Predictors of Timely Colonoscopy After a Positive Fecal Immunochemical Test (FIT) in the CONFIRM Study

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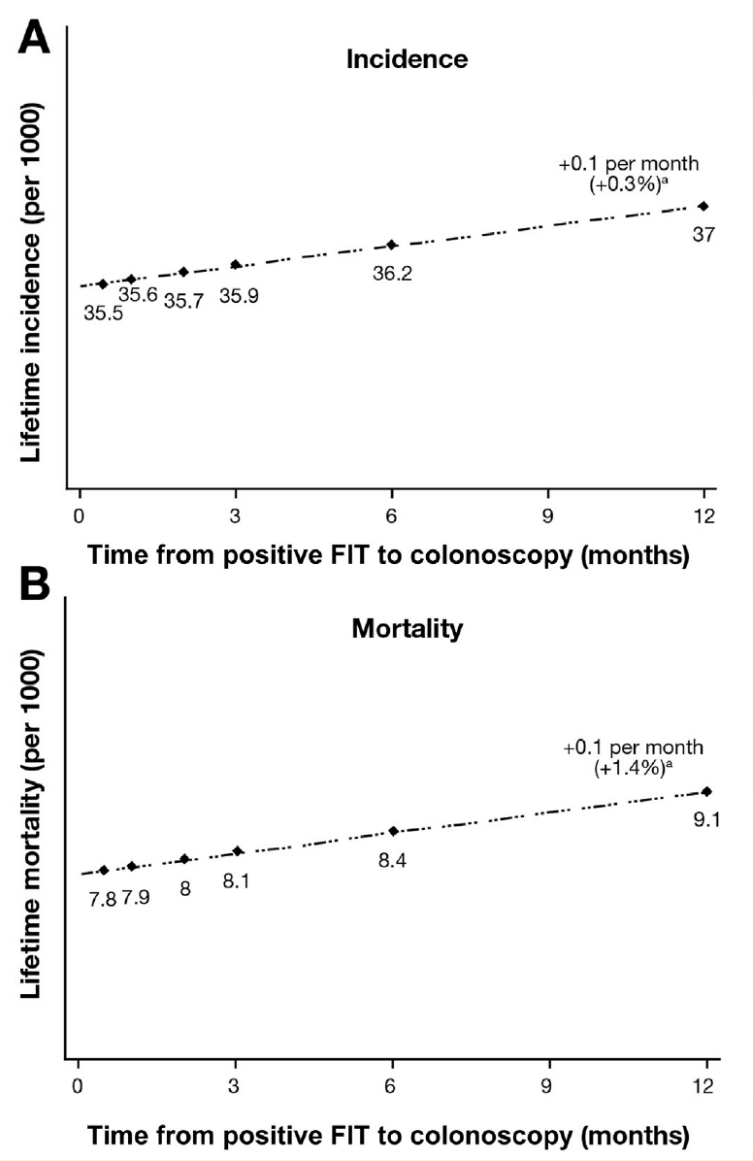
Possible conflicts of interest

- None relevant to the presentation

Stool Based Colorectal Cancer Screening

- Reduces colorectal cancer mortality in RCT's
  - Fecal immunochemical test (FIT) increasingly replacing conventional FOBT
- Stool based screening programs rely on **timely completion** of colonoscopy in those with a positive screening test

Delayed Colonoscopy after FIT + Impacts Screening Effectiveness



- Microsimulation modeling in a screening population
- Examined impact of delay relative to colonoscopy at 2 weeks after a positive test
- Results:
  - CRC incidence ↑ **0.3% /month**
  - CRC mortality ↑ **1.4% /month**

Clin Gastroenterol Hepatol. 2016;14:1445-1451

Timely Colonoscopy after FOBT + Varies By Site

	% Colonoscopy Complete		
System	1 months	3 months	6 months
Kaiser Northern CA	**28.3%**	**73.4%**	**80.9%**
Kaiser Southern CA	**39.3%**	**69.6%**	**74.4%**
Group Health, WA	**14.9%**	**51.3%**	**62.8%**
Parkland Health, TX	**2.4%**	**34.7%**	**50.2%**

N=62384

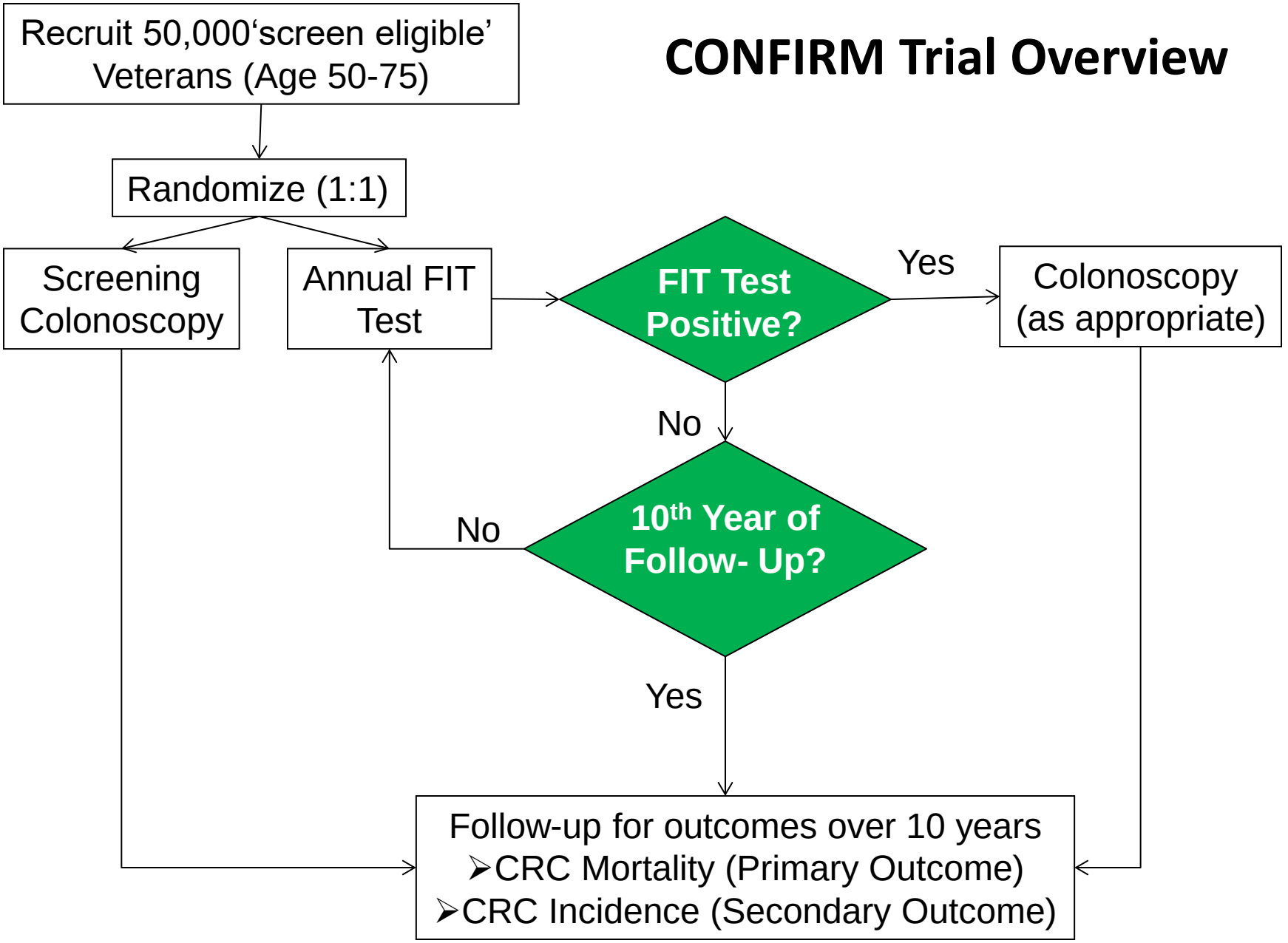
Cancer Epidemiol Biomarkers Prev. 2016;25:344-50

AIM

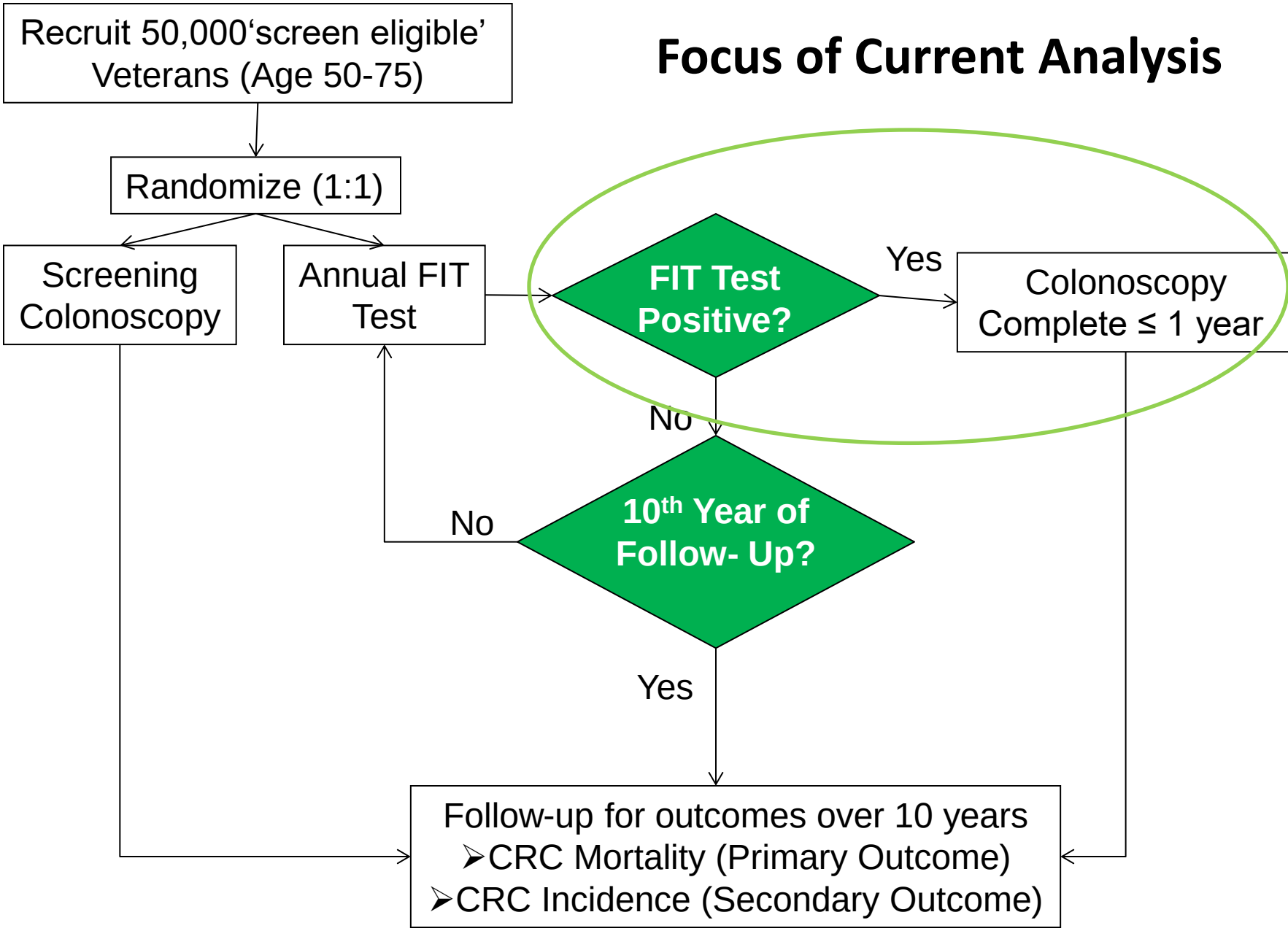
To determine factors associated with timely colonoscopy completion (< 60 days) of a positive FIT

CONFIRM Trial Overview

CONFIRM Trial Overview



Focus of Current Analysis



Methods-Details of FIT intervention

- Initial FIT given by local coordinator; all others sent out centrally to participant through US mail
  - OC-Auto FIT (20 ug hgb/gm stool)
- Participants send completed kit back to central lab (Albuquerque, NM) via Priority Mail
- Results released to both participant and local study investigator (LSI)
  - LSI arranges follow up for those FIT positive via "usual care"

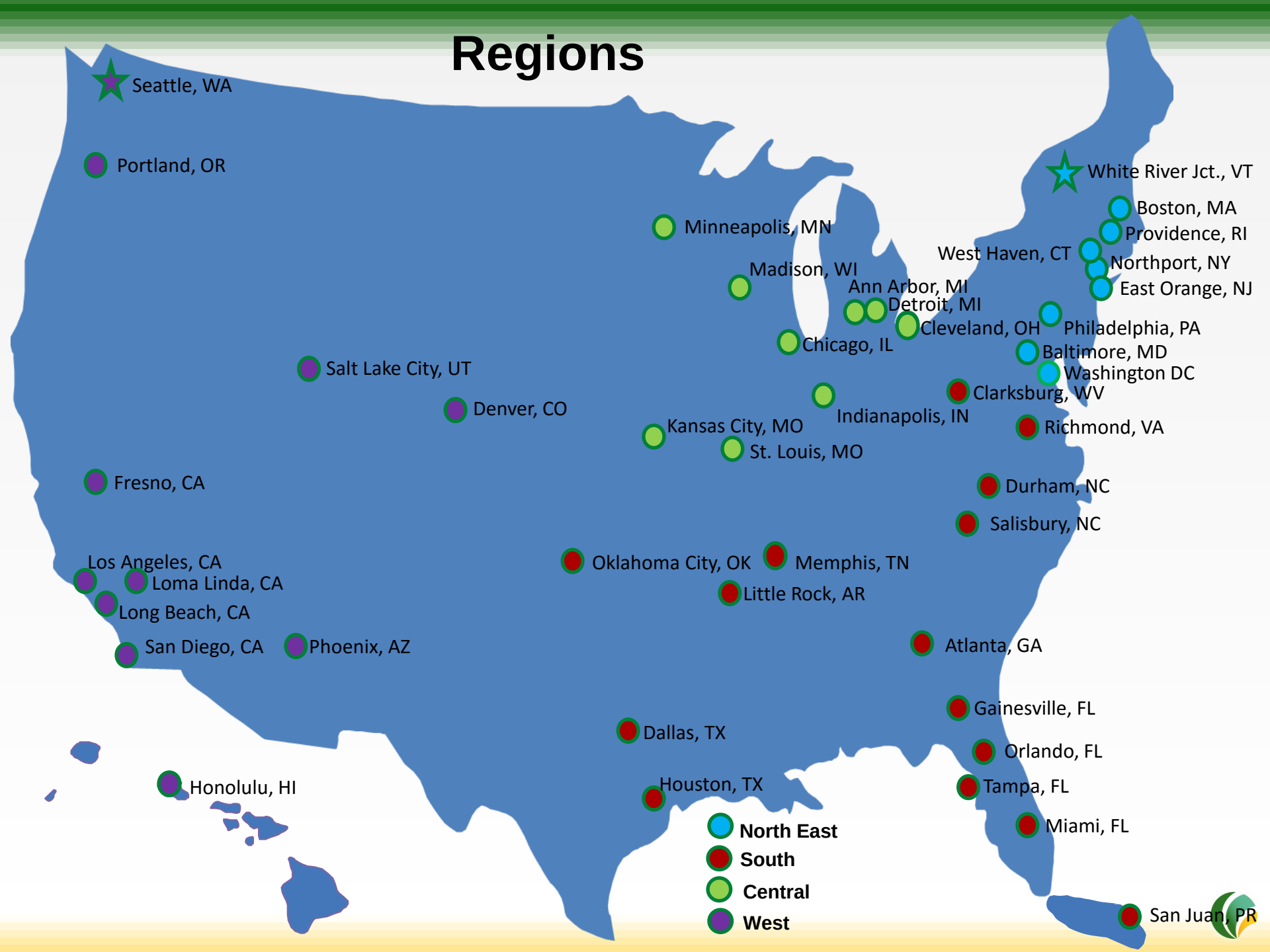
Methods- Main Outcome

- “Timely Colonoscopy” defined as colonoscopy < 60 days of a positive FIT
- Date of positive test available from high throughput Polymedco Diana FIT processor
  - Automated result notification to participant and LSI
- Colonoscopy date determined from dedicated case report form that track all positive FIT
  - Include colonoscopy completed ≤ 1 year of FIT +

Methods-Co-variate Measurement

- Baseline data obtained at enrollment
  - Race/ethnicity
  - Education
  - Habits (Alcohol use, Tobacco use)
  - Prior endoscopy
  - Distance/Time to VA/Insurance information
- Geographic Region
  - 4 regions based on US census categorization

Regions


Seattle, WA
Portland, OR
Minneapolis, MN
Madison, WI
Ann Arbor, MI
Detroit, MI
Cleveland, OH
Chicago, IL
White River Jct., VT
Boston, MA
Providence, RI
West Haven, CT
Northport, NY
East Orange, NJ
Philadelphia, PA
Baltimore, MD
Washington DC
Clarksburg, WV
Richmond, VA
Indianapolis, IN
Salt Lake City, UT
Denver, CO
Kansas City, MO
St. Louis, MO
Fresno, CA
Durham, NC
Salisbury, NC
Los Angeles, CA
Loma Linda, CA
Long Beach, CA
San Diego, CA
Phoenix, AZ
Oklahoma City, OK
Memphis, TN
Little Rock, AR
Atlanta, GA
Gainesville, FL
Dallas, TX
Orlando, FL
Honolulu, HI
Houston, TX
Tampa, FL
Miami, FL
North East
South
Central
West
San Juan, PR

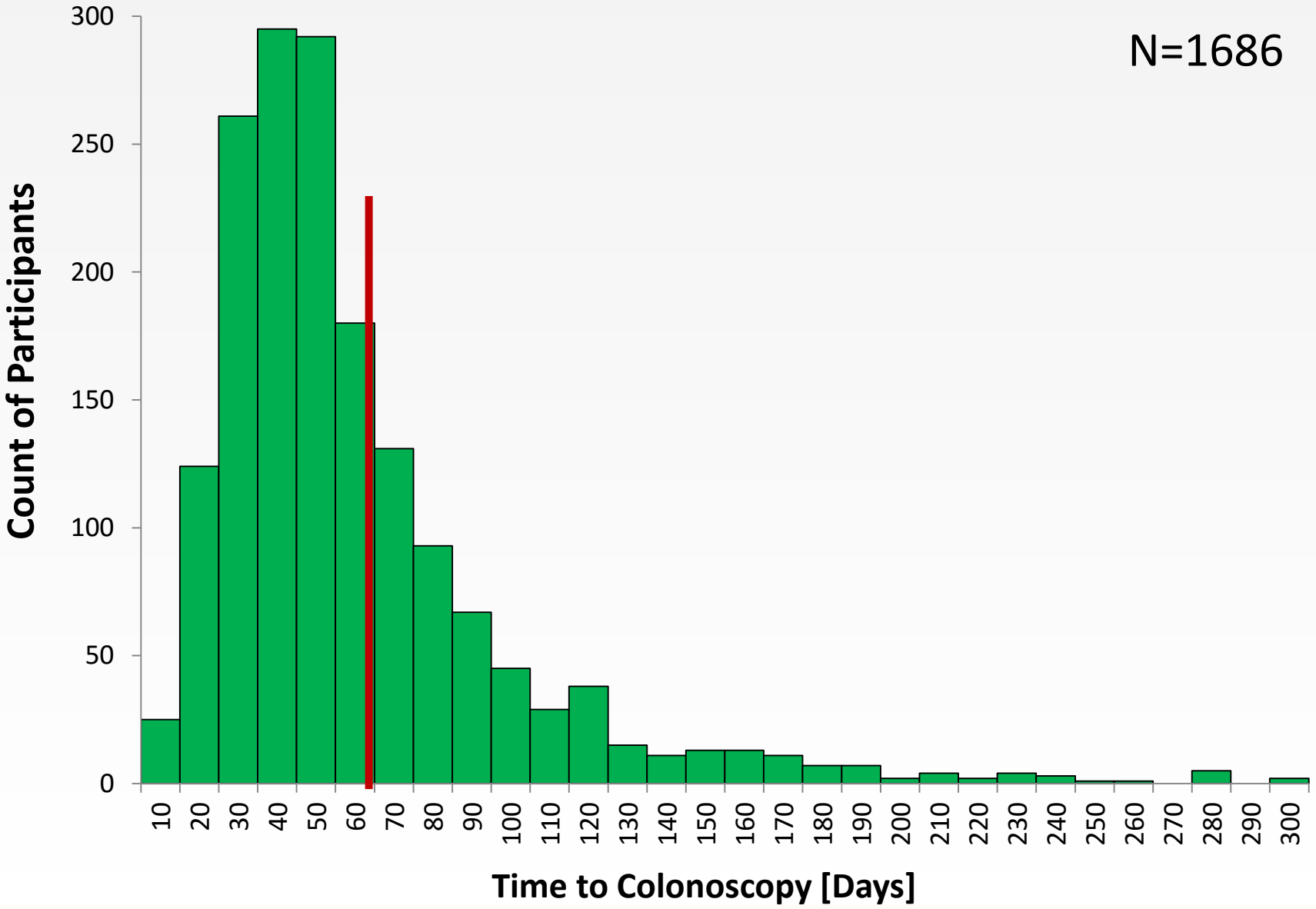
Methods-Statistical Analysis

- Exploratory Analysis examining continuous and categorical covariates with colonoscopy completion < 60 days
  - Two sided t-test (continuous)
  - Pearson's Chi-Square (categorical)
- Predictors of Timely Colonoscopy were modelled using
  - Univariate logistic regression
    - A significance level of $p<0.2$ was used as a threshold for inclusion of variables in a multivariable logistic regression
  - Multivariable logistic regression
    - Estimate the odds of completing timely colonoscopy adjusted for all significant covariates

Results

- 1686 FIT positive Veterans with colonoscopy
  - 95% male
  - 77% white
  - 8.5% Hispanic
- Median time to colonoscopy 45 days (interquartile range 31-67 days)

Number of Days from Positive FIT to Colonoscopy



Exploratory Analysis (continuous)

Mean (SD)	Colonoscopy Done				
	less than 60 days		60 days or more		T-test
	N	Mean (SD)	N	Mean (SD)	
Age [years]	1161	60.4 (6.7)	525	60.4 (6.5)	0.70
Travel distance [miles]		25.6 (31.6)		24.9 (27.1)	0.65
Travel Time [minutes]		39.4 (34.9)		38.5 (29.7)	0.64

Exploratory Analysis (Categorical)

Factor		% Timely Colonoscopy	p-value
Race	White	70.5%	**0.0008**
	Non White	63.3%	
Ethnicity	Hispanic	76.4%	**0.04**
	Non-Hispanic	68.3%	
Prior Colonoscopy	No	67.2%	**0.01**
	Yes	73.7%	
Region	West	65.1%	**0.03**
	South	69.9%	
	Central	70.9%	
	North East	74.9%	

Exploratory Analysis (Categorical)

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	Yes	73.7%	
Region	West	65.1%	**0.03**
	South	69.9%	
	Central	70.9%	
	North East	74.9%	
Education	High School or Less	71.1%	*0.12*
	Some College	65.9%	
	College or Above	70.1%	
Gender	Female	64.1%	0.35
	Male	69.1%	
Alcohol	Yes	69.9%	0.52
	No	68.3%	
Tobacco	Yes	68.2%	0.78
	No	69.2%	

Predictors of Timely (< 60 days) Colonoscopy After FIT Positive Univariate Analysis

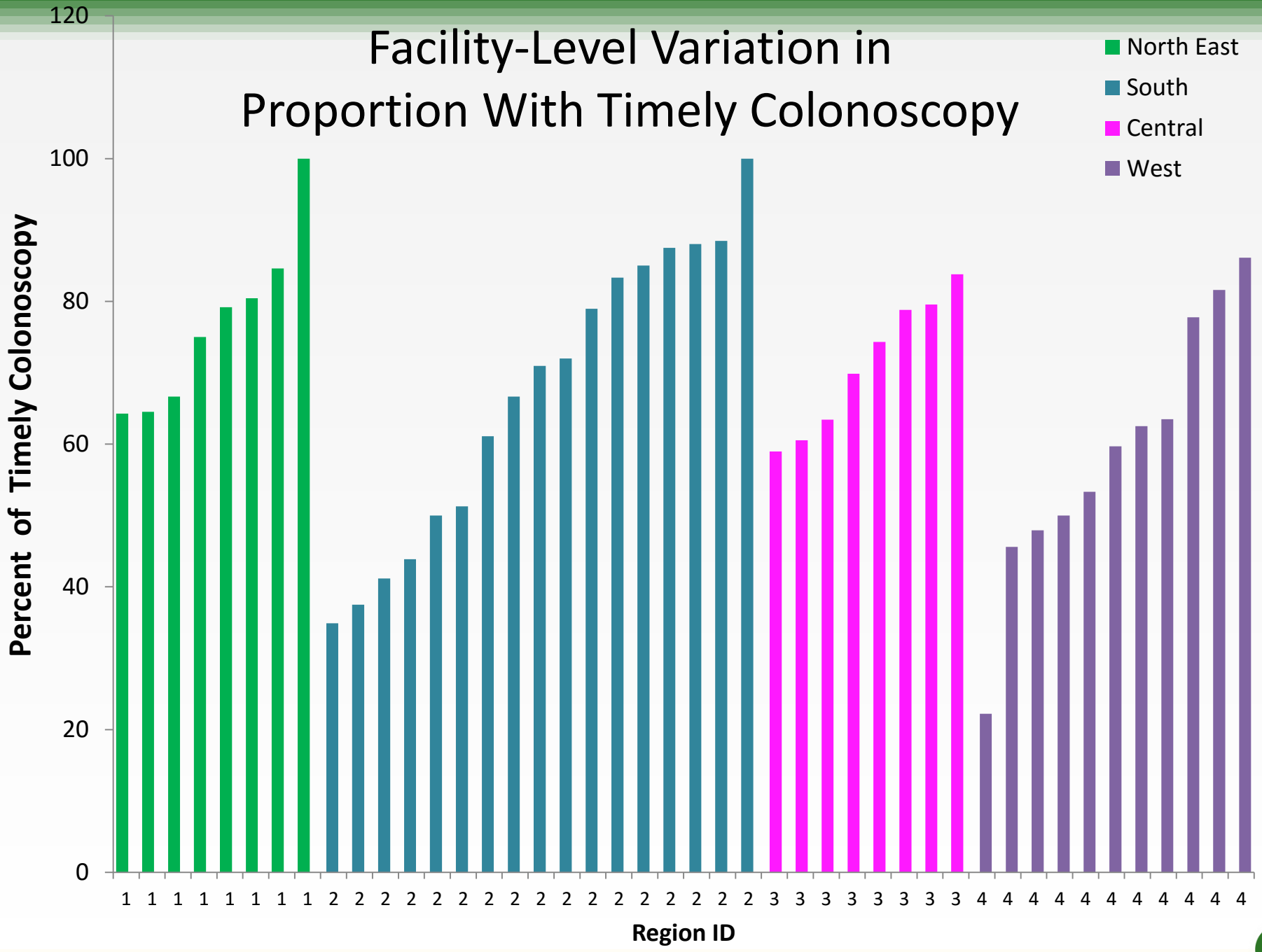
Factor	OR	95% CI
Age (year)	1.00	0.98, 1.01
Race (Non-white vs White)	**0.72**	**0.57, 0.92**
Ethnicity (Hispanic vs Non Hispanic)	**1.50**	**1.00, 2.24**
Gender (Female vs Male)	0.80	0.50, 1.28
Education		
High school or less vs college or more	**0.78**	**0.61, 1.00**
Some College credit but no degree vs College graduate	0.95	0.73,1.24
Alcohol (Drinker vs non drinker)	0.93	0.75, 1.16
Tobacco (Smoker vs non smoker)	1.05	0.83, 1.31
Prior colonoscopy (Yes vs No)	**1.37**	**1.07, 1.74**
Region		
Central vs West	1.42	1.08, 1.88
East vs West	1.63	1.14, 2.34
South vs West	1.19	0.92, 1.53

Age, gender, alcohol and tobacco use insignificant and removed for the model

Predictors of Timely (< 60 days) Colonoscopy After FIT Positive Multivariable Analysis

Factor	OR	95% CI	aOR	95% CI
Age (year)	1.00	0.98, 1.01		
Race (Non-white vs White)	**0.72**	**0.57, 0.92**	**0.73**	**0.57, 0.94**
Ethnicity (Hispanic vs Non Hispanic)	**1.50**	**1.00, 2.24**	**1.59**	**1.06, 2.38**
Gender (Female vs Male)	0.80	0.50, 1.28		
Education				
High school or less vs college or more	0.78	0.61, 1.00	1.08	0.83,1.42
Some College credit but no degree vs College grad	0.95	0.73,1.24	0.90	0.70, 1.17
Alcohol (Drinker vs non drinker)	0.93	0.75, 1.16		
Tobacco (Smoker vs Non smoker)	1.05	0.83, 1.31		
Prior colonoscopy (Yes vs No)	**1.37**	**1.07, 1.74**	**1.33**	**1.04, 1.71**
Region				
Central vs West	**1.42**	**1.08, 1.88**	**1.46**	**1.09, 1.96**
NE vs West	**1.63**	**1.14, 2.34**	**1.68**	**1.16, 2.44**
South vs West	1.19	0.92, 1.53	**1.31**	**1.01, 1.70**

Facility-Level Variation in Proportion With Timely Colonoscopy



Summary

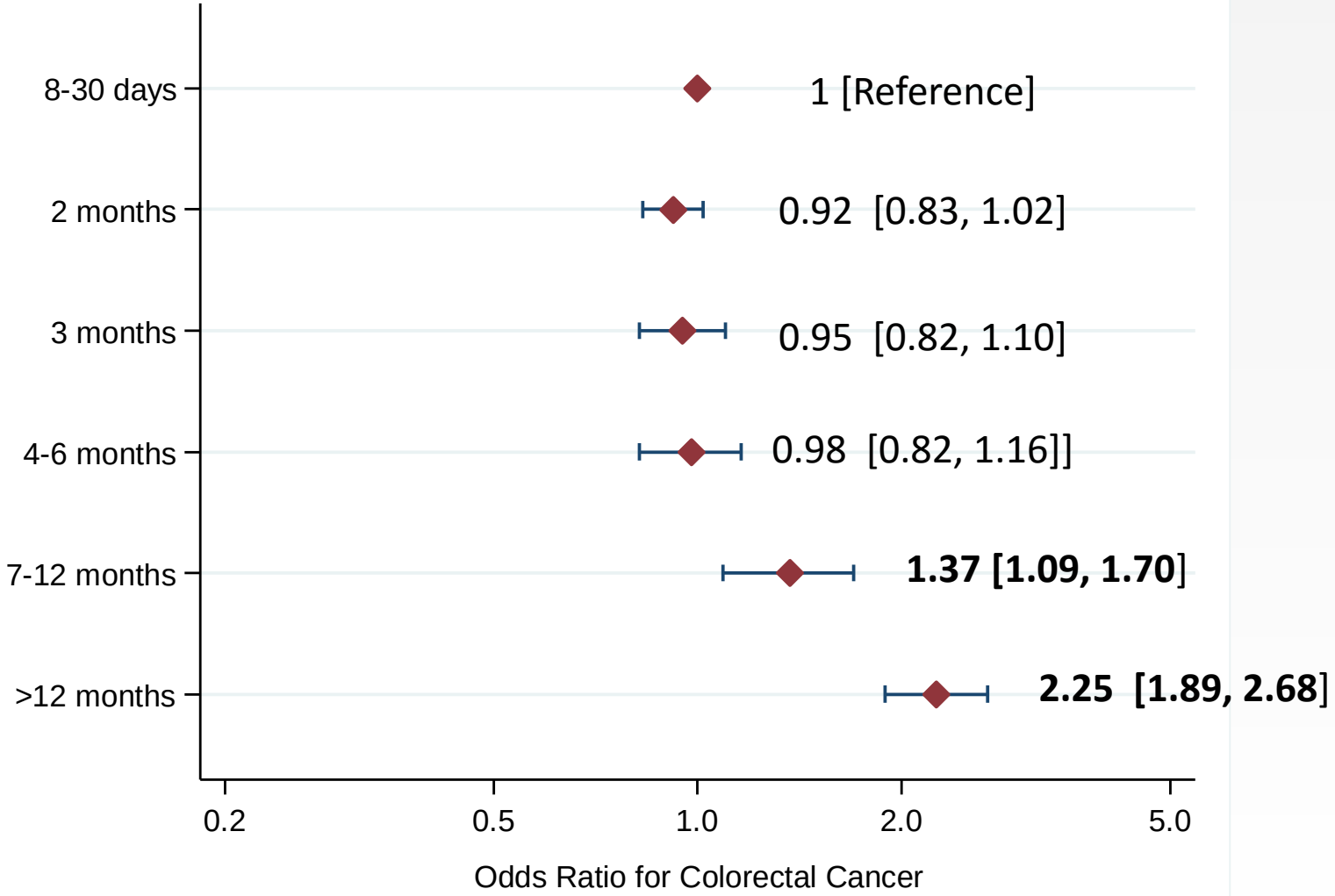
- Non-white participants and those enrolled in West Coast sites less likely to get colonoscopy within 60 days
- Hispanic participants and those with a prior colonoscopy history more likely to get colonoscopy within 60 days

Limitations

- Analysis performed within the framework of a clinical trial only involving US Veterans (generalizability)
- Did not examine all potential factors that could influence timely colonoscopy completion
  - Significant other/availability of a driver
- Cannot examine FIT positive with NO colonoscopy completion
- ? Importance of the 60 day definition of ‘timely colonoscopy’

Colonoscopy Delay After FIT positive& Colorectal Cancer

N=70124



JAMA. 2017;317:1631-1641

Conclusions

- Time to colonoscopy is associated with patient and facility characteristics
- Patient navigation might be explored for persons less likely to complete colonoscopy within 60 days
  - no previous colonoscopy
  - Non-white race
- Regional variation is likely accounted by facility and organizational level factors
  - Site-specific investigation of contributing factors needed

Local Site Investigators - Present

- Aasma Shaukat, MD, MPH
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- Amelia (Beth) Underwood, MD
- Andrew J. Gawron, MD
- Andrew M. Kaz, MD
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- Charles Kahi, MD
- Christian S. Jackson, MD
- Christopher Lenza, DO
- Claudio Tombazzi, MD
- Curt H. Hagedorn, MD
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- Stacy Menees, MD
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- Swati G. Patel, MD
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- William M. Tierney, MD
- William V. Harford, Jr. MD

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- J. Andy Mengshol, MD, PhD
- Juan Diego Baltodano, MD
- Kenneth H. Berman, MD
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- Steven R. Warlick, MD
- Susan Goldsmith, MD
- Toan D. Nguyen, MD

Acknowledgements

CONFIRM is funded and being conducted by the Cooperative Studies Program

Office of Research and Development

Department of Veterans Affairs