activities



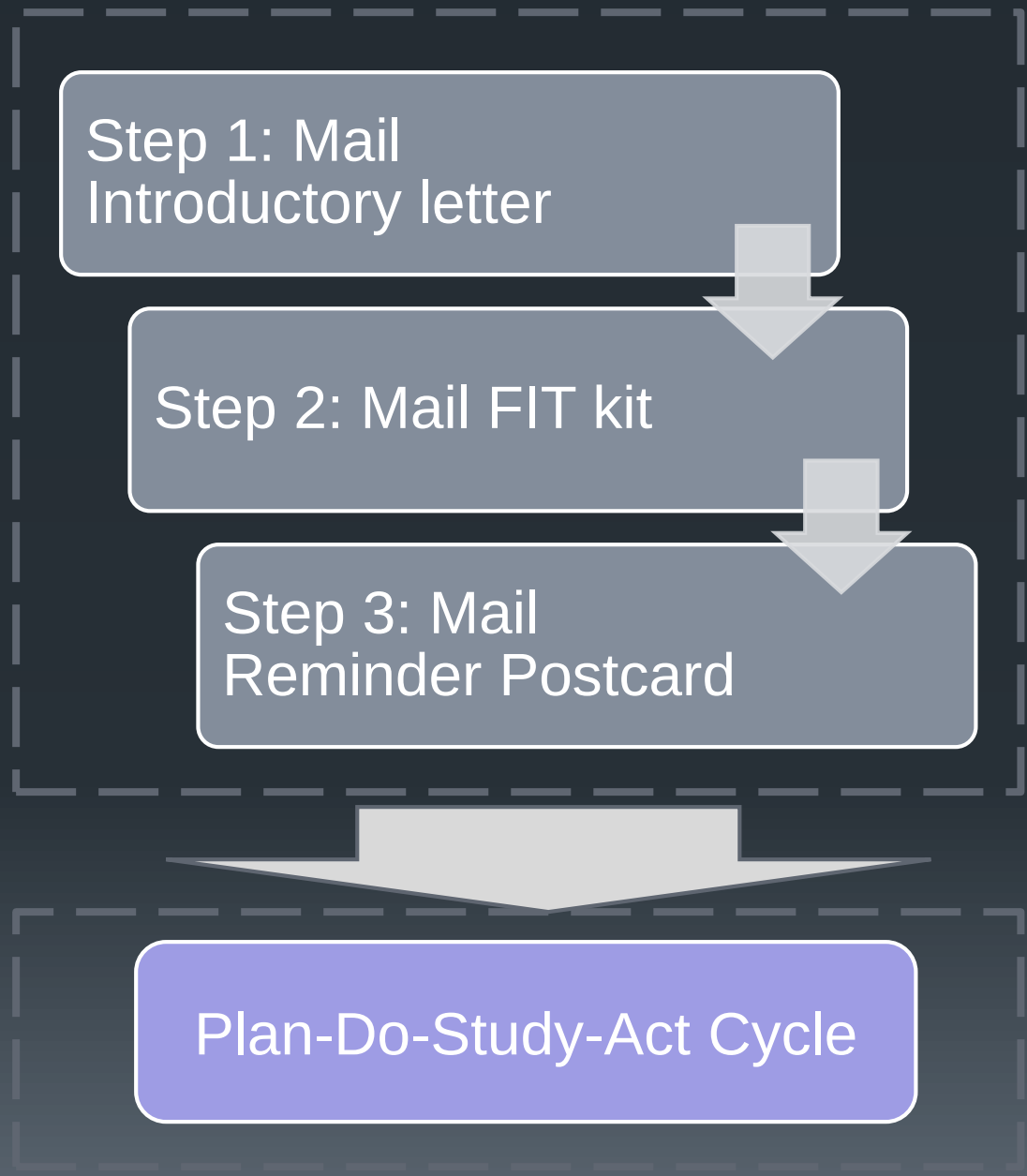
STOP CRC intervention

EMR tools in Reporting Workbench, driven by Health Maintenance;

Step-wise exclusions for:

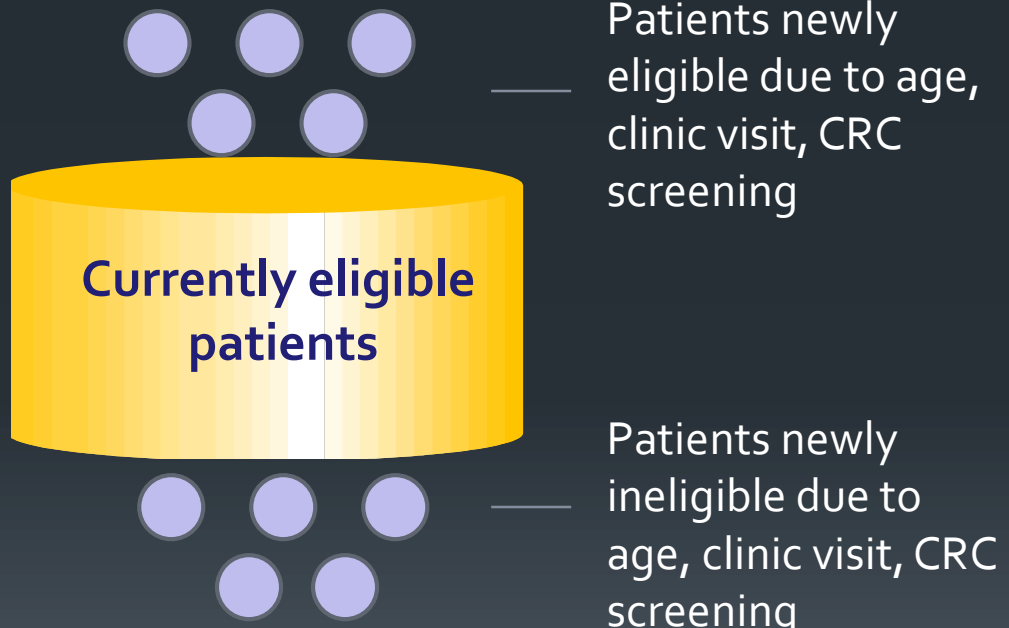
- Invalid address
- Self-reported prior screening
- Completion of CRC screening

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.



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

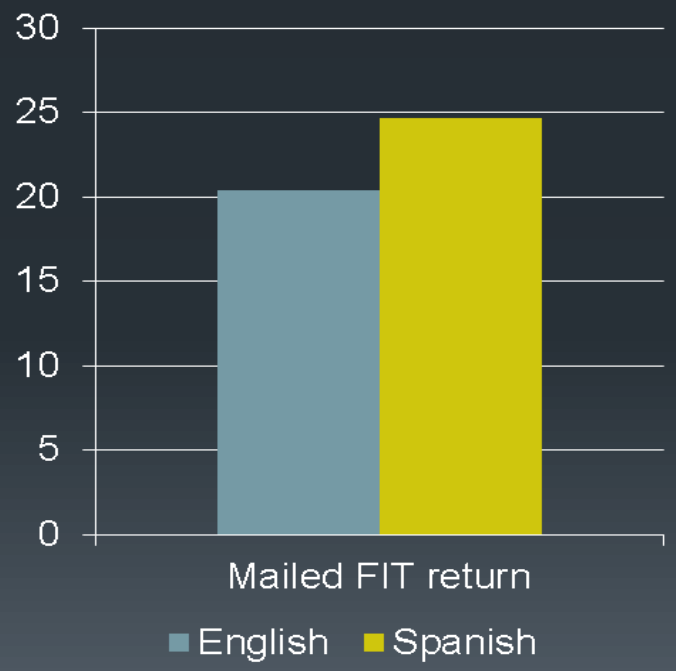
Virginia Garcia Memorial Health Center

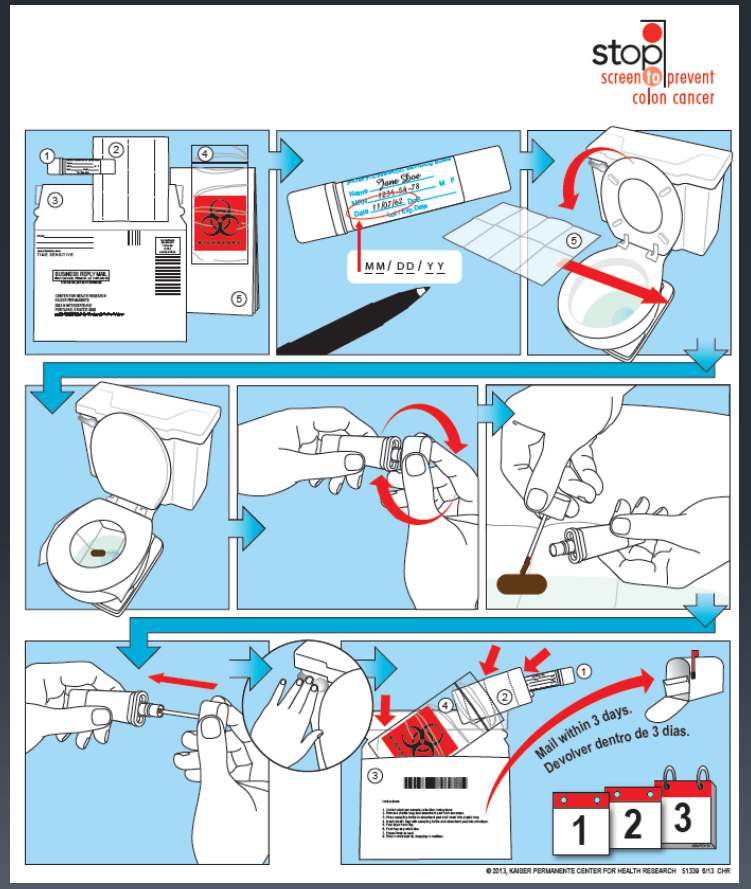
STOP CRC Pilot results

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

Direct-mailing reduces health disparity

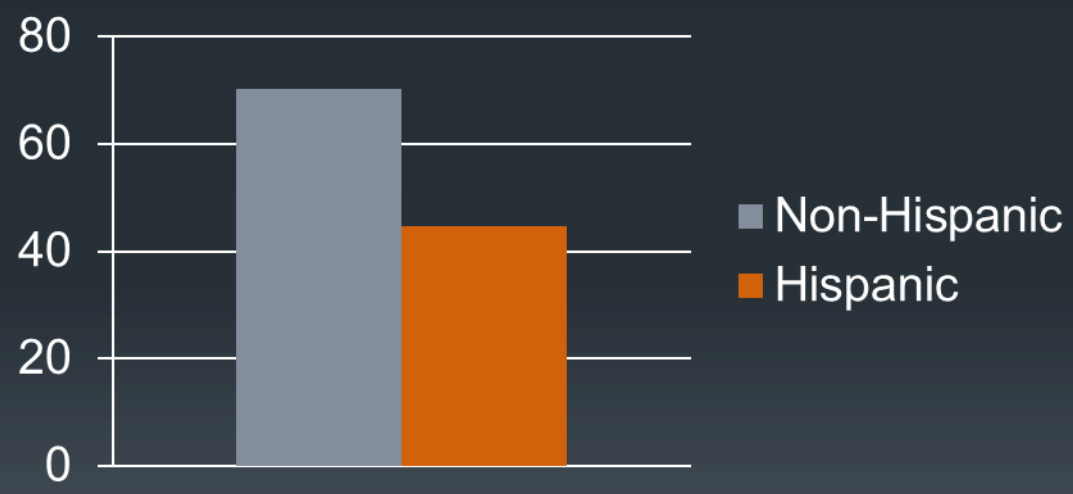
Response to direct-mail program (n = 1034)



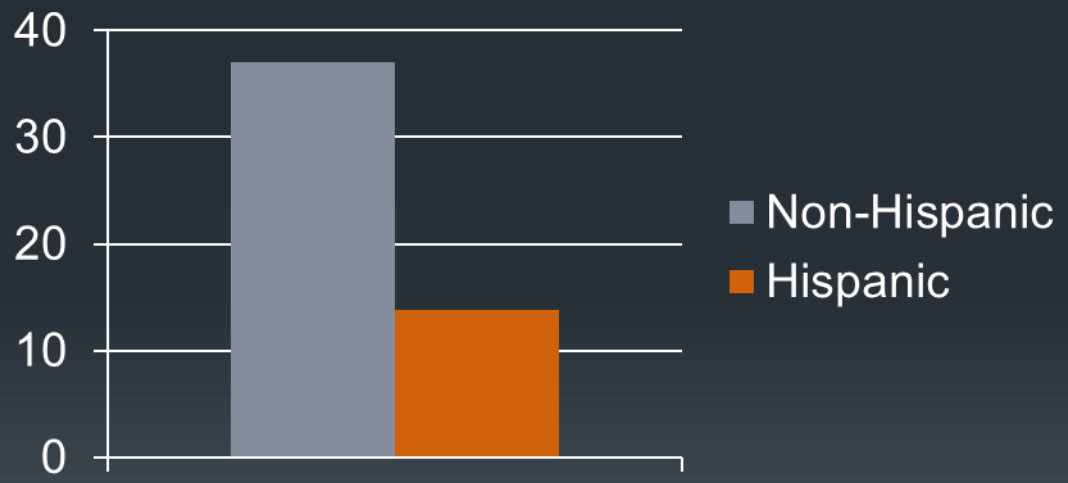


Health disparities persist in f/u colonoscopy receipt

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



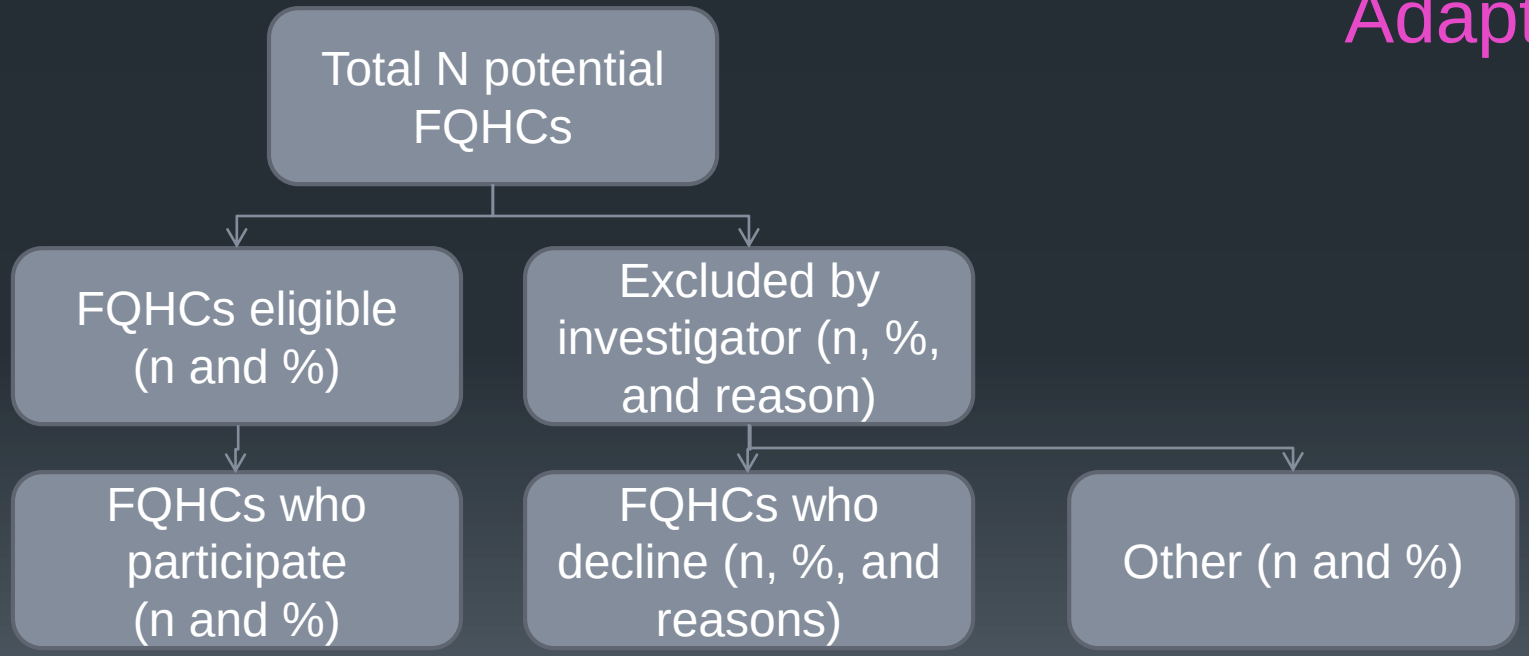
Colonoscopy receipt w/i 60 days (n = 14)



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

STOP CRC health center recruitment

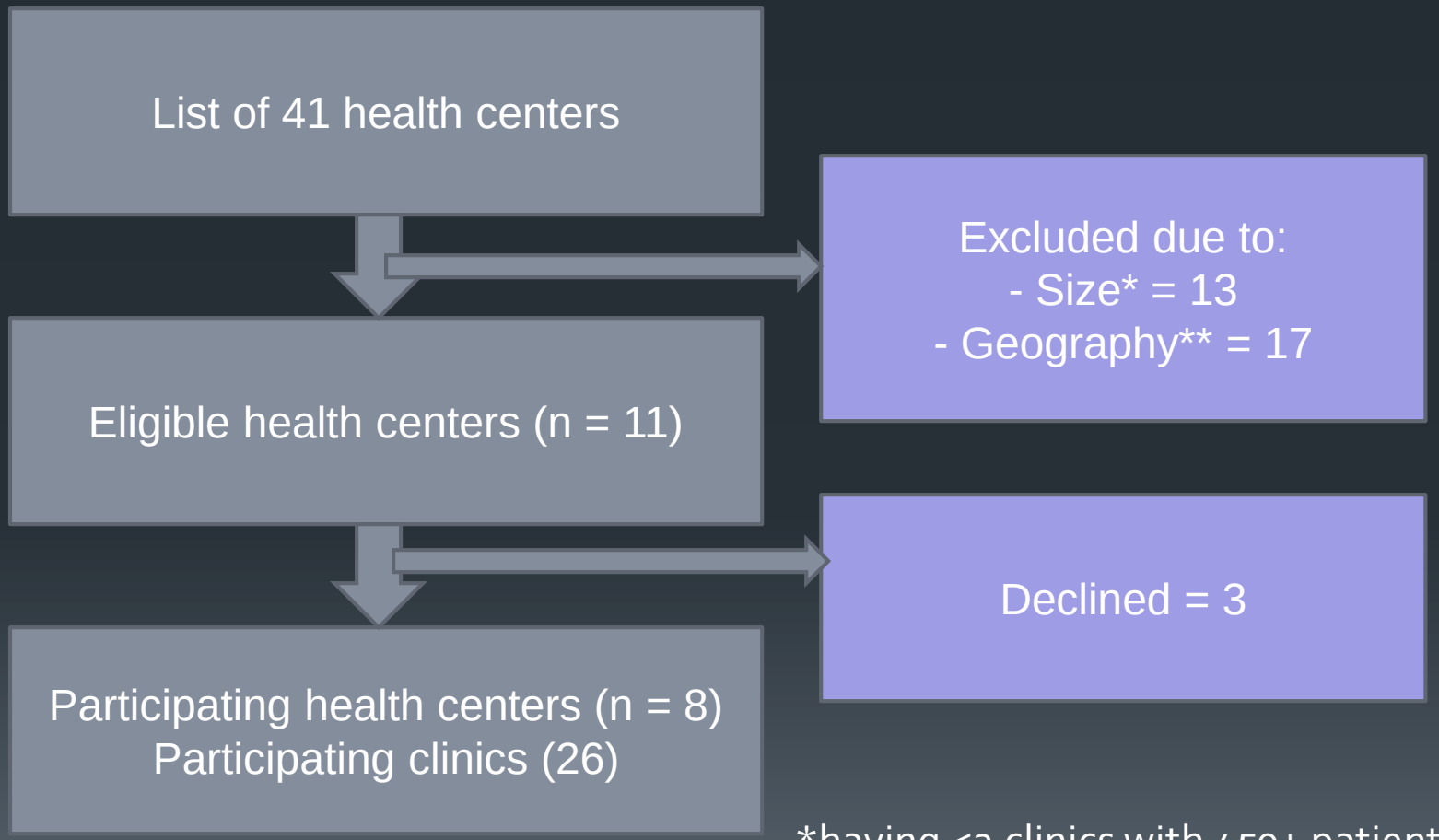
Adapted CONSORT



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).

CONSORT diagram



*having <2 clinics with 450+ patients
** Outside of Oregon, N California or Washington

Health center characteristics, by participation

	% Hispanic	% uninsured	% Medicaid	CRC screening rate (%)
Health Center 1	9	49	15	20
Health Center 2	7	38	17	23
Health Center 3	17	50	14	20
Health Center 4	14	33	37	39
Health Center 5	10	40	15	33
Health Center 6	5	2	19	53
Health Center 7	2	11	20	33
Health Center 8	36	37	26	34
Health Center 9	4	23	12	16
Health Center 10	37	30	5	14
Health Center 11	15	30	16	14

Participating sites

Non-participating sites

Coronado et al. 2015

Reasons for participation & non-participation

Participation

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

Non-participation

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

*Consolidated Framework for Implementation Research

Coronado et al. 2015

Plan-Do-Study-Act Cycles were important

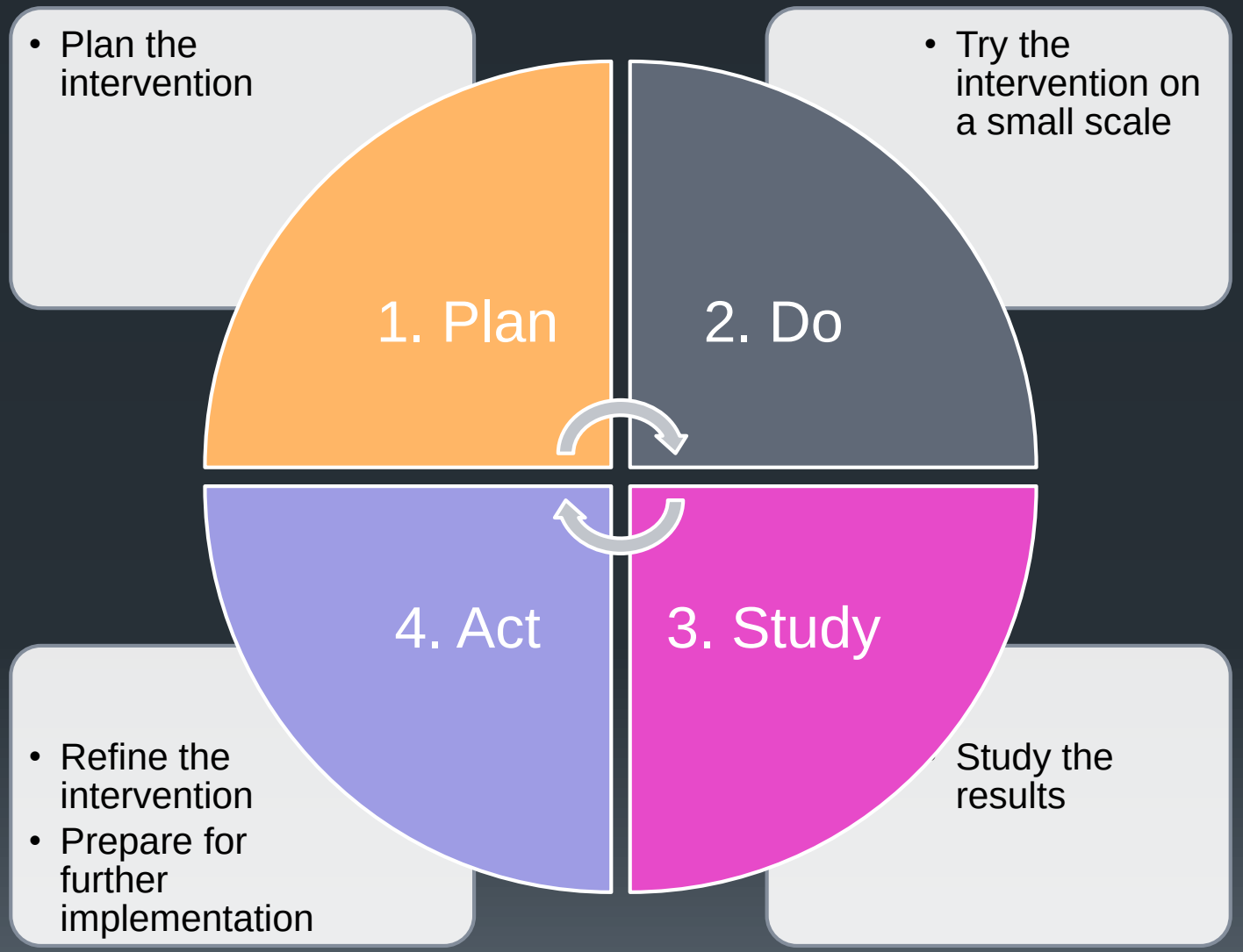
STOP CRC IMPLEMENTATION

STOP CRC Implementation

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

Based on data from 2-years of STOP CRC

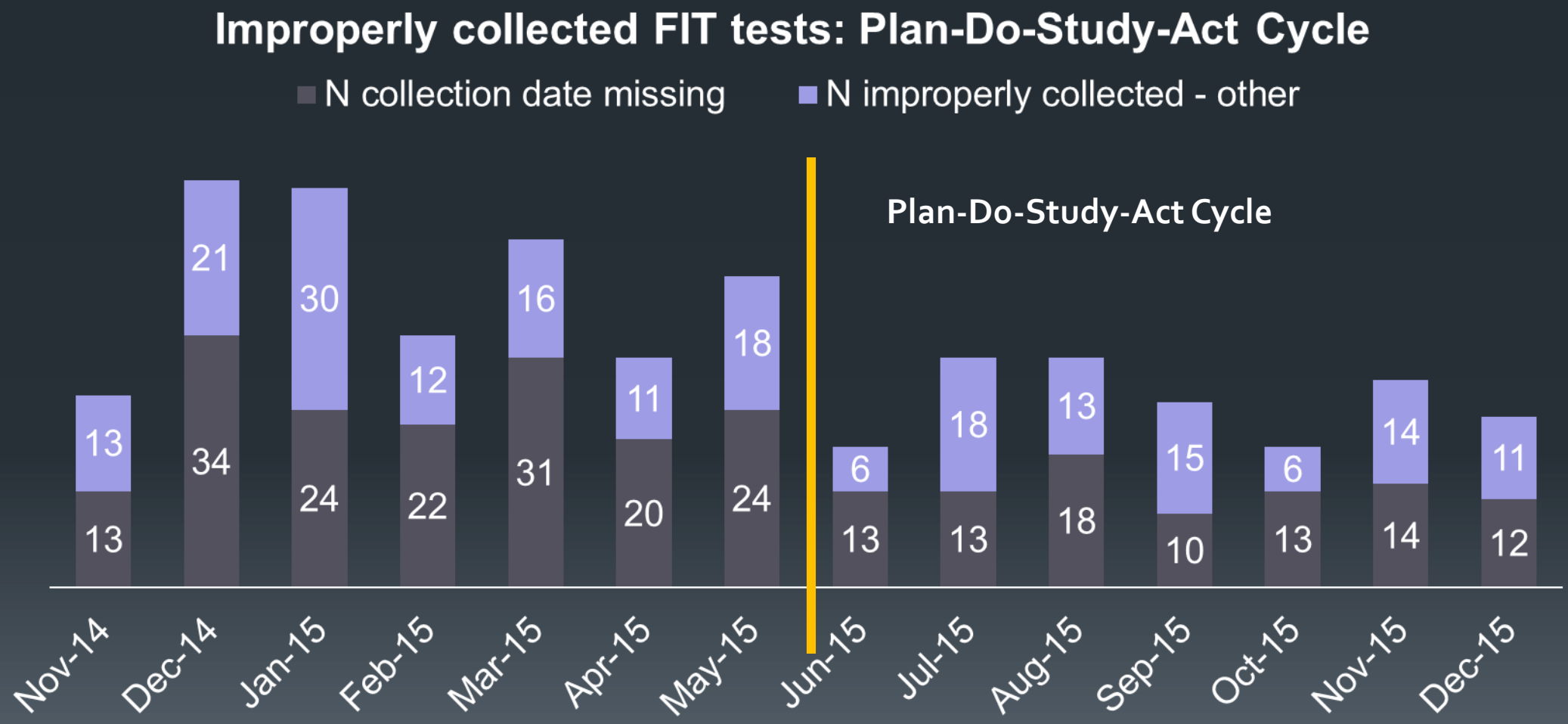
Process Improvement: Plan –Do –Study –Act



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



Data source: Multnomah County Health Department

Action Taken: Highlighted Instruction on Letter

Multnomah County
Health Department

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

stop screen to prevent colon cancer

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

Multnomah County
Health Department

尊貴的 客户端,

這是一個在您出現您狀前提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。本測試將檢查您的結腸健康狀態，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

stop screen to prevent colon cancer

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 iEnsures 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 «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 телефону503-988-5558

Спасибо!

Marty Grasmeder, MD
медицинского

MULTNOMAH COUNTY HEALTH DEPARTMENT #503-988-5558

Action taken: Added Reminder with Instruction

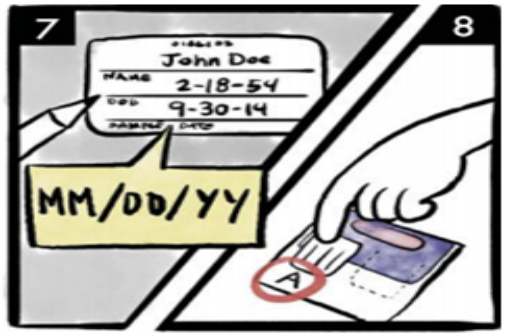
- Don't forget to put the date you collected your poop sample
- No olvide poner la fecha en la que recolectó la muestra de popó.
- 别忘了填寫您採集大便樣本的日期。
- Не забудьте указать дату, когда вы собрали анализ кала

Last Name, First Name
DOB: 01/01/1980
MRN: 1234567

Date:_____

Last Name, First Name
DOB: 01/01/1980
MRN: 1234567

Date:_____



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/

STOP CRC 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

$$\frac{\text{Target Population Reached}}{\text{Target Population}}$$

(For STOP the target population = clinic patients age eligible and overdue for CRC screening)

Reason Not Reached	Percent of People	Outcome
No or bad address	5%	95% Reach
Not on clinic list	14%	81% Reach
Clinics did not mail kit	35-80%	20-65% Reach
Individuals willing to participate (return FIT)	In Process	Effectiveness as Practiced
Effectiveness % completing based on everyone targeted	In Process	Intent to Treat Effectiveness

“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:

Tools enabled by STOP CRC
Reporting Workbench, customized for CRC screening
Batch communication (mailing)
Bulk ordering

- STOP CRC tool dissemination:

Type of health system	N sites
Clinics within STOP CRC health centers	39 clinics
OCHIN-affiliated clinics	Network includes 89 health centers
Non-OCHIN-affiliated clinics	34 Sea Mar clinics

SPREAD TO SEA MAR CHC

Sea Mar Community Health Center

- 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.

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