

2021 NCCRT Annual Meeting – November 15-17



Thank you for joining!
The session will begin shortly.



Ensuring Follow up to Abnormal Stool Tests: Overview of the Problem, the Policy Landscape, and the Best Practices From the Field

Tuesday, November 16, 1:50 PM

Ensuring Follow-Up to Abnormal Stool Tests



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Ensuring Follow Up to Abnormal Stool Tests: *Overview of the Problem and Clinical Implications*

Fola P. May MD PhD MPhil

Vatche & Tamar Manoukian Division of Digestive Diseases at UCLA
UCLA Jonsson Comprehensive Cancer Center
Veterans Health Administration

CRC Screening Modalities

Stool-based strategies



High-sensitivity
FOBT



Fecal Immunochemical Test
(FIT)



Stool DNA-FIT



Serology



Capsule



Urine

Direct-visualization techniques



CT Colonography



Flexible Sigmoidoscopy



Colonoscopy

Stool-Based CRC Screening Modalities



High-sensitivity FOBt
Annual

Sensitivity, CRC: 68%;
Sensitivity, adenoma ≥ 1 cm: 11%;
Specificity: 97%



Fecal Immunochemical Test (FIT)
Annual

Sensitivity, CRC: 74%;
Sensitivity, adenoma ≥ 1 cm: 22%;
Specificity: 97%

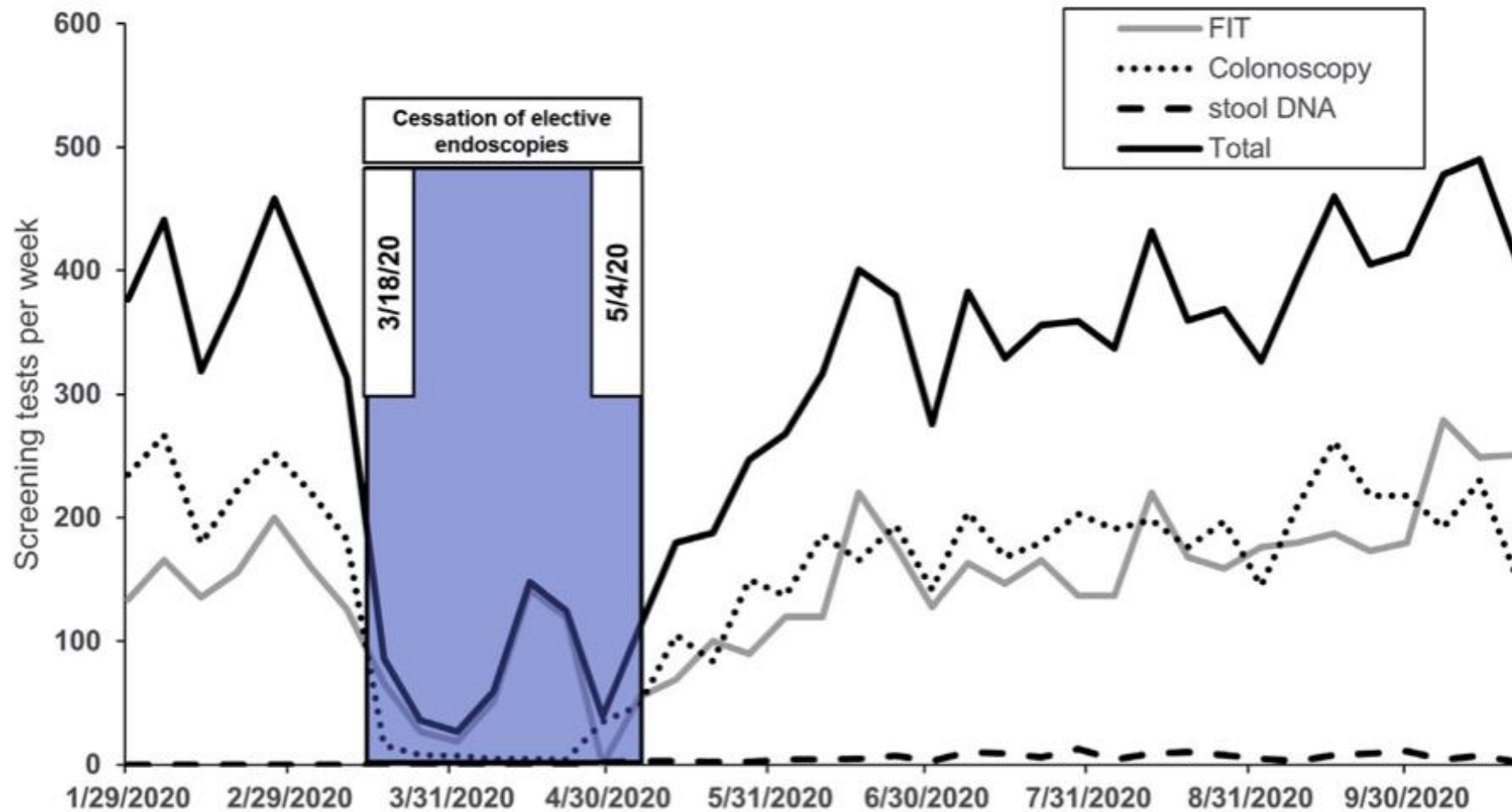


Stool DNA-FIT
Every 1-3 years

Sensitivity, CRC: 94%;
Sensitivity, adenoma ≥ 1 cm: 42%;
Specificity: 91%

Health systems with > 80% CRC screening rates embrace at least one stool-based screening modality.

Trends During COVID-19 Pandemic



All Non-colonoscopic Screening is a Two-step Process

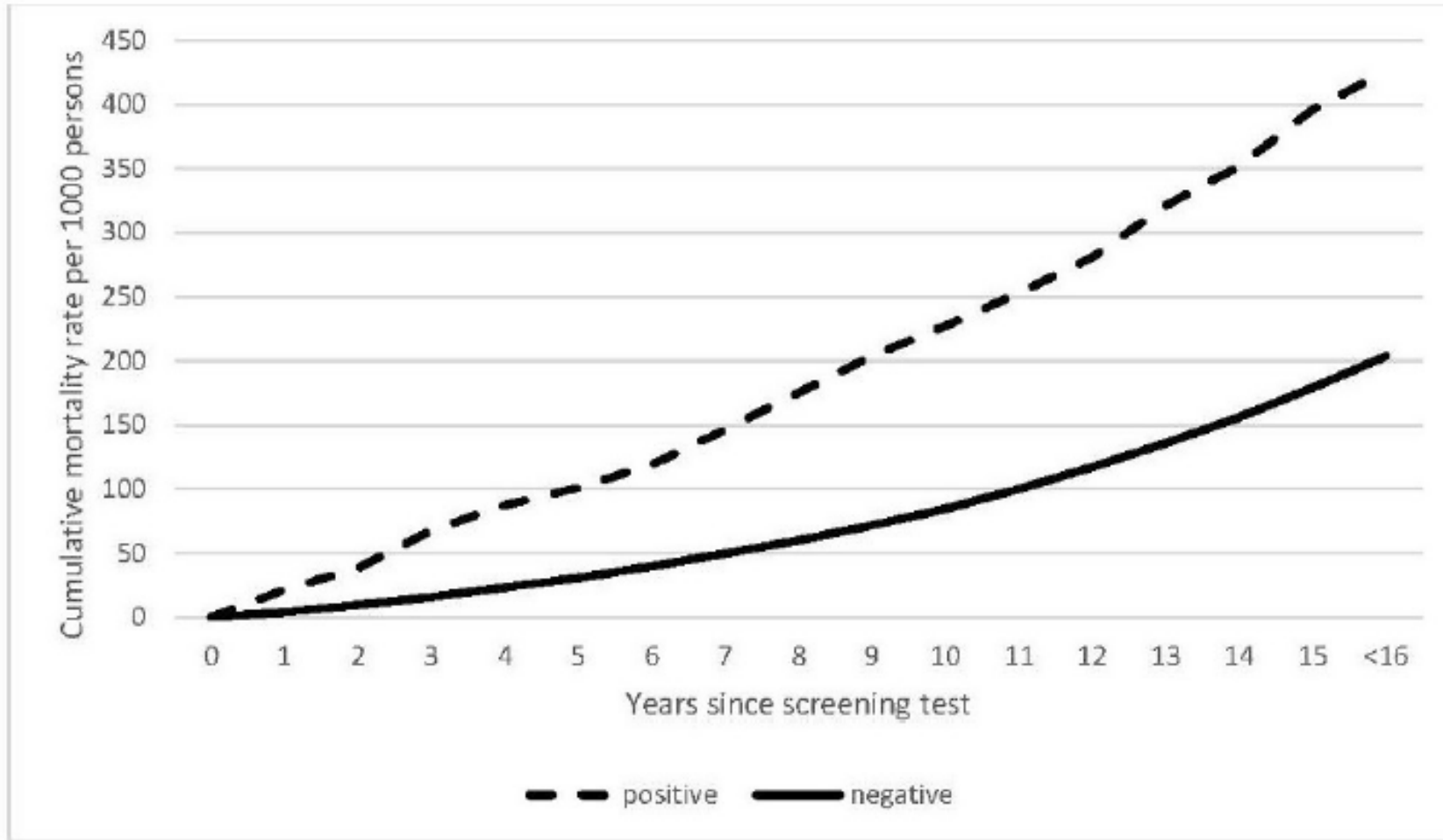


**Abnormal (e.g., positive)
screening result**



**Diagnostic colonoscopy to
detect polyps and CRC**

Increased Risk of Death with Abnormal Stool Test Results



United Kingdom
All FOBTs; 2000-2016
N=134,192

If abnormal result:

CRC mortality:

HR: 7.79

(95%CI=6.13-9.89)

Non-CRC mortality:

HR: 1.58

(95%CI=1.45-1.73)

CRC Incidence Increases 10-12 Months After Abnormal FIT

Table 3. Time to Colonoscopy Among Patients Receiving a Positive FIT Result

	Any Colorectal Cancer		
Time to Colonoscopy ^a	No. of Cases/ Total No.	Rate per 1000 Patients (95% CI)	Adjusted OR (95% CI) ^c
Comparison Group, 1-30 d			
1-30 d	871/28 567	30 (28-32)	1 [Reference]
2 mo	685/24 644	28 (26-30)	0.90 (0.81-0.99)
3 mo	265/8666	31 (27-34)	0.93 (0.80-1.07)
4-6 mo	165/5251	31 (27-36)	0.95 (0.80-1.13)
7-9 mo	58/1335	43 (32-54)	1.27 (0.96-1.67)
10-12 mo	37/748	49 (34-65)	1.44 (1.02-2.02)
>12 mo	174/2304	76 (65-86)	2.19 (1.84-2.60)

Kaiser Permanente Northern and Southern California
2010-2014

N= 70,124 patients with abnormal FIT

*Compared to abnormal-FIT individuals who underwent colonoscopy at 1-30 days, individuals who waited 10 to 12 months were more likely to have CRC at time of diagnostic colonoscopy.
(OR 1.44, 95%CI: 1.02 – 2.02)*

Recent Systematic Review Supports Colonoscopy within 9 months

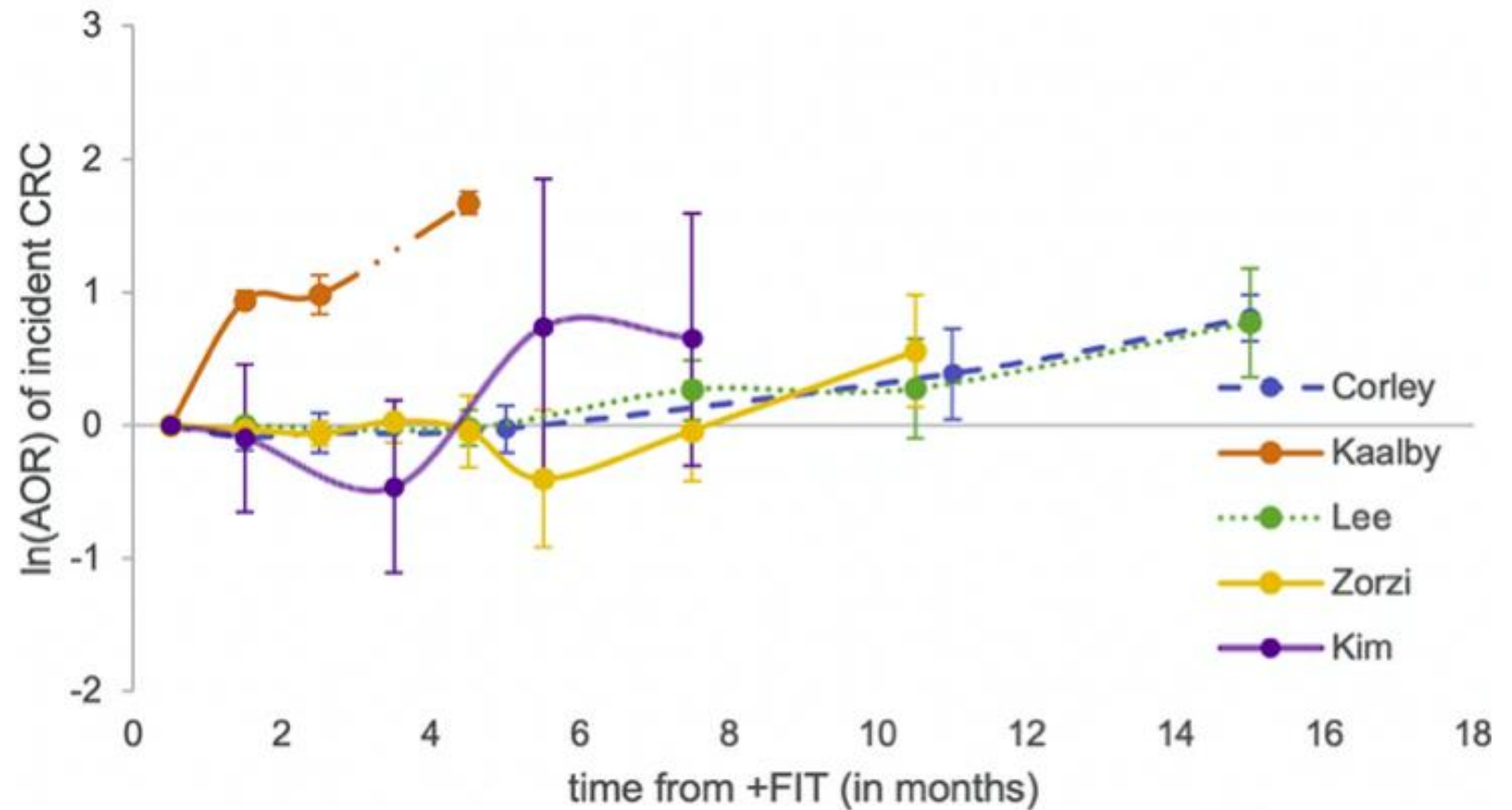
Systematic Review

Relationship between time to colonoscopy after abnormal fecal screening and CRC-related outcomes.

N=8 studies

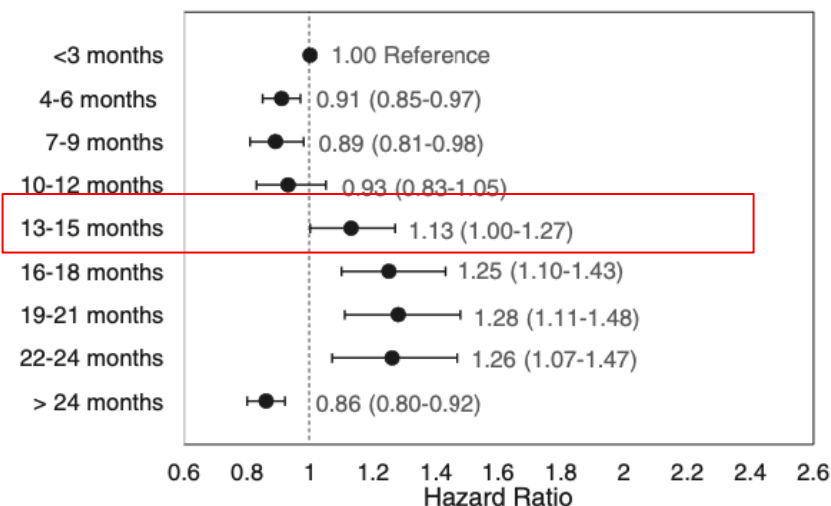
FIT: 5 studies

FOBT: 3 studies

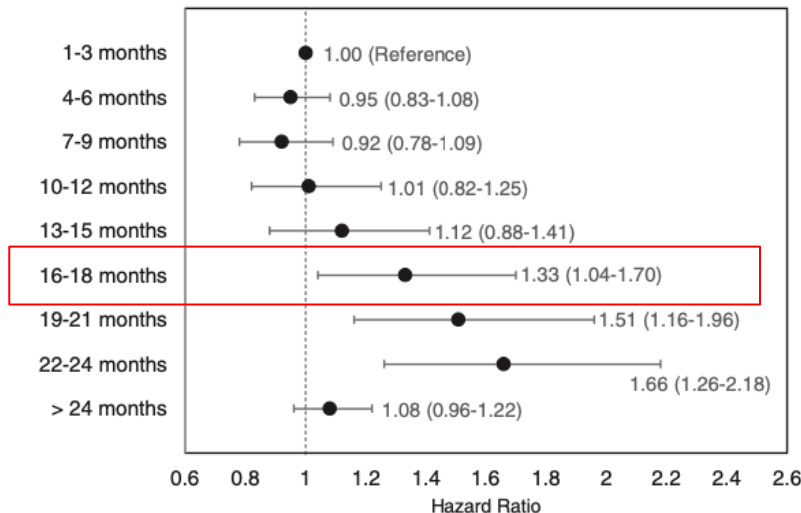


Time to Colonoscopy Associated with Incident CRC, Late-stage CRC, Fatal CRC

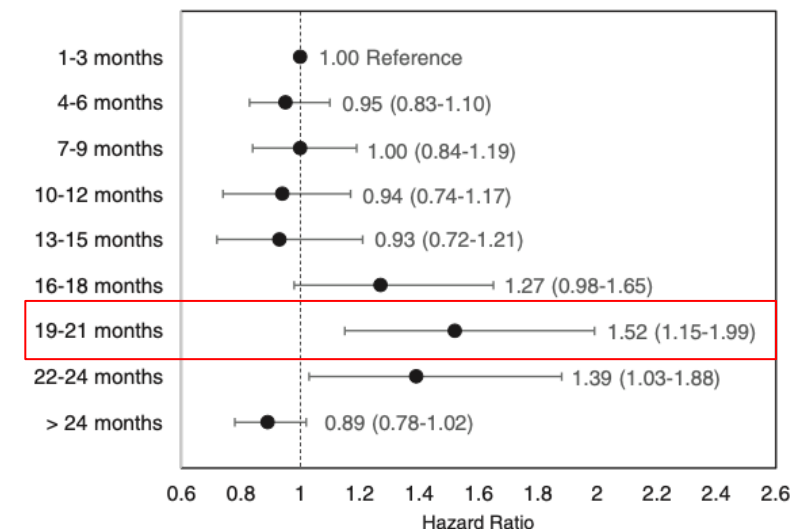
Incident CRC



Late-Stage CRC

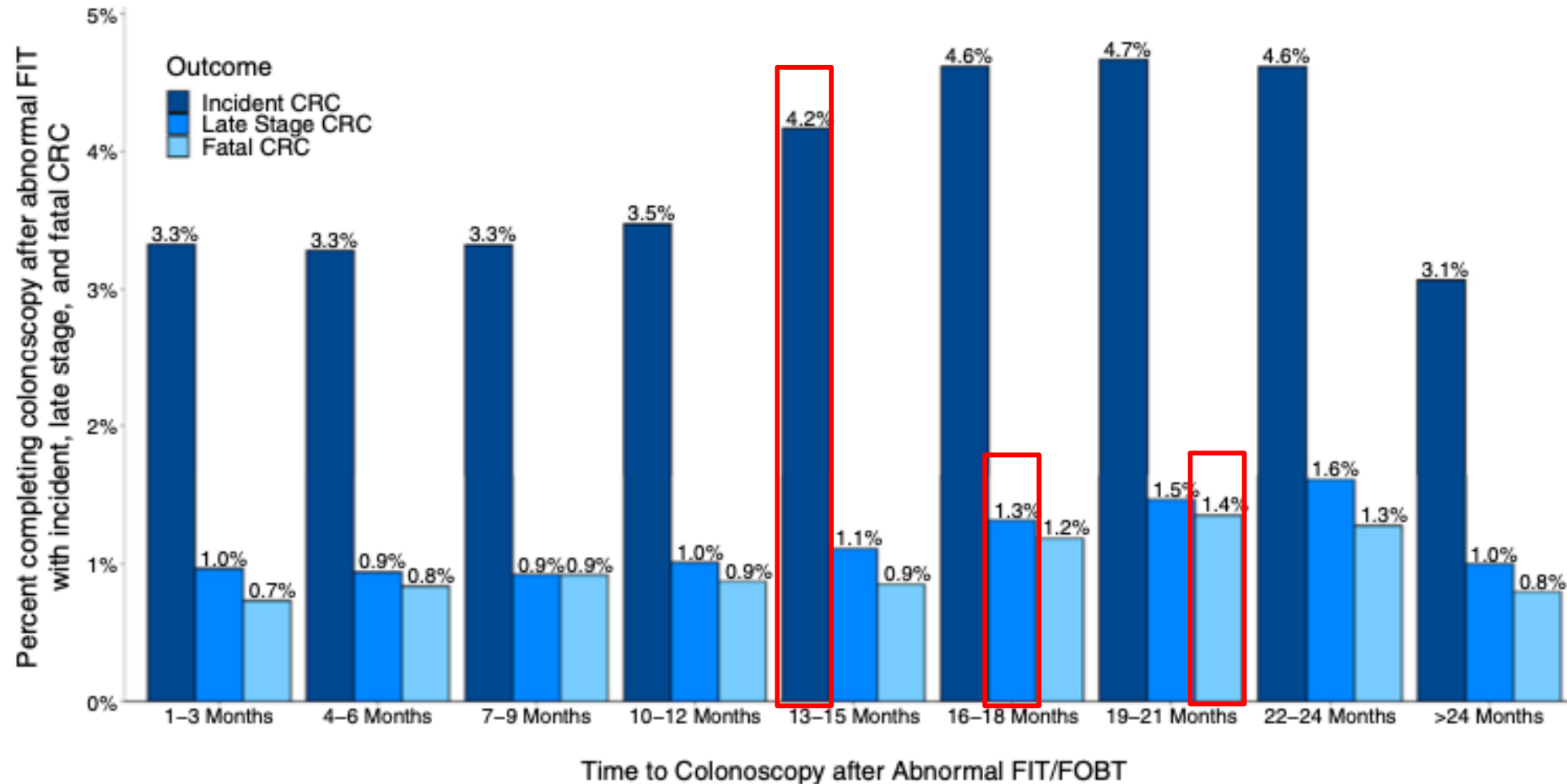


Fatal CRC



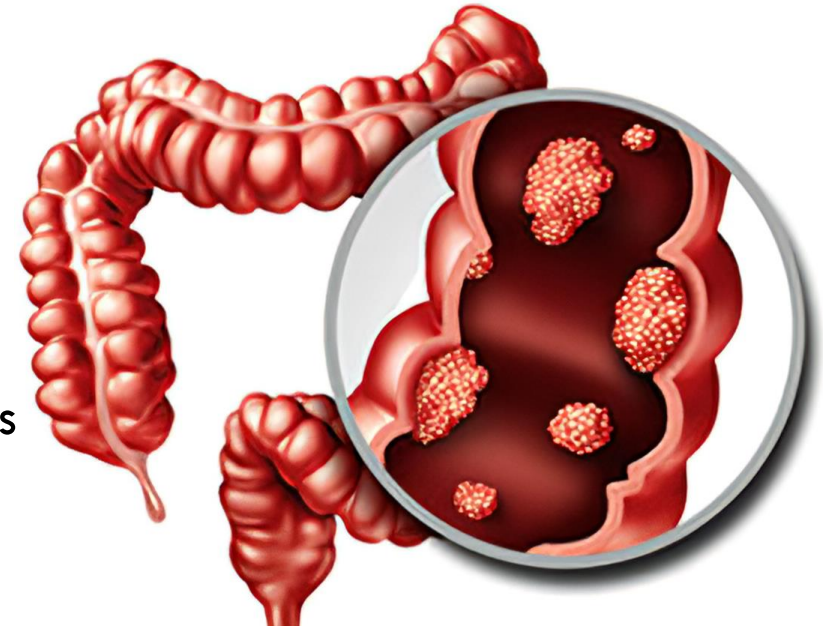
VA Cohort
Abnormal FIT/FOBT 1999-2010

Colonoscopy Should be Performed Well Within One Year of Abnormal FIT/FOBT



Summary

- Non-colonoscopy CRC screening is beneficial but requires follow-up when results are abnormal (“two-step process”).
- Time to follow-up is also a priority; colonoscopy should occur as early as possible but well within 1 year of an abnormal stool-based screening result.
- Lack of timely follow-up after abnormal stool-based screening is associated with poor clinical outcomes:
 - Increased CRC incidence,
 - Advanced CRC stage at presentation,
 - Increased CRC-related mortality, and
 - Increased overall mortality



Thank You!



<https://www.uclahealth.org/gastro/may-lab>





Molly McDonnell
Director of Advocacy
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Catalyst State-by-State Advocacy Program

Fight CRC's Catalyst Program aims to accelerate progress toward turning aspirational colorectal cancer screening goals into reality by increasing access and reducing barriers to colorectal cancer screening. Specifically,

- Ensure coverage for insured populations to include 45-49-year olds, as is now recommended through American Cancer Society & USPSTF draft guidelines.
- Remove patient cost-sharing for follow-up colonoscopies following a positive non-invasive CRC screening test for insured populations.



FUNDING

Fight CRC provides grant funding of up to \$50,000 to state coalitions and provides a facilitator to carry out a robust action planning process



ASSISTANCE

Fight CRC provides funding and technical assistance to support grassroots activities and coalition-building at the state level



MODEL FOR CHANGE

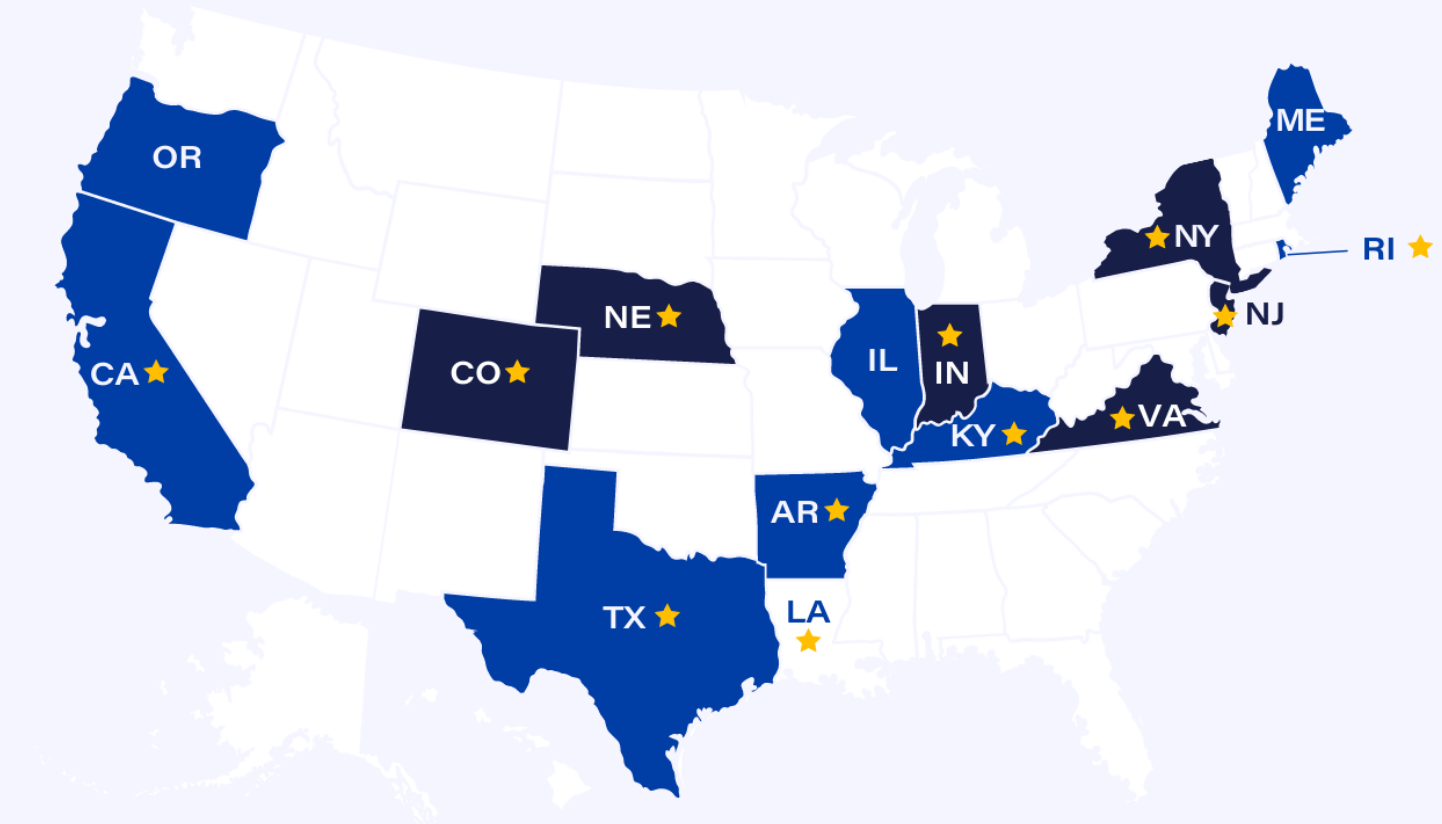
Grantees will serve as a model and offer lessons learned for other communities looking to organize coalitions to advance policies and advocate around the issue of CRC screening.



STATES

Our grantees include **Arkansas, California, Colorado, Kentucky, Louisiana, Nebraska, Rhode Island, and Texas.**

State Policy Landscape



■ Legislation passed

■ Legislation pending

★ Catalyst Grantee State

Catalyst Resources: Arkansas Center for Health Innovation

Removing financial barriers such as cost-sharing is an effective way to improve screening.^{7,8}

Starting on January 1, 2022, most Arkansans ages 45 to 75 will no longer have out-of-pocket costs for follow-up colonoscopies.



Other states, such as Texas and Rhode Island, have also eliminated cost-sharing for these procedures.

Why is this important?



3 out of 5

eligible Arkansans^{***} who had a follow-up colonoscopy had cost-sharing in 2017.³

A study among Medicare enrollees found that removing the 20% coinsurance for a colonoscopy with a polyp removal or a follow-up colonoscopy would be **cost effective** if the screening rate increased by only 0.6 percentage points, from 60% to 60.6%.⁷



¹⁻⁸ Visit <https://achi.net/library/colorectal-cancer-disease-in-arkansas/> for these references. | ^{*}1999 and 2000 data are suppressed. | ^{**}U.S. Preventive Services Task Force. | ^{***}Arkansans ages 50 to 75 enrolled in commercial, traditional Medicaid or Arkansas Works, or Medicare coverage.

Federal Efforts on Follow-Up Colonoscopy



CMS Engagement



**Medicare Physician Fee
Schedule Comment
Letter**



**Letter to Tri-
Agencies**



**Meeting with Tri-
Agencies**





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Abnormal Stool Tests: NCCRT Best Practices Brief

Michelle Tropper, MPH

November 16, 2021

Importance of Follow-up of Abnormal Results

- Stool tests only save lives if they are followed up appropriately when abnormal.
- Colonoscopy within 1 year of an abnormal result rarely exceeds 50%.
- Practices need to develop workflows and implement steps to close the loop on the screening process and verify that the test was completed as ordered.



Clearly Communicate Results and Next Steps to Patients

An abnormal FIT does not mean you have cancer.

It's important to attend all follow-up appointments for tests or treatment.

If polyps are found, most are removed during your colonoscopy.

Colonoscopy is an important step for getting ahead of cancer in your colon.

Source: <http://www.bccancer.bc.ca/screening/Documents/Abnormal-FIT-Brochure.pdf>

The USPSTF clearly states in its colorectal cancer screening guidelines that *“Follow-up of positive screening test results requires colonoscopy regardless of the screening test used.”*

Best Practices for Follow-up of Abnormal Results



Use registries to track patients with abnormal FIT results



Standardized and scripted approach to follow-up



- ✓ Delivering results to patients
- ✓ Scheduling Follow-up tests within one month of receiving abnormal test results



Utilize patient navigators



Identify a clinical champion



Ensure quality screening for a stool-based screening program



- ✓ Stool samples collected at home
- ✓ Verify date of collection with patient
- ✓ Use trained, experienced personnel to develop and report test kits
- ✓ Send test kits to a central laboratory for processing, when possible
- ✓ Monitor test positivity rates

Best Practices for Follow-up of Abnormal Results (continued)



Mailed FIT test outreach

- ✓ Track return rates and follow-up
- ✓ Use closed loop system to track lab orders and diagnostic imaging/referrals ordered

Coordinate follow-up after colonoscopy



Delaying colonoscopy after an abnormal stool test can have major consequences, including increased risk for cancer diagnosis, late-stage cancer at diagnosis, and death from colorectal cancer. – Dr. Samir Gupta, VA San Diego Healthcare System

Establish a medical neighborhood



- ✓ Understand insurance complexities
- ✓ Use consistent language to describe the entire screening process; use “follow-up colonoscopy”, rather than “diagnostic colonoscopy”

Q&A



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Colon Cancer Screening Program

Rina Ramirez, MD, CMO and
Kathleen Felezzola, BSN,
Director of Nursing

Zufall Health Center – A Federally Qualified Health Center since 2004

- Established in 1990 as a volunteer clinic
 - Nine offices in seven counties
 - Fully Licensed Medical and Dental vans
 - Wellness Center
- Serving the underserved population, homeless, farmworkers, residents of public housing and veterans
- HRSA Health Center Quality Leader
- Partnering with ScreenNJ since 2017 and NJCEED since 2009
- In 2020, saw 40,000 patients, 143,000 visits (excluding Covid), if include, 177,000 total visits
 - 90% under 150% poverty; 53% uninsured; 65% Latino; 59% need interpretation services



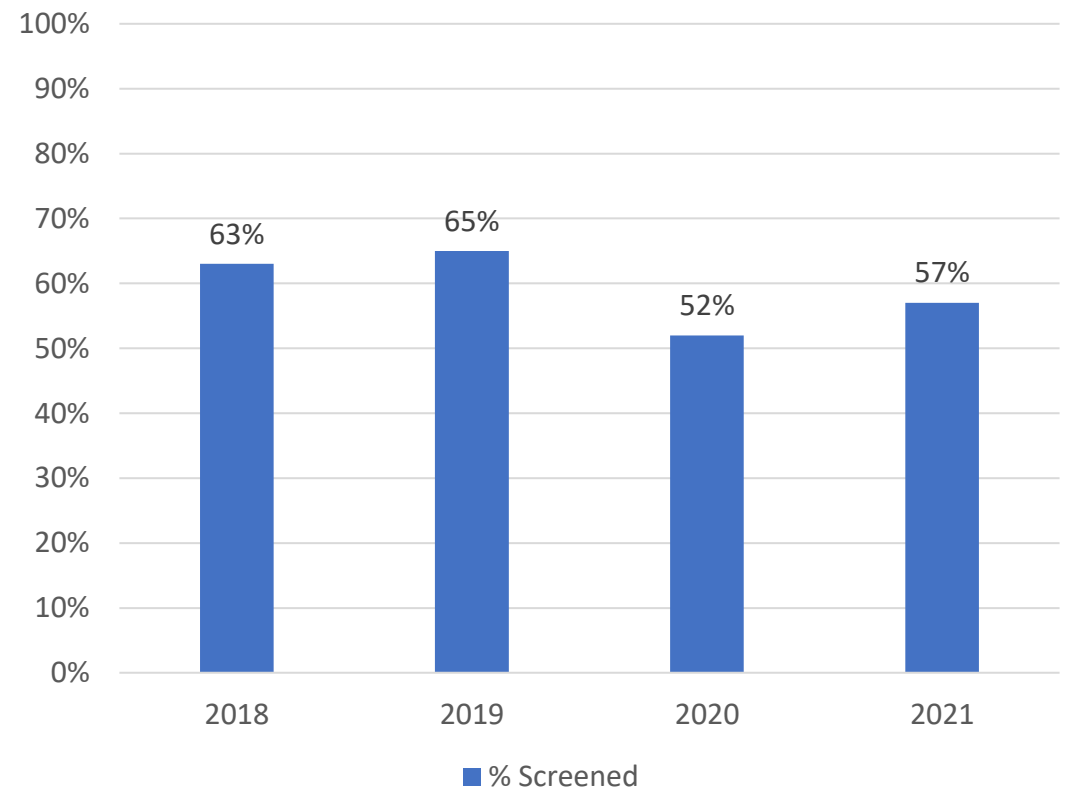
Colon Cancer Screening Rates

between 6,500 – 7,000 eligible patients

Year	% Colonoscopy	% FIT Returned	% Positive FIT
2018	16%	61%	4%
2019	21%	65%	6%
2020	18%	61%	4%
2021 (to 9/30)	19%	66%	6%

- We continue to strive to reach 80%
- Focusing to increase our 2021 rates to pre-pandemic levels
- Concern: status of positive FIT Tests

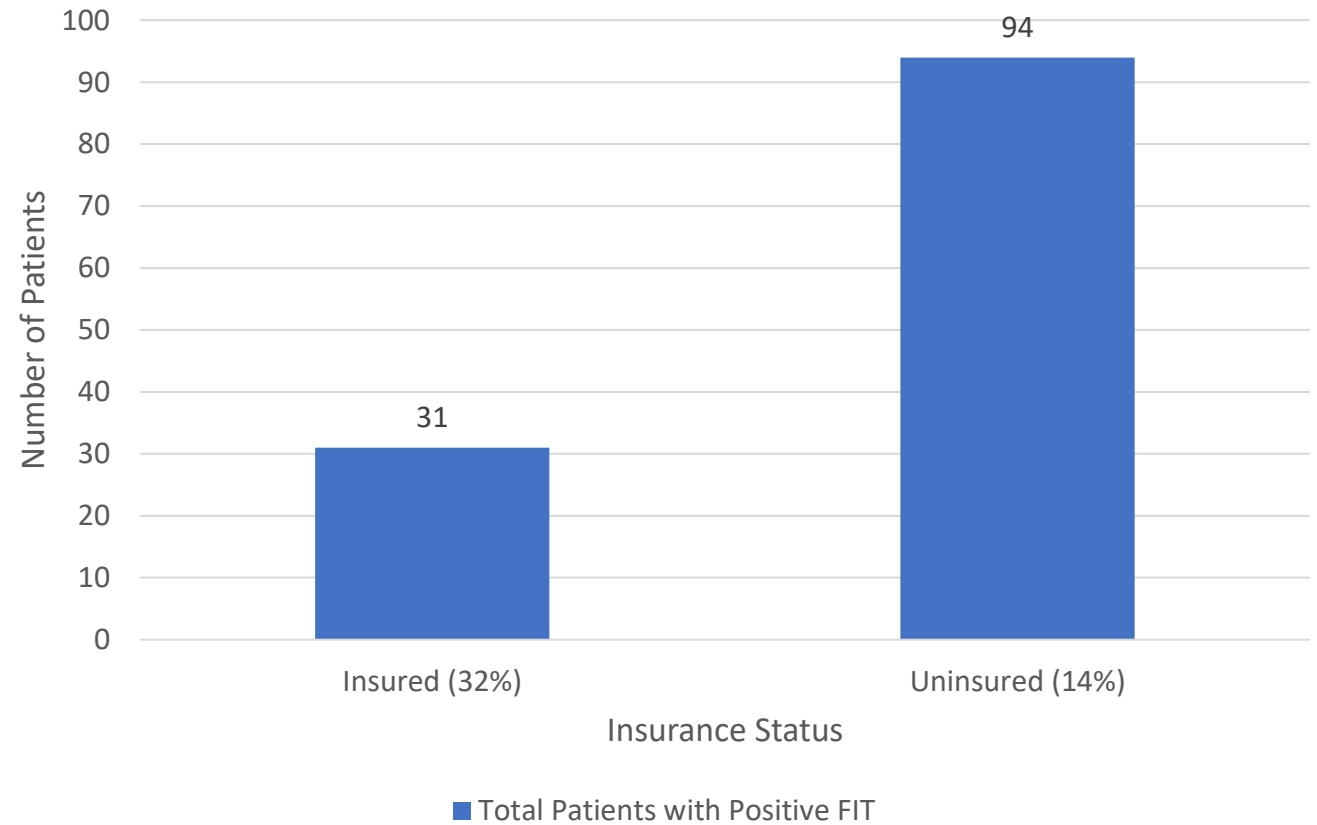
Zufall Colon Cancer Screening Rates - UDS



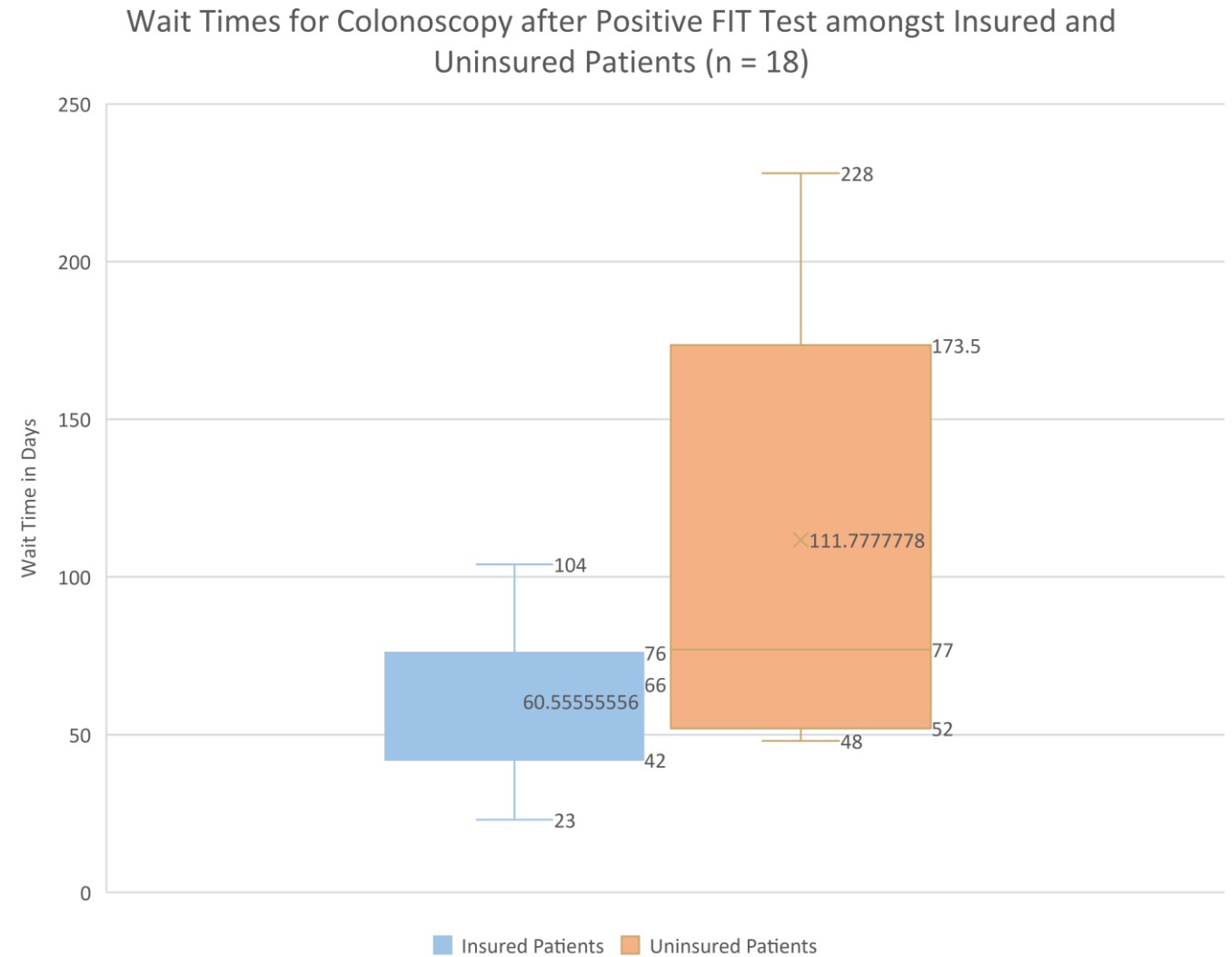
Positive FIT Test and Colonoscopy Completion (Oct 2020- Sept 2021)

Patients with Positive FIT Test and Percent Completed Colonoscopies

Oct 2020 through Sept 2021
(n = 125)

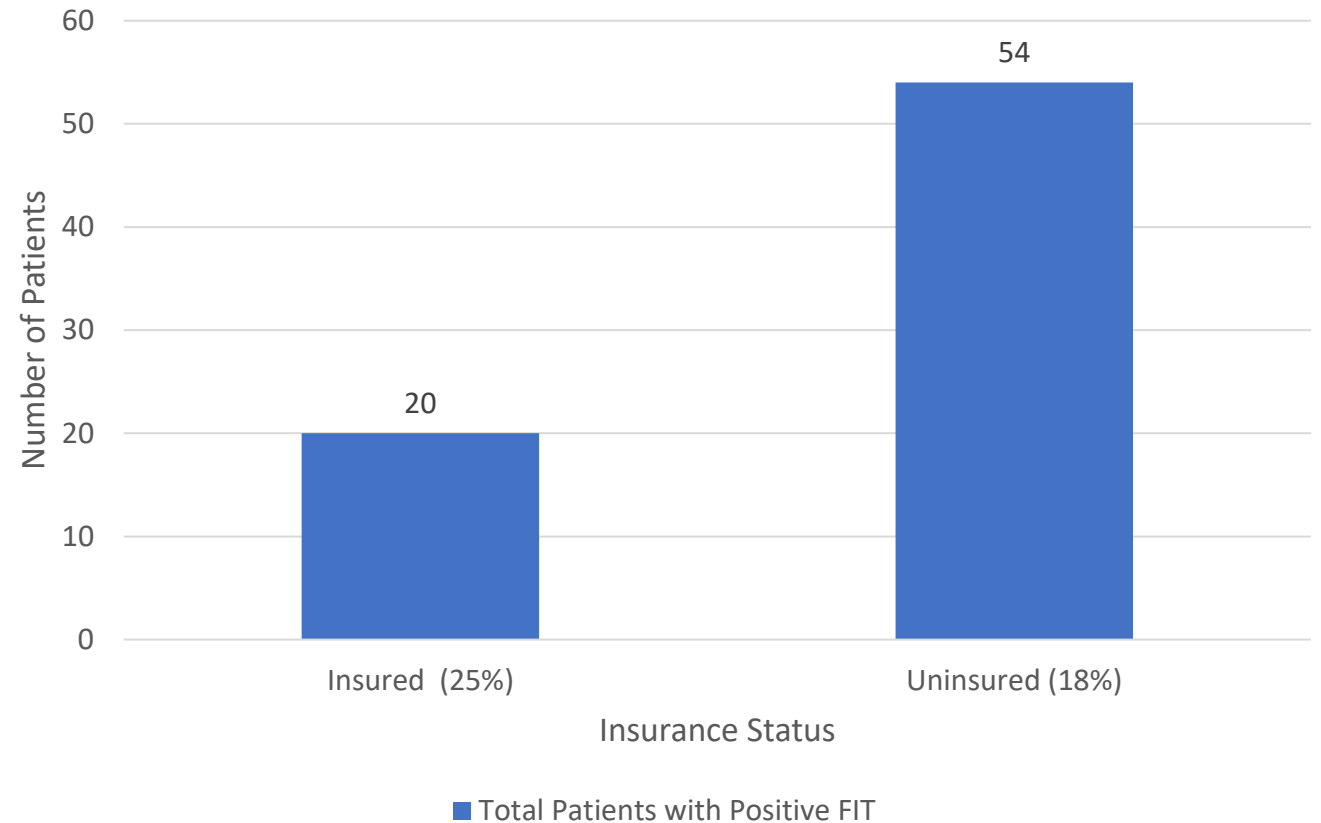


The Impact of Insurance Status on Colonoscopy Wait Times (Oct 2020-Sept 2021)



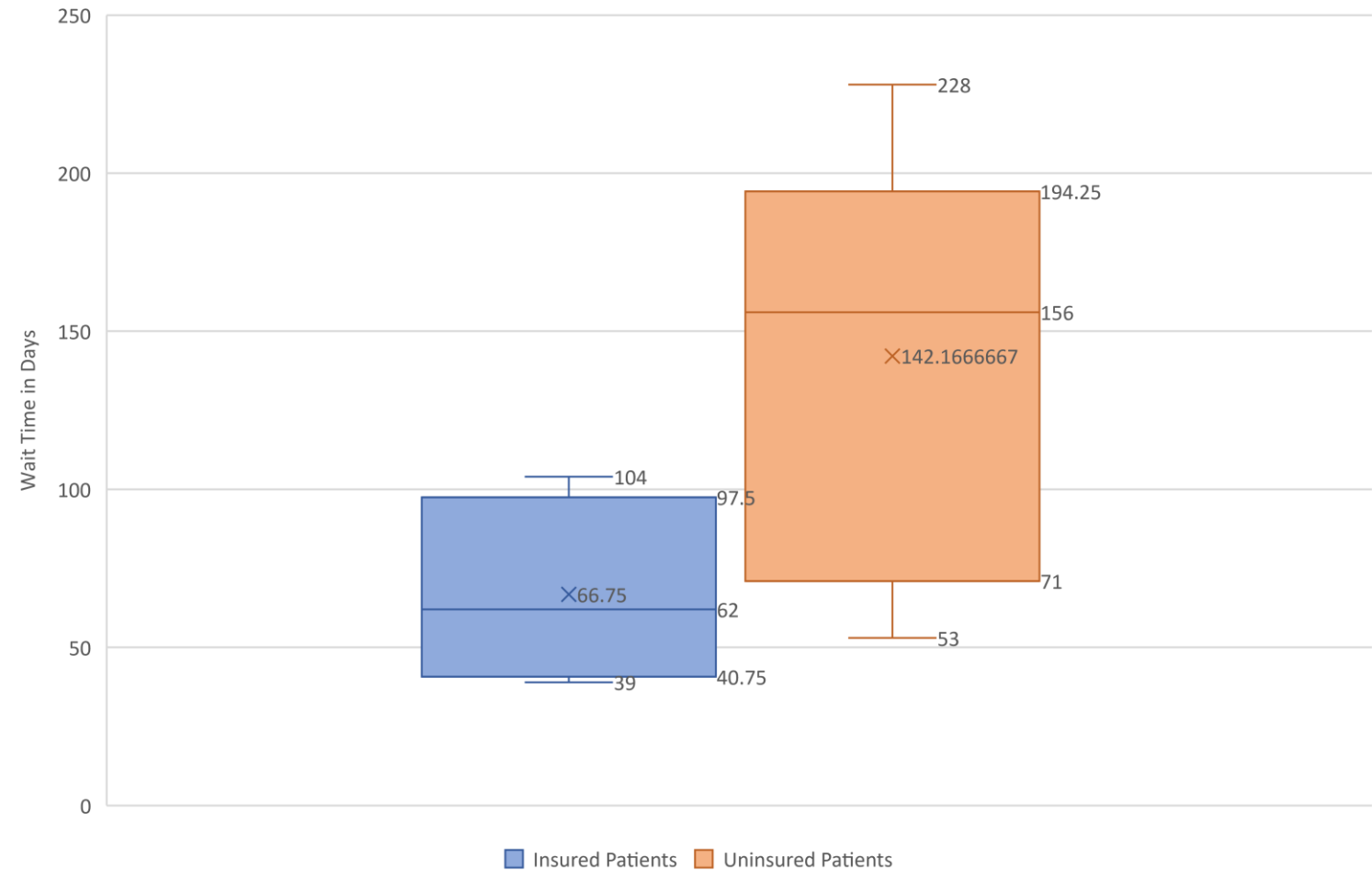
Positive FIT Test and Colonoscopy Completion 6 Months After Positive FIT Result (Oct 2020-May 2021)

Patients with Positive FIT Tests and Completed
Colonoscopies 6 months after Positive FIT Test
(n = 74)



Impact of Insurance Status on Colonoscopy Wait Times (6 months after Positive FIT)

Wait Times for Colonoscopy after Positive FIT Test amongst Insured and Uninsured Patients (n = 10)





- ▶ Navigator/Trainer
- ▶ Navigators at each site
- ▶ Identified GI specialists who will provide needed care to our patients who may have financial barriers to care
- ▶ All Zufall team members including Providers and MA's who see the patients each and every day and can provide education and reinforce the importance of this screening to support this program

WHO WILL MAKE THIS HAPPEN?

Activity

- ▶ Provide FIT-FOBT tests to all eligible patients across all centers
- ▶ Conduct Patient Navigation to encourage return of tests
- ▶ Process the returned kits in-house or prepare them for LabCorp
- ▶ Provide negative results and remind of yearly testing
- ▶ Refer and navigate patients with positive result to colonoscopy services

Expected Outcomes

- ▶ CRC screening rates increase across Zufall's sites
- ▶ Let's get to 80%!!!!



COLORECTAL CANCER SCREENING

Activity

- ▶ FIT tests are distributed, and returns are tracked in Zufall's EMR by staff
- ▶ Timeline is as follows:
 - ▶ FIT kits are given at any visit
 - ▶ Navigator follows up at 3 days, 7 days and 14 days
 - ▶ Navigator confirms lab results or follow up to request lab results 5 days after FIT return/delivery to lab
 - ▶ Gift card given to patient when FIT is returned

Outcome

- ▶ FIT kits are distributed to our target patient population
- ▶ 3500 or more kits will be returned by our target population and processed



Review standing orders!

FIT TEST DISTRIBUTION

Activity

- ▶ Navigators reach out to positive patients with follow-up reminders and assistance with further diagnostic testing, via phone and patient portal
- ▶ Zufall provides patients with funding to eliminate the GI visit Copay
- ▶ Zufall provides Financially indigent patients requiring colonoscopies with subsidies to alleviate financial burdens associated with copays

Outcome

- ▶ Patients with positive FIT tests have access to Colonoscopies



FOLLOW UP

BARRIERS TO FOLLOW UP CARE/COLONOSCOPY

Barrier	Potential Intervention
Financial <ul style="list-style-type: none">Both insured and uninsured patients will delay or decline to have follow up colonoscopy screening due to out-of-pocket expense	<ul style="list-style-type: none">Partner with Providers/Organizations to provide follow up care who will accept Charity Care/Medicaid rates or provide services to those who don't qualify for Charity Care/Medicaid with no or limited out of pocket expense to patientProvide financial assistance to patients who do not qualify for Charity Care/Medicaid or who don't have access to Partner provider/organization
Knowledge Deficit <ul style="list-style-type: none">Patient does not acknowledge need for follow up colonoscopy after educational interaction with Navigator	<ul style="list-style-type: none">Provide clear education prior to FIT test about necessary follow up for positive FIT testSchedule in person or Telemedicine visit with trusted provider to discuss results and necessary follow upProvide clear patient education materials

BARRIERS TO FOLLOW UP CARE/COLONOSCOPY

Barrier	Potential Intervention
Language Barrier <ul style="list-style-type: none">• Patients are not comfortable seeking care from a provider if they are unable to communicate in their language	<ul style="list-style-type: none">• Navigators assist to make appointments;• When possible, navigators arrange for translator to assist at appointments• Navigators follow up with patients after appointments, discuss any questions, pre-procedure questions.
Transportation <ul style="list-style-type: none">• Limited funding and limited access to Public Transportation/Uber in rural areas	<ul style="list-style-type: none">• Schedule transportation through public transportation or ride sharing
Pre-Procedural Prep <ul style="list-style-type: none">• Unable to afford• Limited literacy affects ability to be compliant	<ul style="list-style-type: none">• Provide Prep through 340B program• Follow up by navigator to remind of appointments, prep regimen, ensure understanding, translate as necessary, check in on day of prep to encourage compliance



Thank You!

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- Kathleen Felezzola, BSN
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Questions & Answers