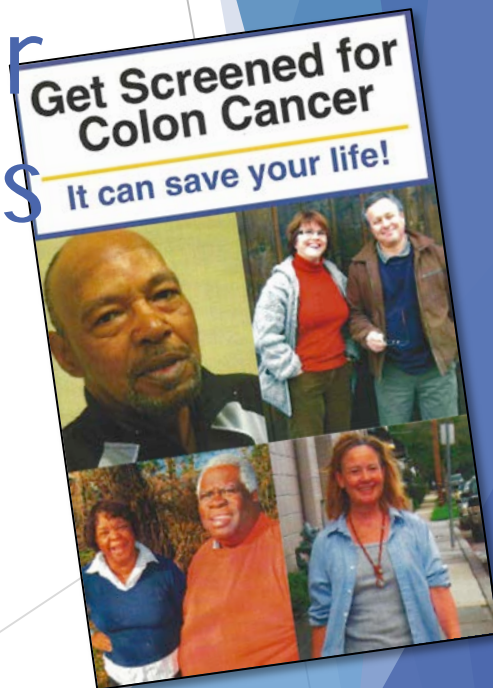


# Rural Community Clinics CRC Screening: Sustainability in Repeat 2<sup>nd</sup> and 3<sup>rd</sup> Year Screenings

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# Disclosure

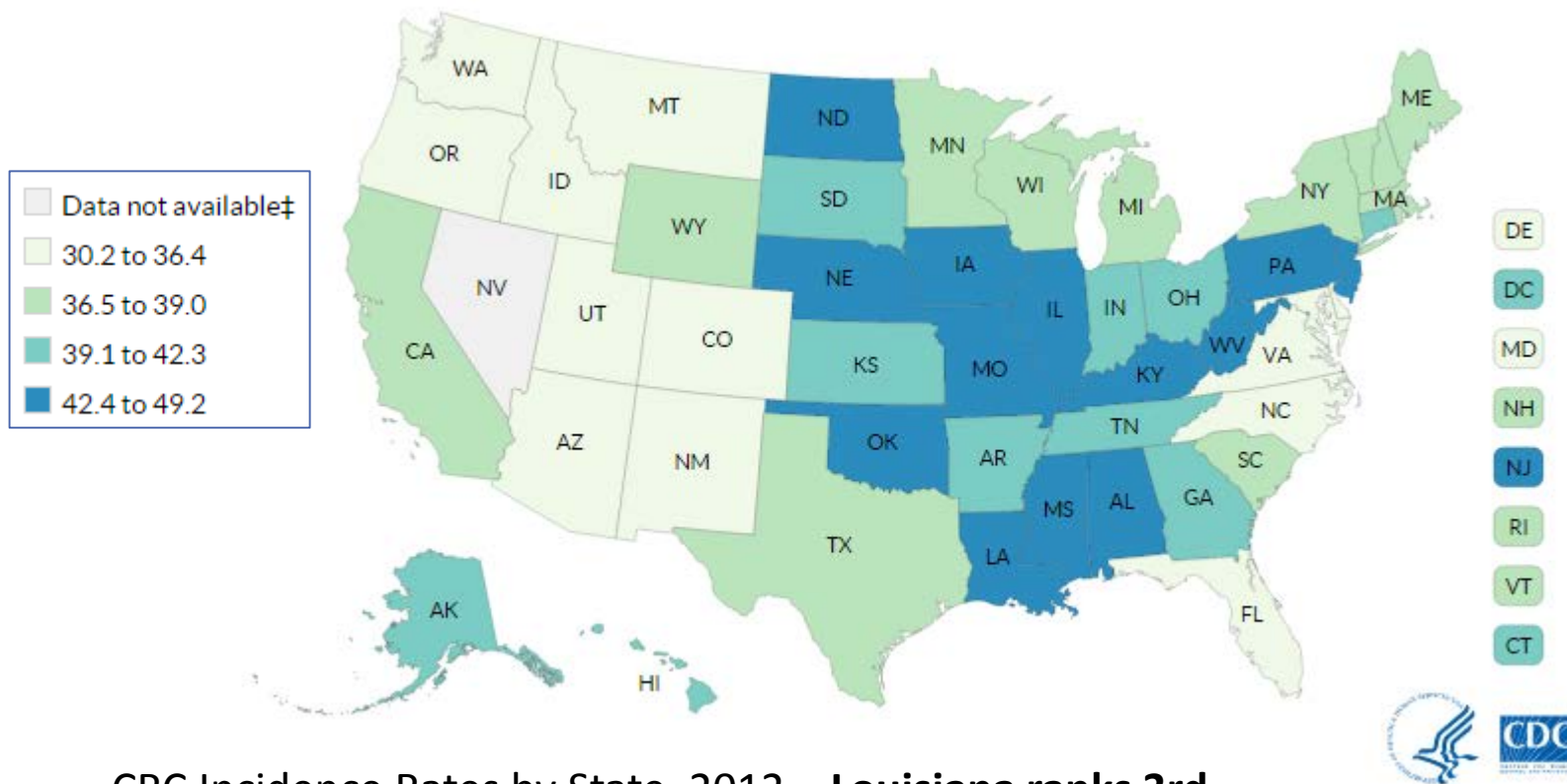
## Research funding:

- American Cancer Society - This study was funded by “Health Literacy Interventions to Overcome Disparities in CRC Screening” (RSG-13-021-01-CPPB) grant from the American Cancer Society
- NIH, LA Clinical and Translational Science Center



# Colon Cancer is Common in U.S.

- Colorectal cancer (CRC) is the 3<sup>rd</sup> most common cancer & 2<sup>nd</sup> leading cause of cancer deaths in the US



CRC Incidence Rates by State, 2012 – **Louisiana ranks 3<sup>rd</sup>**

# Screening Disparities

- Adherence to screening recommendation is lower than other cancer screening initiatives
- Significant disparities exist in certain populations
- Risk factors for poor CRC screening adherence:
  - **Low SES**
  - **Low health literacy**
  - **Minority race/ethnicity**
  - **Rural locality**
- Barriers:
  - Screening information not patient friendly, requires high literacy skills
  - Lack of recommendation & annual prompting
  - Lack of access to tests

# Colorectal Cancer

## Rural Disparities

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### **Rural areas have a disproportionately higher CRC incidence and mortality**

- Rural-urban disparity is largely due to rural individuals being much less likely to receive CRC screening than their urban counterparts.

### **Rural Barriers to CRC screening:**

- Distance to care
- Lower health care utilization
- Limited access to screening
- Lack of colonoscopy
- Providers not up to date on guidelines
- Higher rates of poverty, lower literacy, insurance

*Blake CA Epi Biomarker Prev. 2017, Zhang J Rural Health 2006,  
Davis J Women Health, 2017, Dai J Rural Health 201*



# Federally Qualified Health Centers

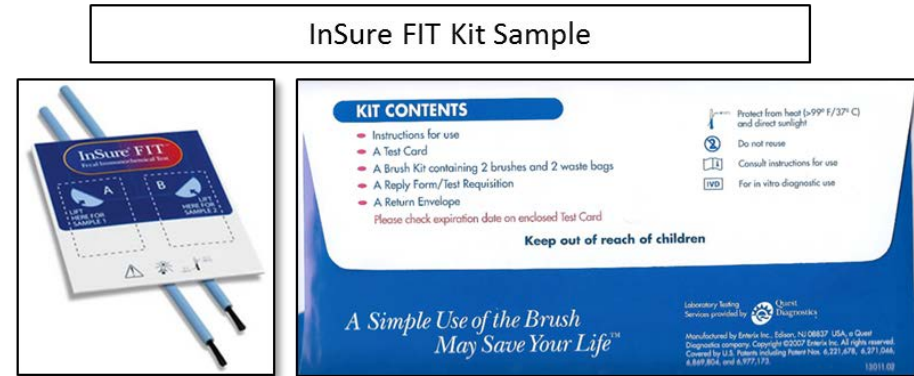
*Uniquely Positioned to Address Disparities*

- Government supported clinics provide services to >23 million regardless of insurance status
- 44 states; over half in rural areas
- 30% rural, 65% belong to racial and ethnic minorities, 72% at or below poverty line
- In 2015 60% designated as Patient Centered Medical Homes (encouraged & incentivized to have EHR & health coaches)



# CRC Screening: Benefits of FOBT (FIT)

- FIT, the most sensitive FOBT, proven effective for the early detection of cancer
- More cost effective, easier to use than traditional FOBT, less restrictions and simpler instructions
- Patients living in rural areas have more difficulty getting colonoscopies.





# “Health Literacy Interventions to Overcome Disparities in CRC Screening”

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5 year RCT in 4 rural FQHCs: 650 patients, ages 50-75

- Compare effectiveness & cost effectiveness of personal calls vs. automated calls to improve initial and repeat CRC screening.
- Conduct process evaluation to investigate implementation and barriers.
- Determine if the effects of either strategy vary by patients' literacy.
- Explore patients' understanding, beliefs & self-efficacy for CRC screening over time.

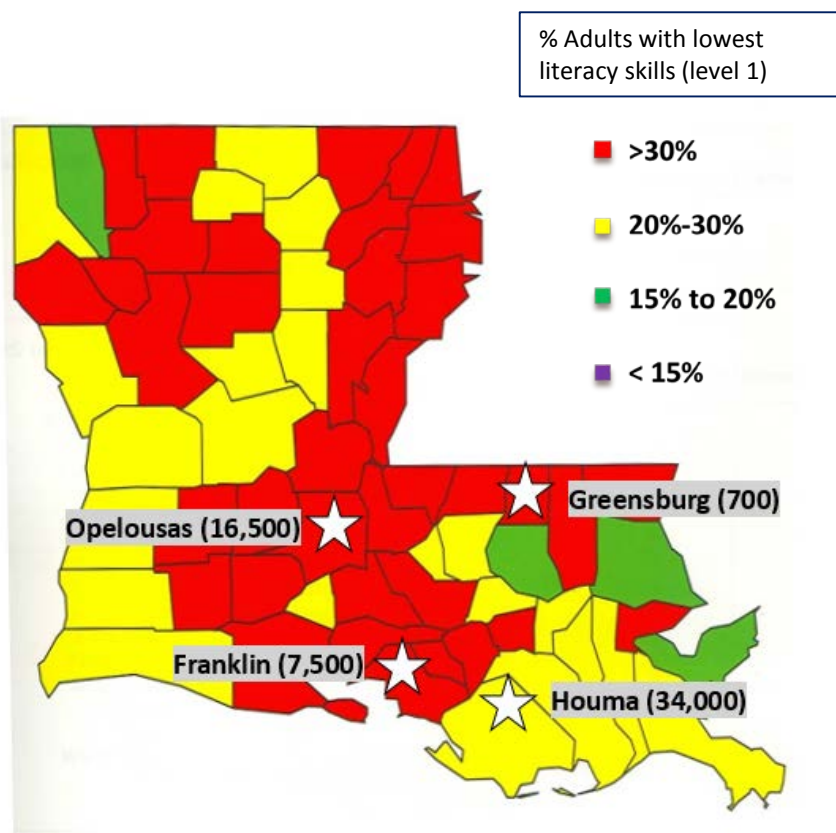




# Study Sites

## 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%

# 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

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

# Survey Instruments

## Questionnaire (Pre and Post):

- Structured survey measuring patient knowledge, beliefs, and self-efficacy about CRC screening
- Administered at baseline and 6 months after enrollment

## Literacy assessed by the REALM

List 1	List 2	List 3
fat	fatigue	allergic
flu	pelvic	menstrual
pill	jaundice	testicle
dose	infection	colitis
eye	exercise	emergency
stress	behavior	medication
smear	prescription	occupation
nerves	notify	sexually
germs	gallbladder	alcoholism
meals	calories	irritation
disease	depression	constipation
cancer	miscarriage	gonorrhea
caffeine	pregnancy	inflammatory
attack	arthritis	diabetes
kidney	nutrition	hepatitis
hormones	menopause	antibiotics
herpes	appendix	diagnosis
seizure	abnormal	potassium
bowel	syphilis	anemia
asthma	hemorrhoids	obesity
rectal	nausea	osteoporosis
incest	directed	impetigo

40. If I find cancer through a FOBT stool test or FIT, my cancer treatment may not be as bad.
- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree
- ☐ Don't Know
41. Having a FOBT stool test or FIT is a good way for me to find colon cancer early.
- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree
- ☐ Don't Know
42. Having a FOBT stool test or FIT will decrease my chances of dying from colon cancer.
- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree
- ☐ Don't Know
43. I am afraid to do the FOBT stool test or FIT because I might find out that something is wrong.
- ☐ Strongly agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree
- ☐ Don't Know
44. I am afraid the FOBT stool test or FIT instructions will be confusing.

# 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

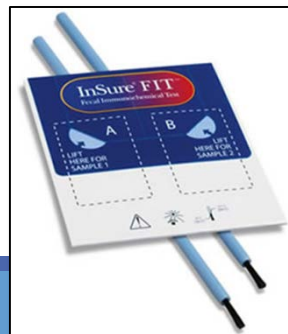


"It's easy to do. It's a no-brainer. Talk to your health care provider."  
- Larry

### 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 Enterix Inc., Edison, NJ 08837 USA, a Quant  
Diagnostics company. Copyright ©2007 Enterix 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.

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# Results – Year 1

**620 patients enrolled** - *(6 withdrew before completing test)*

**(308 – Automated Arm / 306 – Personal Arm)**

## **AC Arm (n=308)**

- 213 (**69%**) completed kits
  - 23 (**7%**) positive
- 124 (**40%**) people needed at least one follow-up call
  - 29 (**9%**) returned FIT after call

## **PC Arm (n=306)**

- 205 (**67%**) completed kits
  - 21 (**7%**) positive
- 127 (**41%**) people needed at least one follow-up call
  - 26 (**9%**) returned FIT after call

# Results – Year 2

## 568 Second kits mailed out

### AC Arm (n=285)

- 111 (**40%**) completed kits
  - 9 (**8%**) positive
- 212 (**74%**) people needed at least one call
  - 40 (**19%**) returned FIT of those called

### PC Arm (n=283)

- 104 (**37%**) completed kits
  - 8 (**8%**) positive
- 209 (**74%**) people needed at least one
  - 31(**15%**) returned FIT after call



# Results to Date – Year 3

**353 Third kits mailed out to date**

## **AC Arm (n=178)**

- 58 (33%) completed kits
  - 10 (17%) positive
- 151 (85%) people needed at least one call
  - 31 (21%) returned FIT of those called

## **PC Arm (n=175)**

- 59 (34%) completed kits
  - 6 (10%) positive
- 139 (79%) people needed at least one
  - 23 (17%) returned FIT after call

# What worked? What's needed?

- 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.
- Sustaining annual screening with FIT is challenging. In years 2 & 3 < 40% completed FIT.
- Follow-up calls were essential in year 2 and year 3. Only 15% - 25% in years 2 & 3 completed FIT without phone prompt.
- Lower cost automated call is just as effective as personal call in all 3 years.

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

- Use of 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.

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