

# Health Literacy in Clinical Trials

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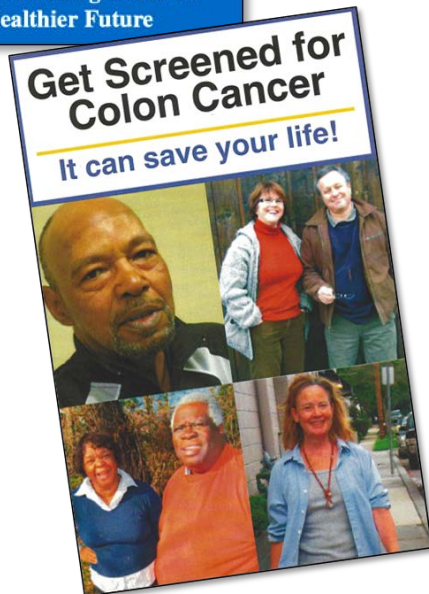
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LSUHSC-Shreveport

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NASEM

**Roundtable on Health Literacy**



# DISCLOSURE

## Research funding:

- American Cancer Society
- Patient-Centered Outcomes Research Initiative (PCORI)
- NIH, LA Clinical and Translational Science Center



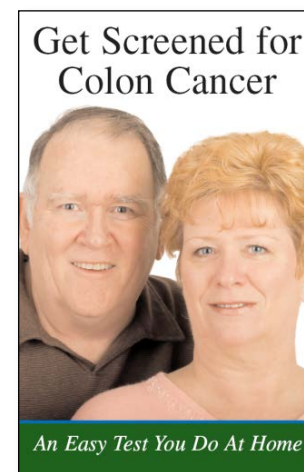
# Goals for Today

- Lessons learned from implementing 2 health literacy interventions to promote colon cancer screening in predominantly rural communities
  - NCI 2007-2012
  - American Cancer Society 2012-2018.
- Outcomes of the studies – what worked and what didn't.
- Challenges and Lessons learned from both.

# Health Literacy Intervention to Improve Cancer Screening (R01 CA 115860-05)

*5 year evaluation in  
8 FQHC's*

- Test the effectiveness of health literacy interventions to improve initial and repeat use of CRC and breast cancer screening
- Explore patient, provider and system factors that facilitate or impede initial and repeat screening.



# Federally Qualified Health Centers

*Uniquely Positioned to Address Disparities*

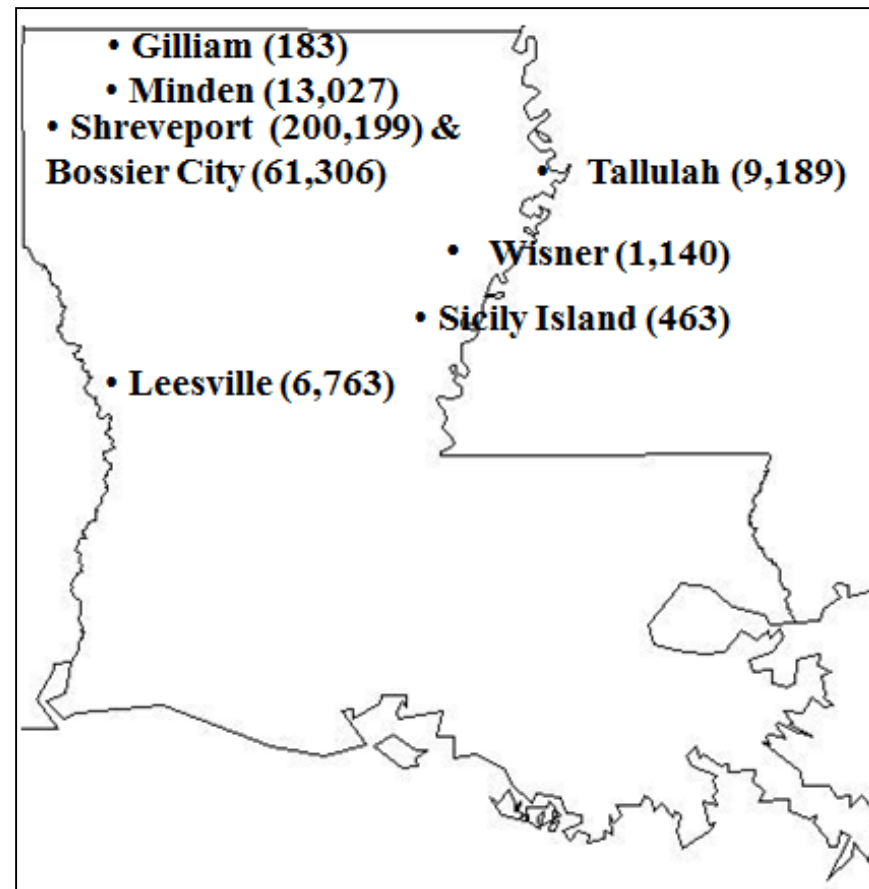


- Government supported clinics provide services to >20 million regardless of insurance status
- Located in areas designated as medically underserved
- >1/3 patients uninsured, 2/3 belong to racial and ethnic minorities, 93% <200% poverty line
- *Our target – The 5 FQHCs in predominately rural North LA.*



# Study Clinics & Patients

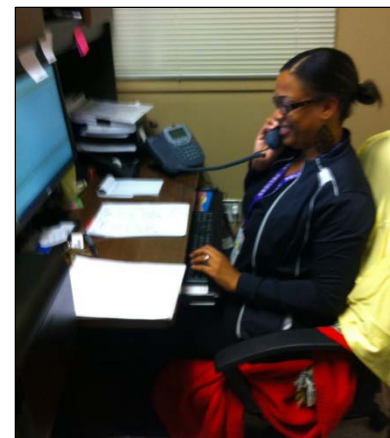
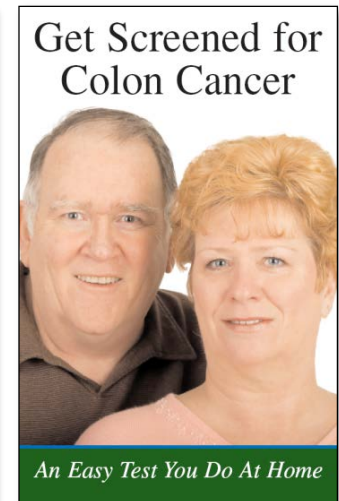
- Baseline screening rates are extremely low
  - 5-9% mammography
  - 1-2 CRC
- Patients
  - 77% Female
  - 67% African American; 32% White
  - 67%  $\geq$  HS grad
  - 56% read  $\leq$  8th grade level
  - 59% have no insurance
  - 89% had seen their PCP last year





# Intervention to Make Information and Services Easy to Obtain, Understand, and Use

- Recommendation
- FOBT & no cost mammogram
- Pamphlets developed with patients and providers
- Short videos that tell story – developed and acted with patients. 3 minutes long.
- Simplified FOBT instructions (3<sup>rd</sup> grade)
- Nurse manager to teach & support with follow-up calls



**TEST RESULTS CARD**  
*Home test for hidden blood in stool*

Test Tissue	Description	Check One	
		Blue Cross	No Blue Cross
1	1st bowel movement check	<input type="checkbox"/>	<input type="checkbox"/>
2	2nd bowel movement check	<input type="checkbox"/>	<input type="checkbox"/>
3	3rd bowel movement check	<input type="checkbox"/>	<input type="checkbox"/>
4	Test performance check tissue <small>(You should see a blue green cross.)</small>	<input type="checkbox"/>	<input type="checkbox"/>

\_\_\_\_\_

*Please fill out this card and mail it back to the clinic.  
Your information will always be kept private.*

Name: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone: ( ) \_\_\_\_\_

Age: \_\_\_\_\_

Check one: \_\_\_\_ Male \_\_\_\_ Female


# Colon Cancer Pamphlet

## (5<sup>th</sup> grade level)

# Mammogram Pamphlet


## (5<sup>th</sup> grade level)

### Get Screened for Colon Cancer



**An Easy Test You Do At Home**

### Do It Now While You're Healthy!




*"I do my colon cancer test at home every year. It gives me peace of mind."*

*"The test is safe and private."*

*"It's just so easy to do. It's a no-brainer."*


- If you are 50 years old or older – you need to get tested for colon cancer even if you feel fine.
- The test looks for hidden cancer before you have problems.
- Colon cancer tests are completely confidential.
- Getting tested regularly is the only way to prevent colon cancer.
- Men and women need to be tested every year.

### Where Is My Colon?



### Testing Can Save Lives!

- Anyone can get colon cancer but it is more common with men and women over 50.
- If you have a family history of colon cancer – testing is even more important for you.
- Testing for colon cancer is one way to help you live a long, healthy life!



*"I get tested because I want to be healthy for my children and grandchildren."*

Louisiana State University  
Health Sciences Center  
Shreveport

### What Is The Easiest Way To Test?



- The easiest test is a tissue test called EZ Detect. It looks for hidden blood in your stool. The test is painless and convenient.
- All you do is drop the tissue in the toilet after you've had a bowel movement. Do this on 3 different days.
- If a blue cross appears on the card, you need to call the clinic. This does not necessarily mean you have cancer, but you need to see the doctor.
- Mark your results on the card enclosed in the packet and mail it to the clinic.
- The doctor needs this information to take the best care of you.



*"The tissue test needs to be done every year so we can catch any problems early. Remember, colon cancer can be cured if we find it early."*

### Have You Had Your Mammogram?



**Regular Screening Leads To A Healthier Future**

### All Women 40 And Over Need To Get Mammograms



*"The nurse scheduled my mammogram. It was easy, convenient and did not take long."*

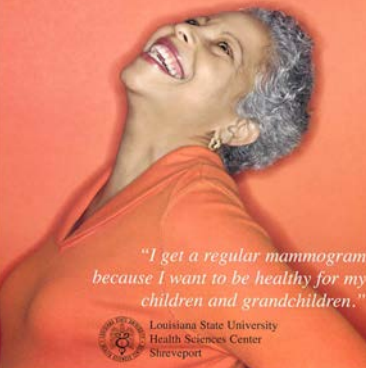
- Even if you look and feel fine it is important to get a mammogram.
- Mammograms look for hidden cancer before you have problems.
- The test is completely confidential.
- Your chance of getting breast cancer increases as you get older.
- Cancer can show up at any time, so it is important to get a mammogram every 1 to 2 years.
- If cancer is caught early, it can be treated.



*"I was surprised how easy the whole thing was."*

### Testing Can Save Lives!


- All women are at risk for breast cancer.
- You are at higher risk if your mother, sister or daughter has had breast cancer.
- Finding breast cancer early can help you live a long, healthy life!



*"I get a regular mammogram because I want to be healthy for my children and grandchildren."*

Louisiana State University  
Health Sciences Center  
Shreveport

### What Is A Mammogram?




- A mammogram is a simple X-ray of your breasts.
- It can find cancer that is too small for you, your doctor or nurse to feel.
- The person who takes your X-ray will place your breast between 2 plastic plates.
- The plates press your breast and make it flat. This may be uncomfortable for a couple of seconds, but helps to get a clear picture.
- The test only takes a few seconds.

### How Do I Get A Mammogram?

Ask your doctor. The doctor will order one and the nurse will schedule it for you at a nearby hospital.

The hospital will send the results to your doctor.

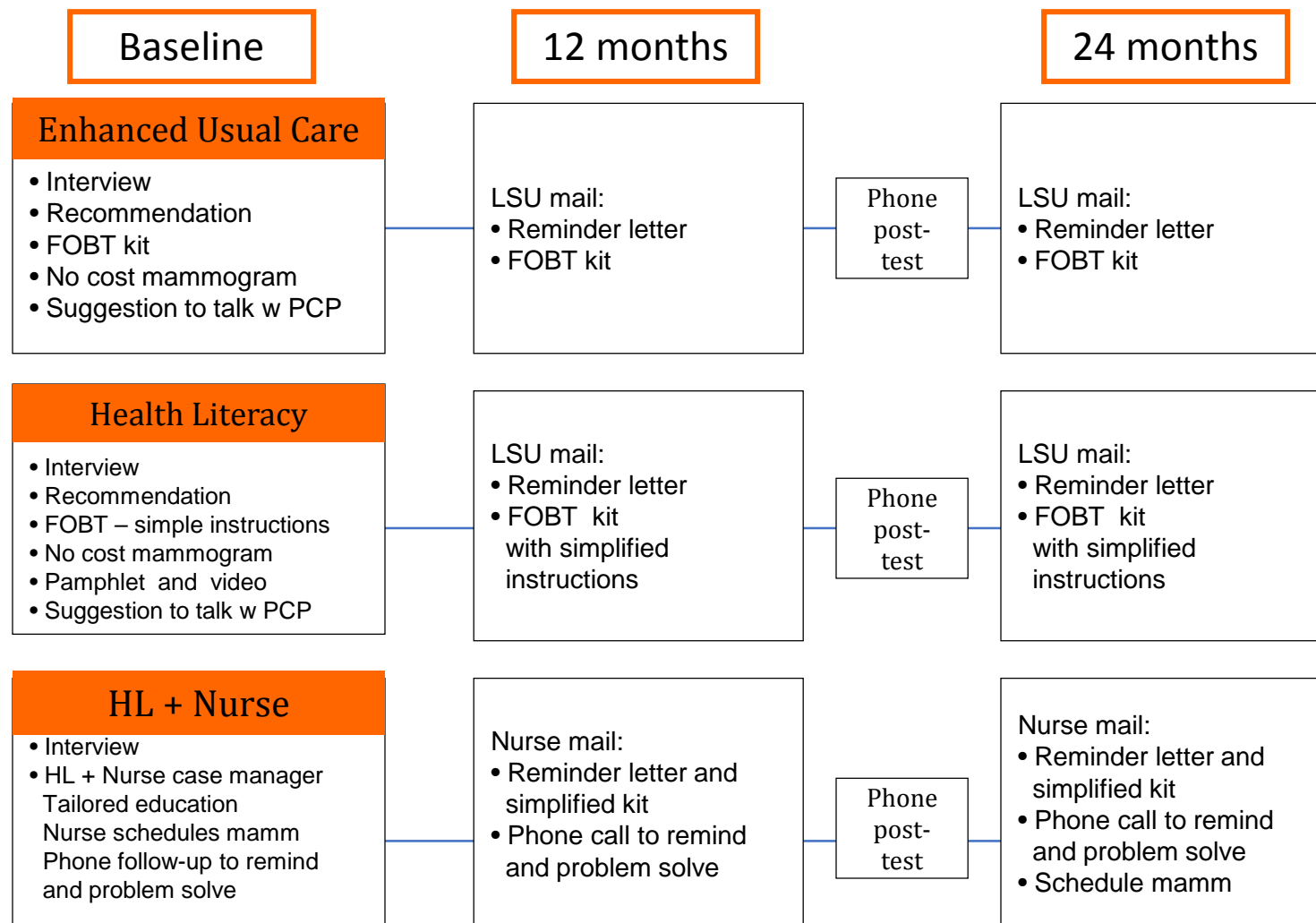




# Health Literacy Intervention

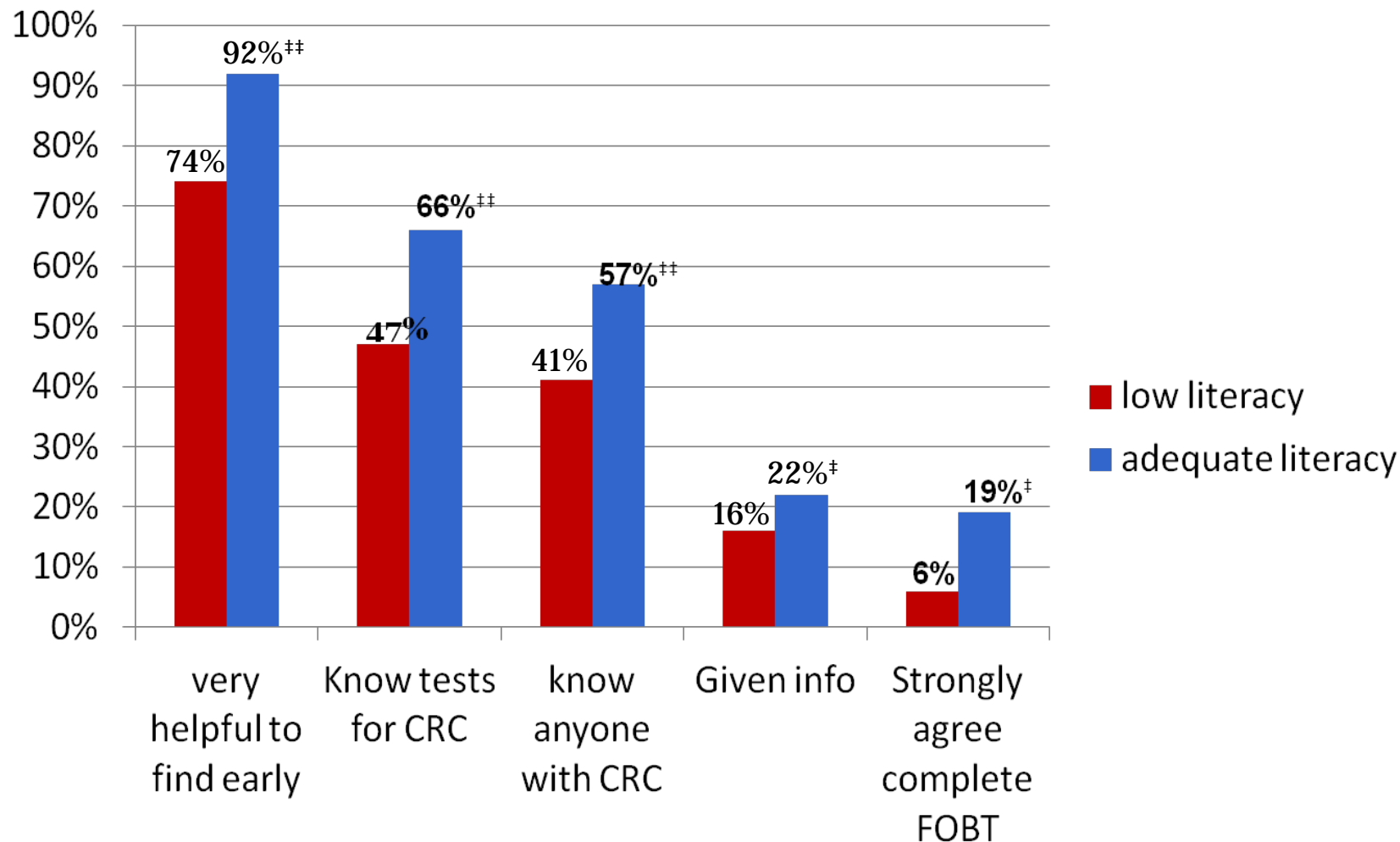
May 2008 – August 2011

3 FHQCs randomly assigned to 1 of 3 study arms



# Literacy Impacts CRC Screening Knowledge & Confidence

*Baseline Survey ( 51 items)*



<sup>†</sup> p<.05   <sup>††</sup> p<.0001

# FOBT Screening Completion by Study Arm

1<sup>st</sup> n=961  
2<sup>nd</sup> n=561  
3<sup>rd</sup> n= 206

	By Arm			p-value*
	EUC	HL	HL + Nurse	
1 <sup>st</sup> year FOBT returned	39%	57%	61%	.02
2 <sup>nd</sup> year FOBT returned	36%	33%	51%	<.001
3 <sup>rd</sup> year FOBT returned	34%	60%	47%	.21

\*p-values adjusted for age, marital status, &  
literacy- take clustering by clinic into account

CRC baseline: 1-2%

CRC screen - 14% needed diagnostic colonoscopy

- 8 patients had polyps removed

# Challenges

- Community clinics focus on service not research fidelity
- Challenging to find qualified RAs in rural areas
- Hiring RAs from clinic staff is a “Catch 22”
- High physician turnover in rural areas
- Follow-up calls are feasible but phones commonly disconnected then reconnected.
- Patients lose FOBTs / forget to complete.
- At LSU Wait for **diagnostic** colonoscopy up to a year during this study.



**LSU Colonoscopy  
Referrals**



# Lessons Learned from Study

- Strong relationship with CEOs and clinic is essential.
- Including providers & patients in material development is key.
- Clinic in-service & study orientation helps inform and enlist staff.
- RA giving recommendation and FOBT before PCP visit is feasible and well received by providers and patients.
- Videos revealed RA and patient barriers – pamphlets and FOBT kits were easier to use as teaching tools
- Nurse follow-up call to problem solve screening was time consuming.
- Practical, cost-effective strategies are needed to sustain screening.



FQHC Patients



Nurse Manager

# More Lessons



- **The clinics did not have an effective system to promote regular cancer screening if patients don't have a scheduled clinic appointment.**
  - Hence few patients in our control and education groups were screened again in 2 years.
- **Women tend to be more open about talking about mammograms. Some felt pride in getting them.**
  - Getting a mammogram is “cool”. It’s a “women’s thing”.
  - Patients did not seem to feel pride when completing FOBT
  - Nurses reported men & women did not like talking about BMs or the concept of colonoscopy

# Building on the R01: “Health Literacy Interventions to Overcome Disparities in CRC Screening”



**5 year RCT in 4 rural FQHCs: 620 patients, ages 50-75**

The primary aims

- Compare effectiveness of Personal Calls vs. Automated Calls to improve initial and repeat CRC screening.
- Compare cost effectiveness of Personal Calls vs. Automated Calls for initial and repeat CRC screening.

The secondary aims

- Conduct process evaluation to investigate implementation and barriers.
- Determine if the effects of either strategy vary by patients' literacy.

The exploratory aim

- Explore patients' understanding, beliefs & self-efficacy for CRC screening over time.

# Study Sites



## 4 South Louisiana Rural Community Clinics\*

\*CRC screening Rate 3% - 5%

### Patient Enrollment

(N = 620)

#### Race

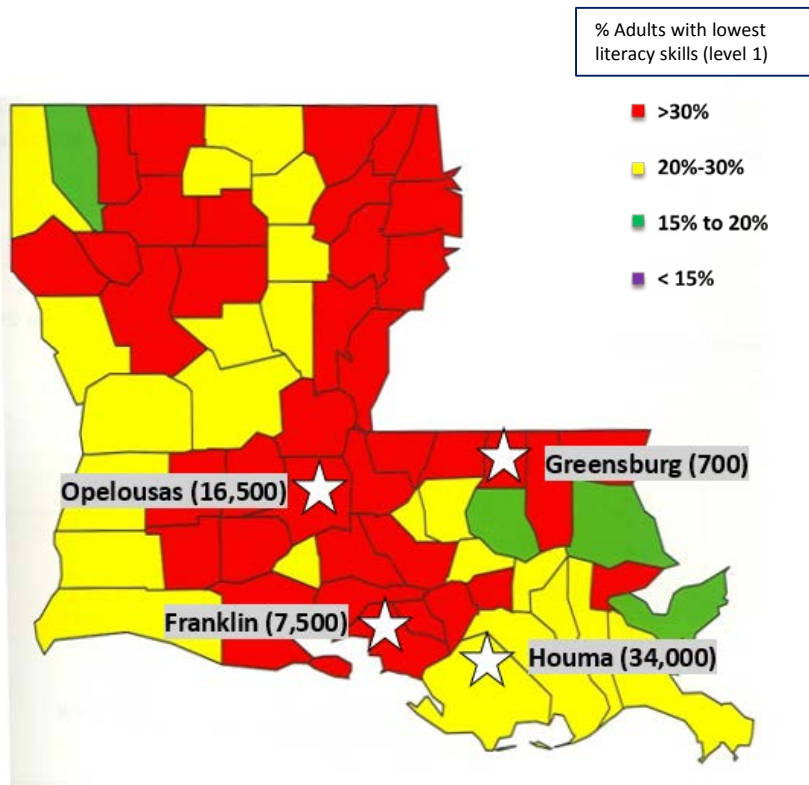
African-American	66%
White	34%

#### Gender

Female	55%
Male	45%

#### Literacy

< 9 <sup>th</sup> Grade Reading Level	40%
>= 9 <sup>th</sup> Grade Reading Level	60%





# Materials

## Simplified FIT Instructions: 3<sup>rd</sup> Grade Reading Level

### How to do the test

When you are ready to have a BM (poop), bring the test kit into the bathroom with you.

**You will do the test 2 times using 2 different BMs.**

### Do not do the test if you have:

- Hemorrhoids that are bleeding.
- Blood when you pee or see blood in the toilet.

### Get things ready.

- Take any cleaners out of your toilet. Flush the toilet 2 times.



### Use the bathroom.

- After your BM, wipe. Do not put the toilet paper in the toilet. Put it in the blue bag from your kit.



### Start the test.

- Get the card, lift the tab where it says "sample 1".
- Before you flush the toilet, gently wipe the brush over your poop for 5 seconds.
- Shake the brush lightly to remove any clumps.



- Gently dab the brush on the white square under the tab for 5 seconds. It's okay if the card changes color.



- Put the used brush in the same bag as your toilet paper. Throw this bag away.



- Write your name, your date of birth, and today's date on the label. Peel off the label and stick it over the flap on your card to seal the tab.



- Store the card with your first sample and the rest of the kit in the bathroom until you do the 2nd sample. Do not put test in refrigerator!

### Do it all again.

- At your **next** BM, use the 2nd brush to brush it on "sample 2" of the card.
- Write your name, your date of birth, and today's date on this label.
- Put the card in the envelope and mail your test to the lab.
- You need to mail your test within 2 weeks of your first BM.



Turn over

## CRC Educational Pamphlet: 4<sup>th</sup> Grade Reading Level

### What you need to know about colon cancer screening:

- If you are 50 to 74 years old, you need to get tested for colon cancer even if you feel fine.
- Both men and women need to be tested.
- The test looks for hidden blood before you have problems.
- Getting tested can save your life.



Tell your health care provider if you have a family history of colon cancer. You may need a different kind of test.

### The Fecal Immunochemical Test (FIT) is the easiest way to get tested for colon cancer

- The test is painless and easy.
- You do it at home.
- It looks for hidden blood in your stool (poop).
- It is recommended by the American Cancer Society.
- You need to do the test **every year**.

"I can do my colon cancer test at home every year. It gives me peace of mind."  
- Maria

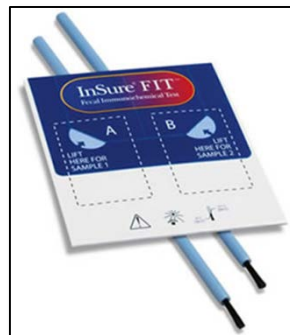


"It's easy to do. It's a no-brainer. Talk to your health care provider."  
- Larry

### How will I get my results?

- Mail the test in the special envelope to the lab.
- The lab will let your health care provider know the results and you will get the results within a month.

## InSure FIT Kit Sample



### KIT CONTENTS

- Instructions for use
- A Test Card
- A Brush Kit containing 2 brushes and 2 waste bags
- A Reply Form/Test Requisition
- A Return Envelope

Please check expiration date on enclosed Test Card

Keep out of reach of children

- Protect from heat (>99° F/37° C) and direct sunlight
- Do not reuse
- Consult instructions for use
- For in vitro diagnostic use

A Simple Use of the Brush  
May Save Your Life™

Laboratory Testing  
Services provided by

Quant Diagnostics  
Manufactured by Entera Inc., Edison, NJ 08837 USA, a Quest  
Diagnostics company. Copyright ©2007 Entera Inc. All rights reserved.  
Controlled by U.S. Patents including Patent Nos. 6,921,678; 6,921,686;  
6,869,804, and 6,977,173.

18011.00

# CRC Screening Brochure

## Remember:

- Anyone can get colon cancer but it is more common with men and women over 50.
- Doing the FIT test every year is one way to help you live a healthy life!
- You have to do it **every year**.
- Don't wait. Do it now!



Teche Action Clinic - Franklin  
Franklin, LA  
(337) 828-2550

Teche Action Clinic - Houma  
Houma, LA  
(985) 851-1717

Southwest LA Primary Health  
Opelousas, LA  
(337) 942-2005

Vamado Family Practice  
Greensburg, LA  
(225) 222-3206

## Get Screened for Colon Cancer

It can save your life!



## What you need to know about colon cancer screening:

- If you are 50 to 74 years old, you need to get tested for colon cancer even if you feel fine.
- Both men and women need to be tested.
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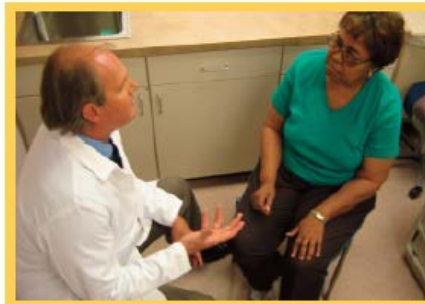
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Tell your health care provider if you have a family history of colon cancer. You may need a different kind of test.

## How will I get my results?

- Mail the test in the special envelope to the lab.
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## Methods

**Enrollment:** RA gives patients CRC survey, screening recommendation, HL patient education, simplified FIT instructions, and FIT kit. Patients randomized to PC or ATC arm



**IF No FIT kit returned:  
4 Weeks & 8 weeks**



PC Arm: a personal follow-up call from a prevention coordinator reminding patients to complete & mail FIT kits & discuss any barriers perceived by the patient

ATC Arm: automated follow-up call with voice recording uses plain language and motivational messages encourages patients to complete & mail the FIT

**6 Months**

Central RA calls & re-administers baseline survey as well as satisfaction survey with all patients



## Methods - Year 2 & 3



### 12 Months

PC Arm: mail outreach reminder cards and FIT kits for CRC rescreening, re-implement personal call strategy at 4 & 8 weeks

ATC Arm: mail outreach reminder cards and FIT kits for CRC rescreening, re-implement automated call strategy at 4 & 8 weeks

### 24 Months

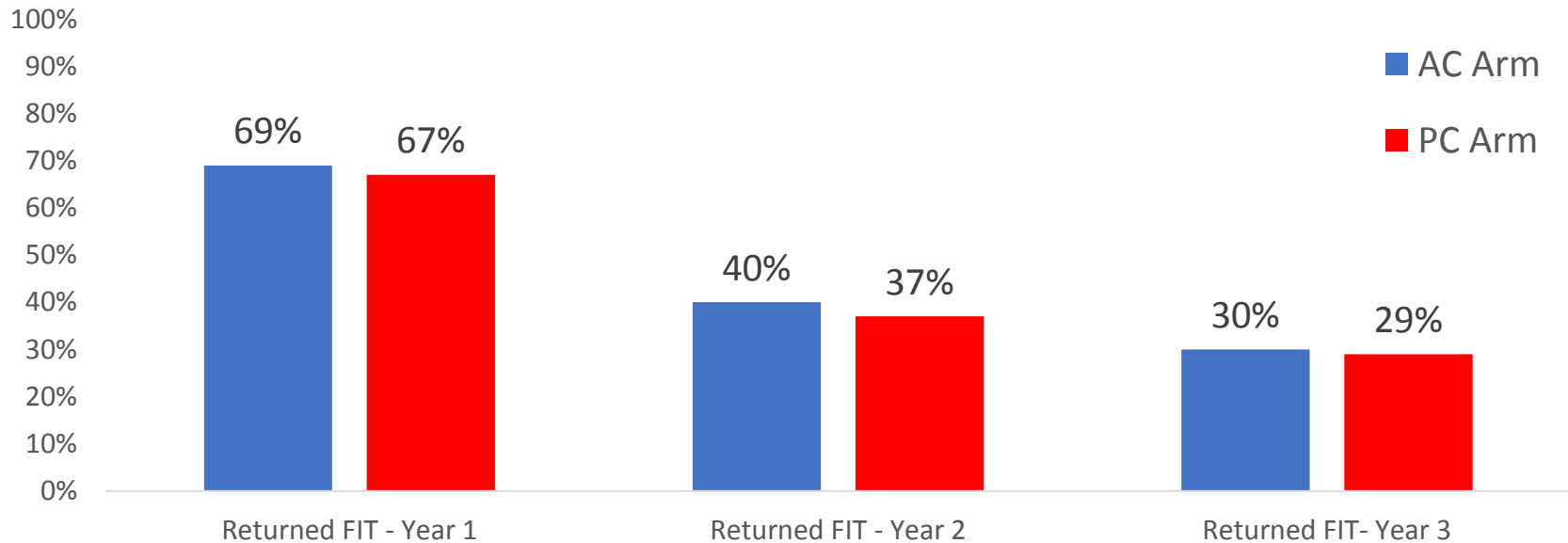
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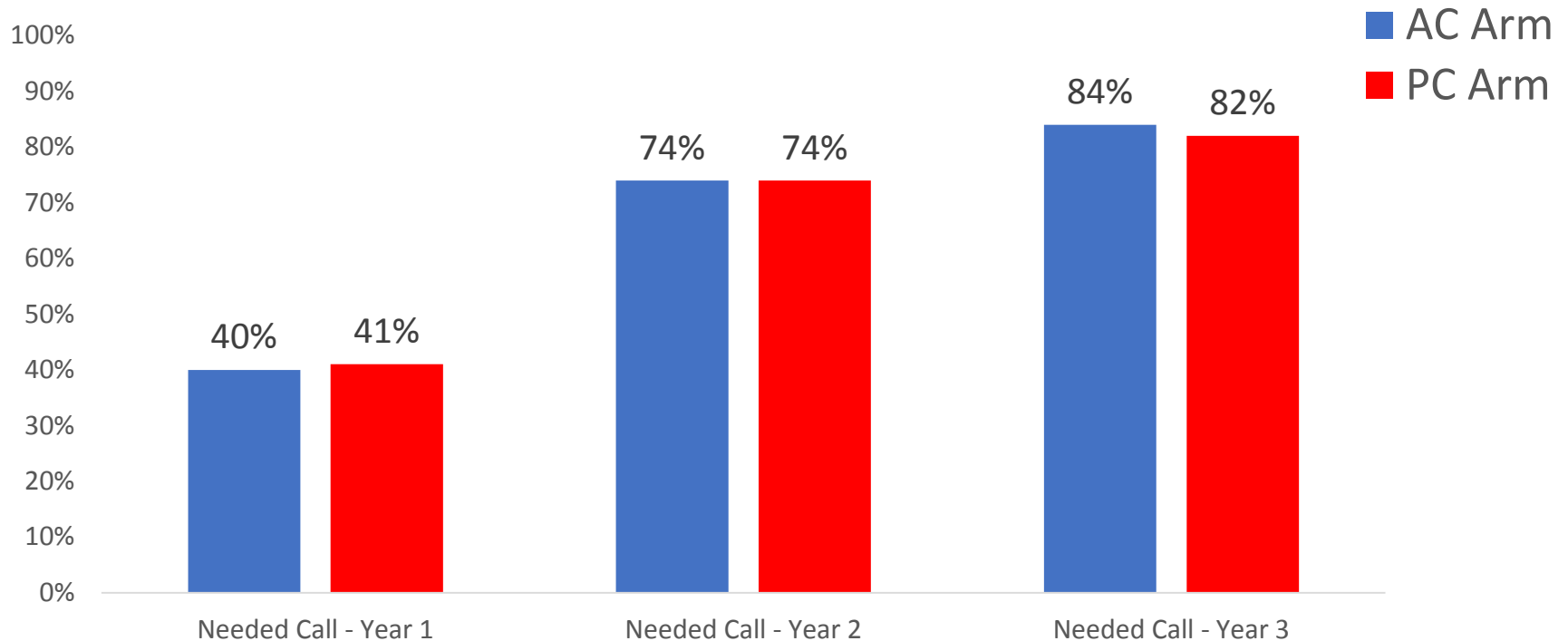
# FIT Screening Results over 3 years

baseline screening rate 2-5%



- Providing FIT & clinic-based education increased screening.
- Lower cost automated call equally effective as personal call

# Automated & Personal Calls Needed Over 3 Years



- Follow-up calls were essential in year 2 & year 3. Only 15% in year 2 and 25% in year 3 completed FIT without phone prompt.

# Lessons & Challenges with Clinics



- Regulatory paper work is a barrier for community clinic RAs
- RAs need very concrete research instructions and frequent “teach back” of protocol
- Frequent face-to-face clinic visits with food build relationships & enhance fidelity
- Arranging for diagnostic colonoscopy for uninsured was challenging

# What was Learned?



- Providing FIT + literacy appropriate education at regularly scheduled clinic visit with follow-up call (if needed) increased CRC screening rates of low income, rural patients. Almost 70% completed initial screening.
- Sustaining annual screening with FIT is challenging. In years 2 & 3 < 40% completed FIT.
- Follow-up calls were essential in year 2 & year 3. Only 15% in year 2 and 25% in year 3 completed FIT without phone prompt.
- Lower cost automated call is just as effective as personal call in all 3 years.
- Automated call tracked whether patient listened to complete message, hung-up during call, went to voicemail, requested another kit.



# What's Needed? Times have changed.



## **Creative approaches are needed to promote long term screening**

- Offer screening options and use decision aids to help patients identify CRC test that they find most acceptable and feasible.
- Use of text or automated calls to remind patients to complete test.

## **Environment has changed**

- When we began this grant, none of the clinics had Electronic Health Records. They now all have them.
- Louisiana has now taken Medicaid expansion, so colonoscopy is a reality for patients in these rural areas.
- Because of Medicaid expansion, more gastroenterologists are having clinics in rural areas one or two days a week. More rural hospitals are offering colonoscopies.