



Flu-FIT Programs: Maximizing Opportunities for Colorectal Cancer Screening

Michael Potter, MD

Professor, Family and Community Medicine

Director, San Francisco Bay Area Collaborative Research Network

University of California, San Francisco



Clinical and Translational Science Institute / CTSI

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Objectives

- Describe the need for innovative approaches to address colorectal cancer screening disparities
- Describe the evidence-based Flu-FIT program
 - Research and Best Practices
- Review Flu-FIT materials and discuss keys to successful implementation.
- Answer questions and discuss issues specific to resource-limited rural and urban health settings

US Colorectal Cancer Statistics

CA: Cancer J Clin, 2012;62:10-29, *MMWR* 2011;60:884-9; and *CA: Cancer J Clin*,2014;64:104-117.

- 3rd leading cause of cancer in adults
 - >140,000 new cases/yr
- 2nd leading cause of cancer death in adults
 - >50,000 deaths/yr
- US mortality reductions in last 35 years
 - 28.6/100,000 1976 → 16.7/100,000 in 2007
 - Half of the reduction is believed due to screening
- US incidence reduction of more than 30% in the last decade

Colorectal Screening – USPSTF (2008)

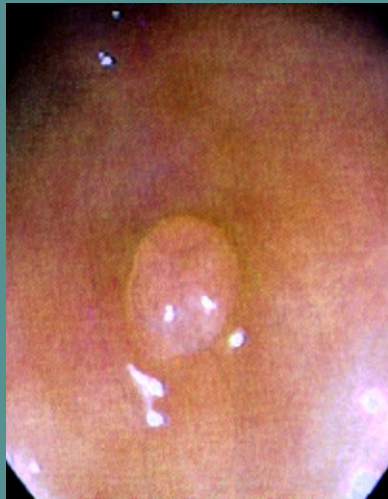
- Which Tests: *(A Level)*
 - *Fecal Occult Blood Tests annually (preferably with high sensitivity guaiac tests or fecal immunochemical tests),*
 - *Flexible Sigmoidoscopy every 5 years with interval FOBT every 3 years, or*
 - *Colonoscopy every 10 years*
- When to Test
 - *Ages 50-75 (A Level)*
 - With discretion ages 76-85 (C Level)
 - Do not screen after age 85 (D Level)

Why Stool Testing Gets an “A” from USPSTF

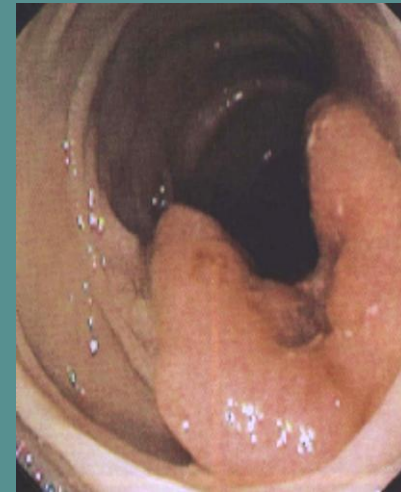
When provided annually to average risk patients with appropriate follow up, high sensitivity guaiac fecal occult blood tests (HSgFOBT) or fecal immunochemical tests (FIT) can provide the *same number of life-years gained* as colonoscopy-only strategies.

Zauber AG et.al. Ann of Int Med. 2008, 149; 659-669

CRC Screening – How it saves lives



• **Adenoma**



• **Carcinoma**

- *Most carcinomas develop **over many years**. Goal is to find and remove advanced adenomas and early stage cancers.*

CRC Screening in the US & South Dakota

(CDC BRFSS data, 2012)

	Any FOBT last 12 mos	Lower Endoscopy last 10 yrs	Either Test
United States	10.4%	61.7%	65.1%
South Dakota	5.9%	62.0%	64.4%

National Campaign -- 80% by 2018

What are some of the disparities?

(MMWR 2011;61:41-5)

US CRC Screening Rate (NHIS data): 59%

Other Disparities				
Age 50-64	55%		Age 65-75	68%
No HS diploma	45%		College graduate	67%
Foreign born (in US<10yrs)	21%		US born	61%
No source of care	21%		Has usual source	62%
No insurance	21%		Private/military	65%

Disparities by race and ethnicity

(CDC BRFSS data, 2012)

US CRC Screening Rate (NHIS data): 59%

	Any FOBT last 12 mos	Lower Endoscopy last 10 yrs	Either Test
White (non-Hispanic)	9.2%	58.5%	61.5%
Black (non-Hispanic)	8.4%	53.0%	55.5%
Asian	6.9%	44.5%	45.9%
American Indian / Alaska Native	6.1%	46.5%	48.1%
Hispanic / Latino	5.6%	45.3%	47.0%

What are the national trends?

MMWR 2011;60:884-9.

- Over the last decade colonoscopy rates continue to increase so that more than 60% adults age 50-75 have had one?
- At the same time, FOBT rates have dropped from over 20% in the last year down to approximately 10% in the last year.
- *In the “AGE OF COLONOSCOPY” ... what are we going to do for those average risk patients who prefer inexpensive, non-invasive procedures or have limited access?*
- *How will we reach the ACS/CDC goal of “80% by 2018” without more emphasis on FOBT?*

Advantages of HSgFOBT and FIT...

- Inexpensive and Accessible
- Can be offered by any member of the health team
- Can be done in privacy and at home
- Is non-invasive and has no risk of pain, bleeding, bowel perforation, or other adverse outcomes
- Only requires colonoscopy if abnormal
- Many patients prefer it.

But, creating a High Quality HSgFOBT or FIT Program still Requires Work.

- Select and order HSgFOBT or FIT kits appropriate for your setting
- Identify eligible patients, organized in-reach and outreach
- Train staff to communicate with patients using appropriate, often tailored test instructions for home use
- Assure high test completion rates, and implement high quality test processing procedures.
- Assure annual test completion if normal
- Follow up abnormal results with colonoscopy

Especially Important in resource limited settings: Assure Colonoscopy Access Before You Start

- If you give out 1000 FIT kits, then expect:
 - 500 kits to be returned (50% return rate)
 - 25 abnormal tests (5%) requiring colonoscopy follow-up.
- Additionally, you may identify patients with higher than average risk who should get colonoscopy instead of FIT
- *Don't start program until you have resources to provide follow-up.*

•Which Stool Tests to Use?



- Avoid standard guaiac FOBT – not as sensitive as HSgFOBT or FIT.
- HSgFOBT requires dietary changes and have higher false positive rate
- Immunochemical Tests (FIT) eliminate dietary restrictions and can be completed and returned without delay.
- Use brands that have been tested in large clinical trials. Ideally, should be developed in a laboratory using automated readers rather than in the clinic.

Flu-FOBT and Flu-FIT Programs: *Why Pair CRC Screening with Flu Shots?*

- Creates a screening opportunity for individuals not reached or responding to other methods.
-
- Engages non-clinician staff in an efficient, yearly cancer screening campaign, and promotes awareness of best practices to deliver HSgFOBT/FIT
- Provides a message to clinic staff, patients and the community that “Just like flu shots, home stool tests should be done every year”

AND, *in the process, your clinical team will learn what it takes to a good job with HSgFOBT and FIT.*

San Francisco General Hospital Family Health Center



Colorectal Cancer Screening *and you*



• 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!

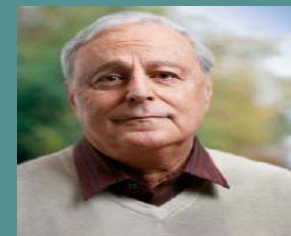
• Có Thể Ngừa Được Ung Thư Ruột Già!

- Xét nghiệm phân hằng năm làm dễ dàng.
- Xét nghiệm phân hằng năm có thể cứu sinh mạng quý vị.
- Bác sĩ và y tá đề nghị làm xét nghiệm ung thư ruột già 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

(Ann Fam Med, 2009;7:17-23)

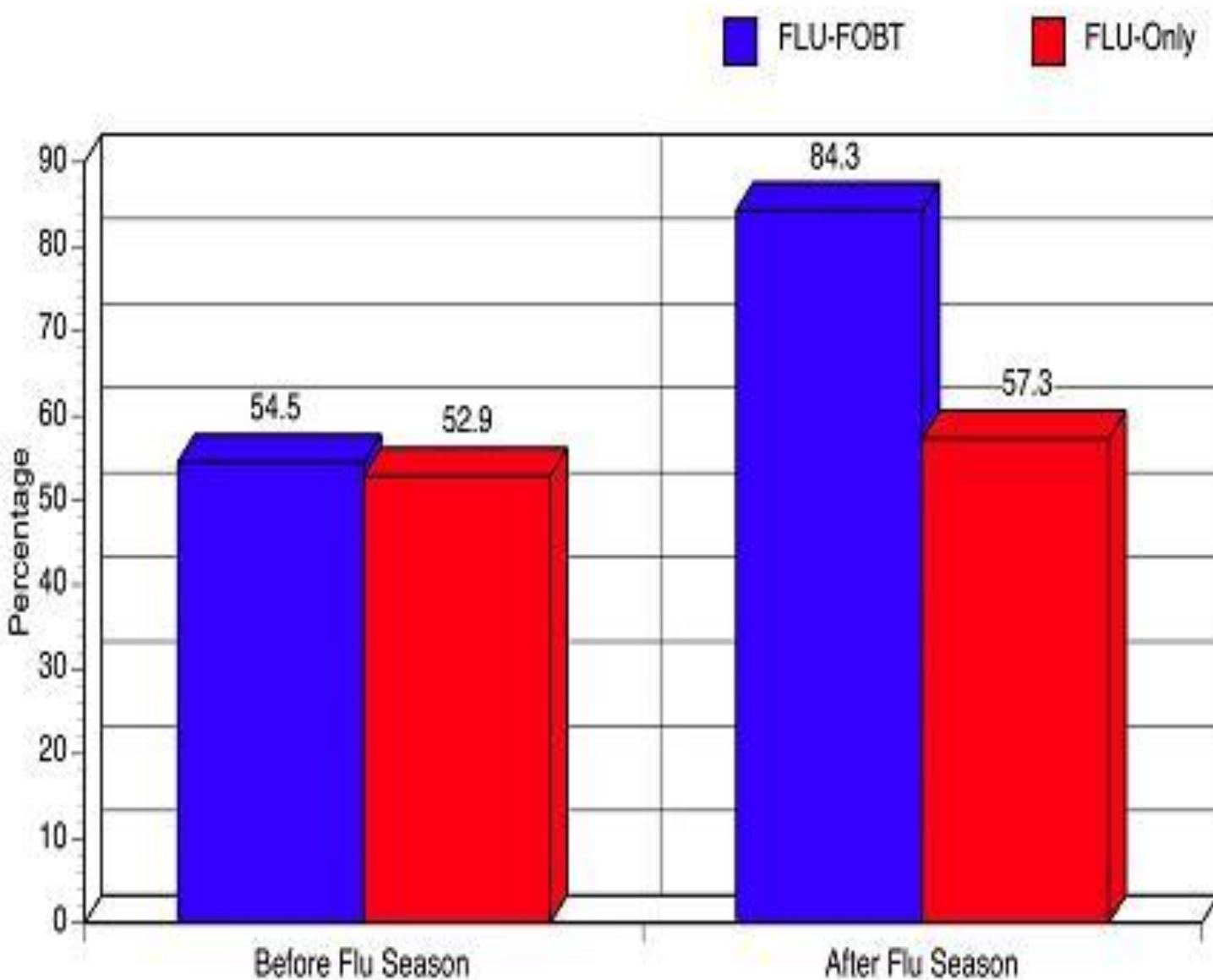
Intent-to-treat analysis, all flu shot patients assessed for eligibility by research staff beforehand, with telephone reminders

	FLU Only Arm N=246	FLU-FOBT Arm N=268
CRCS Up-to-Date Before (Oct 2006)	52.9%	54.5%
CRCS Up-to-Date After (Mar 2007)	57.3%	84.3%
Change: $p < 0.001$	+4.4 points	+29.8 points

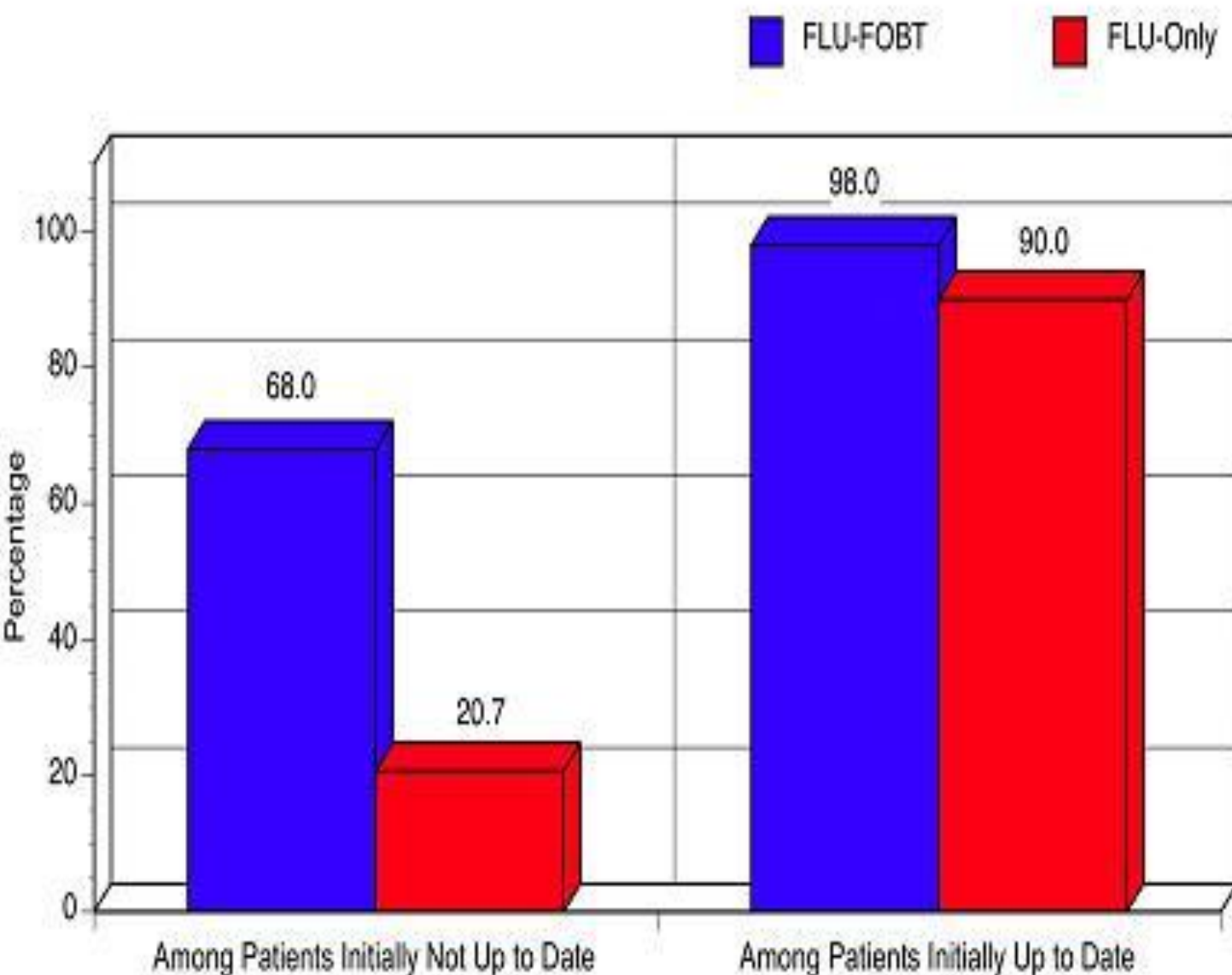
Odds Ratio for Unscreened Becoming Screened in
Multivariate Analysis: 11.3 (5.8-22.0)

CRCS up to date defined as having FOBT within 12 months, FSIG within 5 years or colonoscopy within 10 years

Change in Percentage of Patients up to Date with Colorectal Cancer Screening During Flu Season



Percentage of Patients up to Date with Colorectal Cancer Screening by End of Flu Season: Subgroup Analyses



Flu-FOBT and Flu-FIT

Dissemination Research Projects

- San Francisco Dept of Public Health
 - CDC R18 Grant (2008-2011) **“Translation of an Evidence-Based Colorectal Cancer Screening Intervention to Primary Care Settings Where Disparities Persist”**
- Kaiser Permanente Northern California
 - HMO Cancer Research Network (2008-2009) **“Preparation for the FLU-FIT Program at Kaiser Permanente Santa Clara”**
 - ACS Research Scholars Grant (2009-2012) **“Colorectal Cancer Screening During Annual Flu Shot Clinics at Kaiser Permanente”**
- Walgreens Pharmacies
 - Stewart Trust (2009-2010) **“Comparison of CRC education vs FIT distribution in an Annual Flu Shot Campaign”**

Randomized Trial: 6 CHC's in San Francisco integrating Flu-FOBT into Primary Care Visits (i.e. not just during flu shot clinics)



Results – RCT in 6 SFDPH Clinics

(Am J Prev Med, 2011)

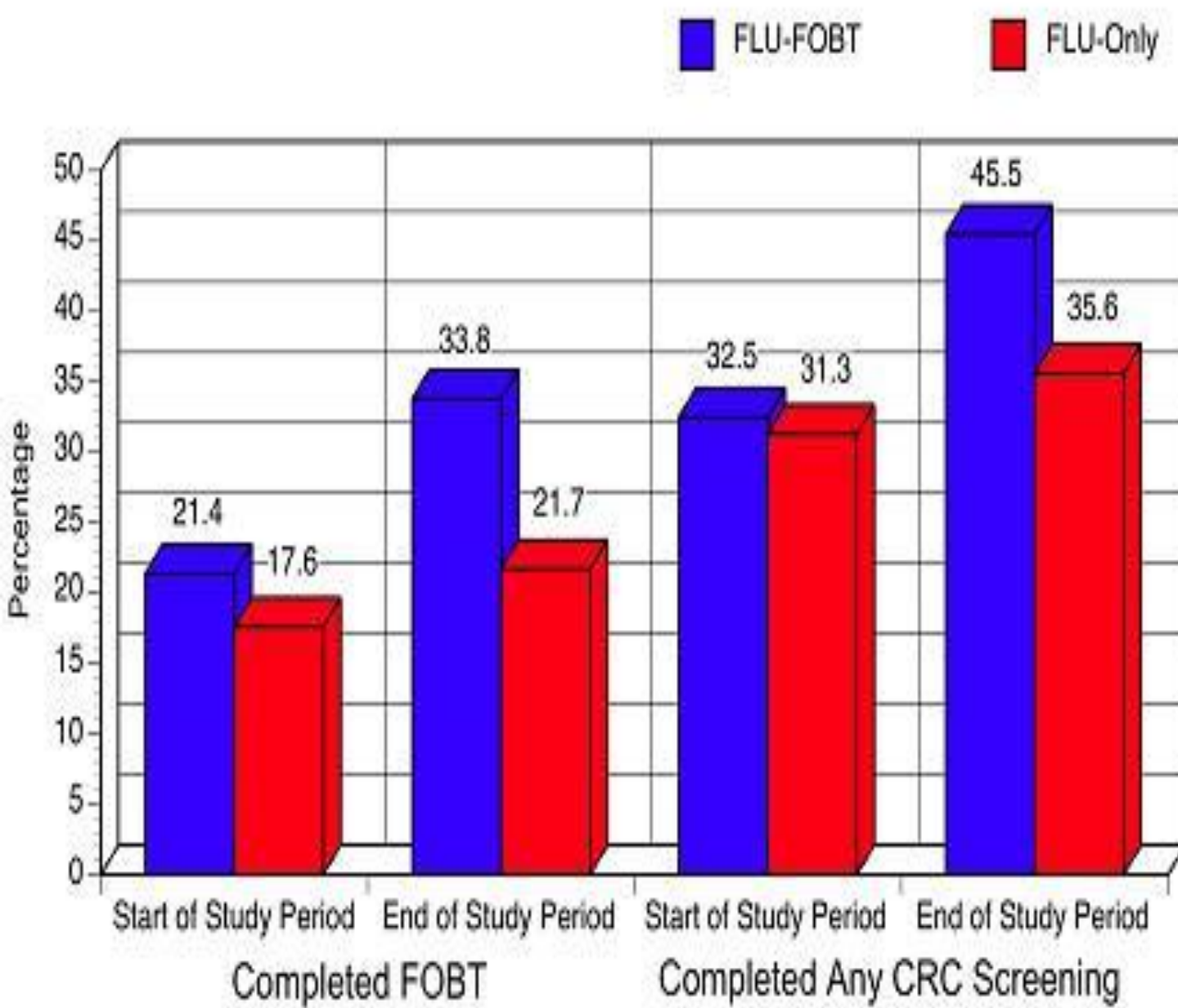
Intent -to-treat analysis , eligibility assessed during flu shot clinic by nursing staff, with no post-intervention phone calls

Data for flu shot recipients in 6 SFDPH clinics	FLU Only Arm N=677	FLU-FOBT Arm N=695
CRCS Up-to-Date before (Oct 2009)	31.3%	32.5%
CRCS Up-to-Date After (Mar 2010)	35.6%	45.5%
Change (p=0.02)	+4.3 points	+13.0 points

Odds Ratio for Unscreened Becoming Screened in Multivariate Analysis: 2.22 (1.24-3.95)

CRCS up to date defined as having FOBT within 12 months, FSIG within 5 years or colonoscopy within 10 years

Change in Past-Year Colorectal Cancer Screening Rates (FOBT and any CRCs Test) during Study Period



Lasting Results of the Intervention

(Health Educ Research , 2012)

Observational Data -- Established patients aged 50-75

Data for 6 SFDPH clinics participating in the FLU-FOBT RCT	Number of Flu Shot Recipients N	CRCS Up-To-Date Among Flu Shot Recipients N (%)
March 2008 (before)	3260	1385 (42.5%)
March 2009 (after)	3634	1982 (54.5%)
March 2010 (1 yr later)	4333	2440 (55.8%)

- *More Patients got Flu Shots and CRCS over time*

CRCS up to date defined as having FOBT within 12 months, FSIG within 5 years or colonoscopy within 10 years

FLU-FIT Program at Kaiser Permanente





Kaiser RCT: Fresno, Richmond, Redwood City, South San Francisco and Union City (with less support, no postcard reminders)



Results – KPNC RCT

(Am J Pub Health, 2012)

Intent-to-treat analysis, patients due for screening

Test(s) completed within 90 days	FLU Only Arm N= 2884	FLU-FIT Arm N=3351	P value
FIT	336 (11.7%)	900 (26.9%)	<0.001
Flex Sig	68 (2.4%)	62 (1.9%)	0.16
Colonoscopy	61 (2.1%)	86 (2.6%)	0.24
Any Test	438 (15.2%)	996 (29.7%)	<0.001

Odds Ratio: 2.77 (2.41-3.18);

Outcomes similar for all demographic subgroups in stratified analyses.

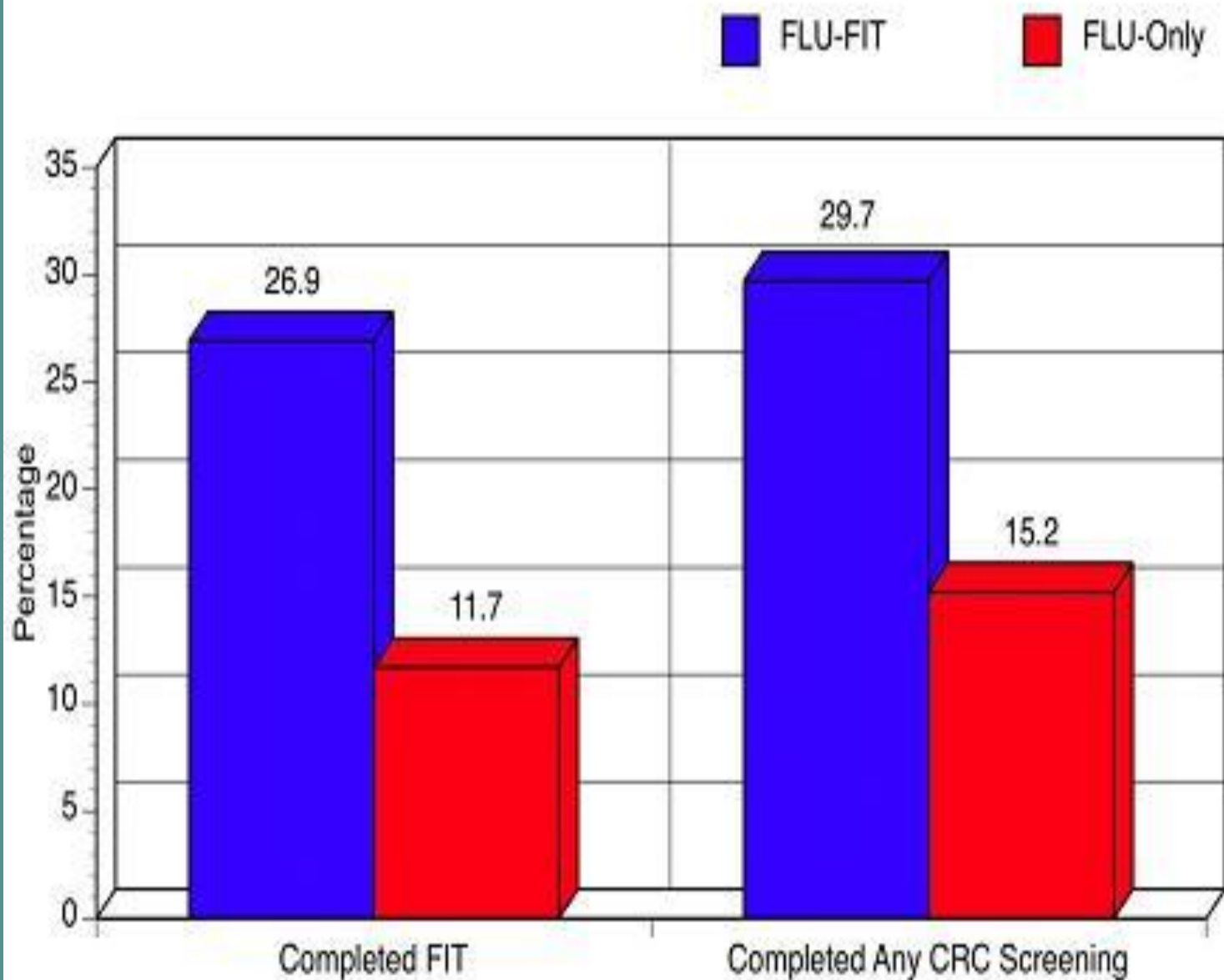
In FLU-FIT Arm,

53.9% of eligible patients given FIT (range 47%-60% by facility)

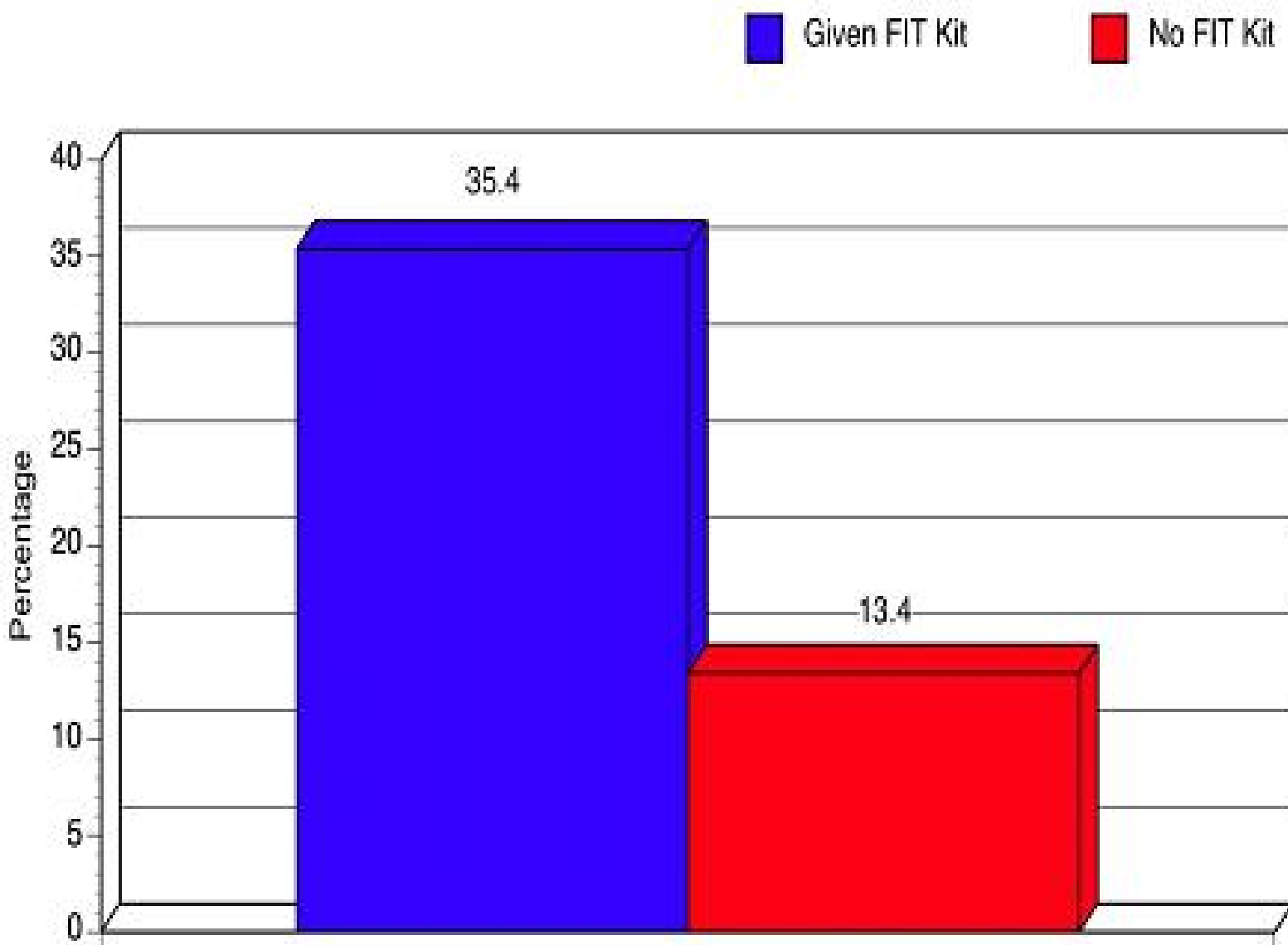
35.4% of those given FIT, completed FIT within 3 months (no postcard reminders)

Colorectal Cancer Screening Rates (FIT and Any CRCS Test) 90 Days after Flu Vaccination

(all patients due for screening at baseline)



FIT Screening Rates 90 Days after Flu Vaccination, Among Those Due for CRCS at Time of Vaccination



2011 Dissemination and Implementation Study Targeting All KPNC Facility Flu Shot Clinic Sites



- Endorsed but not required by KPNC Regional Leadership
- Disseminated through Regional Flu Shot Clinic Coordinators
- Hands-on training offered at KPNC's Center for Innovation in San Leandro, CA.
- Webinar offered to new and experienced flu shot clinic sites
- Internal KPNC website with KPNC-specific procedures and downloadable materials created



Walgreens Pilot Study *moving FLU-FIT into the community*



Results comparing Flu-FIT with FLU plus education/referral for colorectal screening

(J Am Pharm Assoc 2010;50:181-7)

Phone Interviews 3-6 months after the Intervention	FIT Provided N=86	Education/ Referral N=28	P value
Discussed Screening with PCP	20%	50%	<0.01
Completed Any CRC Screening Test	59%	15%	<0.01
Scheduled Any CRC Screening Test	0%	19%	<0.01
Said “Pharmacies should educate”	94%	86%	0.22
Said “Pharmacies should offer FIT”	91%	82%	0.30

- Pharmacists could play a positive role: *educating, referring, and/or providing FIT to eligible patients*
- Challenges to address: *methods to assess eligibility, closing the loop with primary care, and providing incentives for pharmacies to offer these services.*

Other are increasingly exploring the idea of opportunistic pairing of public health interventions

- Mammo/FIT (Grace Hillyer, New York City mammography suites)
- Mammo/Colo (Ruth Carlos, Ann Arbor VAMC mammography suites)
- Flu/Mammo (Doug Shenson, SPARC/community-based flu shot clinics)
- Vote & Vax Programs (Doug Shenson, SPARC, polling places)
- Pharmacies and FIT (Australian National Program)

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: Standing 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 prepackaged 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

Questions for You

- What are your experiences with colorectal cancer screening in your clinical settings?
- What would it take for you to try a Flu-FOBT or Flu-FIT Program in 2014 in your community?
 - With whom would you partner?
- How would you measure success?

Go to <http://flufit.org>
for More Information

- Videos on other materials on the project
- Training materials for staff
- Patient education materials and videos
- Demonstrations of the project and how it works
- Link to downloadable **ACS FLU-FOBT Manual**
- Link to NCI Research Tested Innovation Program website
- Link to AHRQ Innovations Exchange website
- Our Research Papers

Summary

- Colorectal Cancer Screening is an essential but underperformed preventive service that saves lives
- HSgFOBT or FIT is an important component of any population-based screening program.

Summary

- Flu-FOBT and Flu-FIT Programs
 - Add to other efforts to increase CRCS
 - Can be implemented in diverse clinical settings with diverse patient populations
 - Works best when introduced with effective leadership and training, coupled with follow-up reminders and navigation for abnormal results
 - Proven strategy to “kick-start” clinic-based screening activities

Special Acknowledgements

- American Cancer Society and Centers for Disease Control and Prevention for support to develop and disseminate the Flu-FOBT and Flu-FIT Programs
- SF Dept of Public Health, Kaiser Permanente, Walgreens Pharmacies, and members of the SF Bay Area Collaborative Research Network for participating in our research program

THANK YOU!!!