

Test Characteristics of Five Fecal Immunochemical Tests for Detecting Advanced Colorectal Neoplasia

Barcey T. Levy, PhD, MD¹; Jeanette Daly, PhD¹; Yinghui Xu, MS¹; Seth Crockett, MD²; Richard Hoffman, MD¹; Navkiran Shokar, MA, MD, MPH³; Jeffrey Dawson, ScD¹; Kim Parang, MA¹; Daniel Reuland, MD, MPH²; Marc Zuckerman, MD³; Avraham Levin, MD¹

¹University of Iowa, Iowa City, IA; ²University of North Carolina, Chapel Hill, NC; ³Texas Tech University Health Sciences Center, El Paso, TX



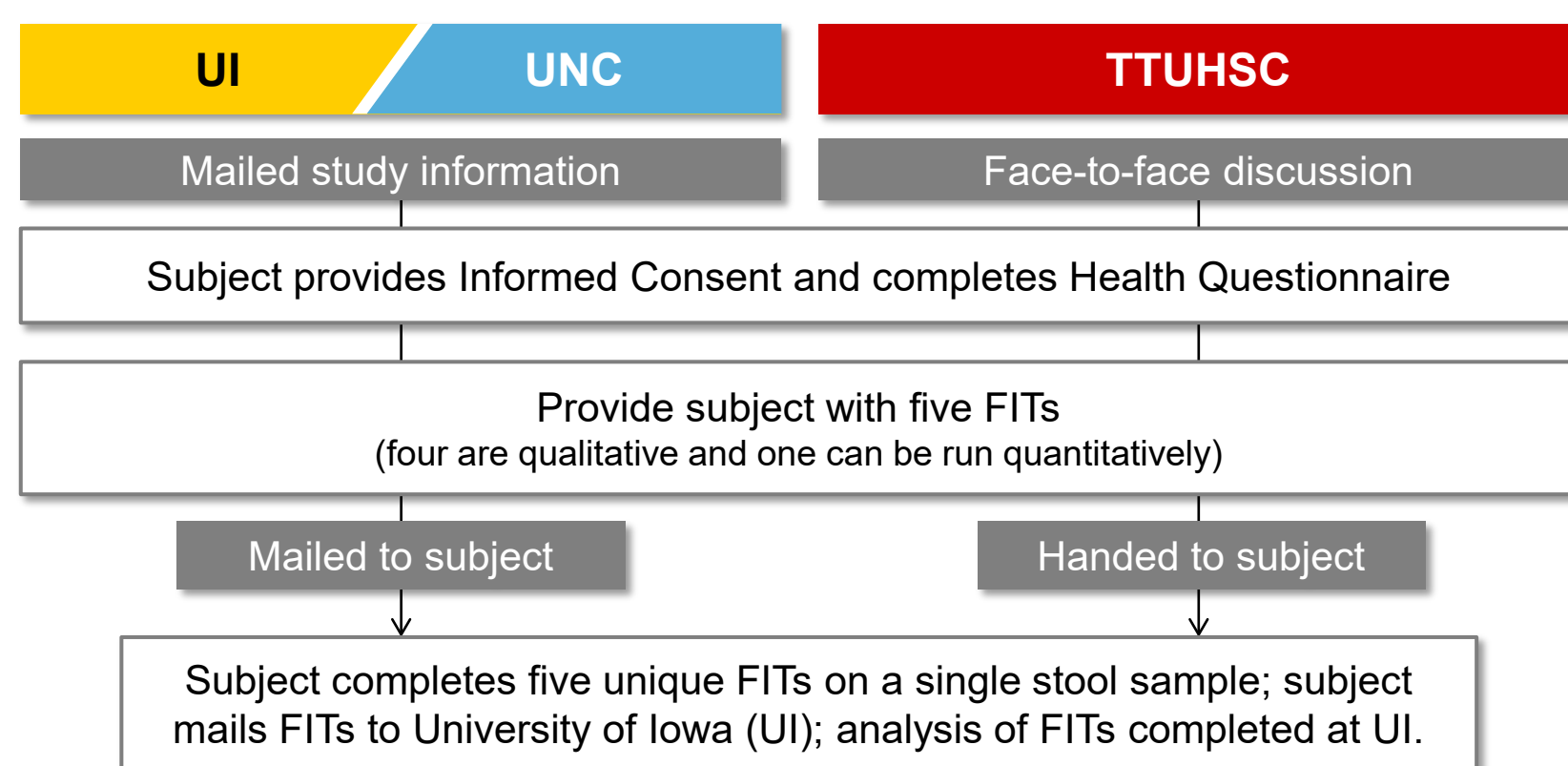
Introduction

- Colorectal cancer (CRC) is the 3rd most common cause of cancer death worldwide.¹
- Modeling estimates for screening found no difference in life-years gained between annual fecal immunochemical tests (FITs) and 10-year-interval colonoscopy.²
- Screening colonoscopy is one of the leading contributors to US health care costs.³
- Many countries use FIT as the primary screening modality for CRC.
- FIT, followed by colonoscopy, if positive, is a much less expensive option for CRC screening and much more accessible for wide segments of the population.
- FIT testing is preferred by many and most practical for population-based screening.⁴
- Although FITs are FDA-cleared, that standard is not based on real world testing.^{5,6}
- There are limited data on the test characteristics of various FITs for detecting advanced colorectal neoplasia (ACN). ACN is defined as either advanced adenoma or carcinoma.

Purpose

To present preliminary results on the test performance of five of the most commonly used FITs for detecting advanced colorectal neoplasia, using information from the corresponding colonoscopy and pathology reports as the gold standard.

Methods



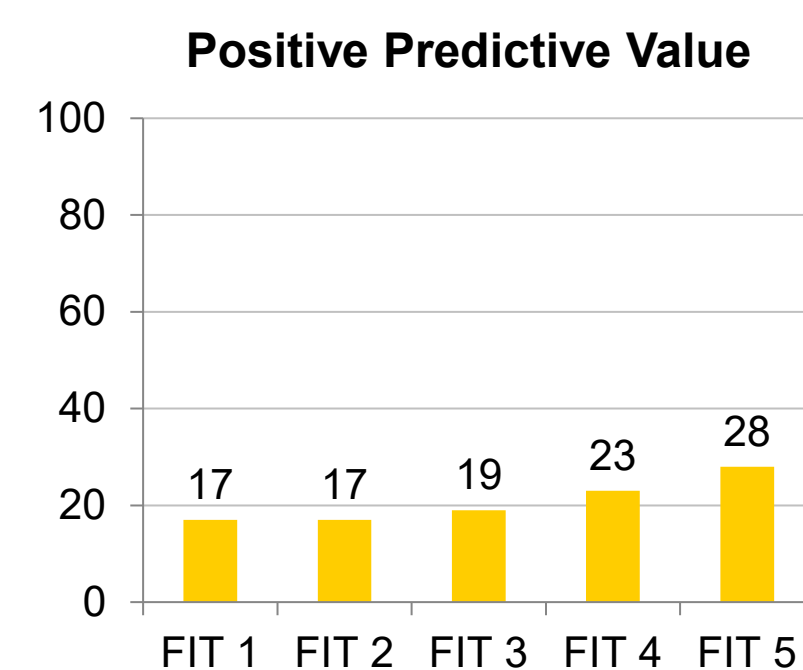
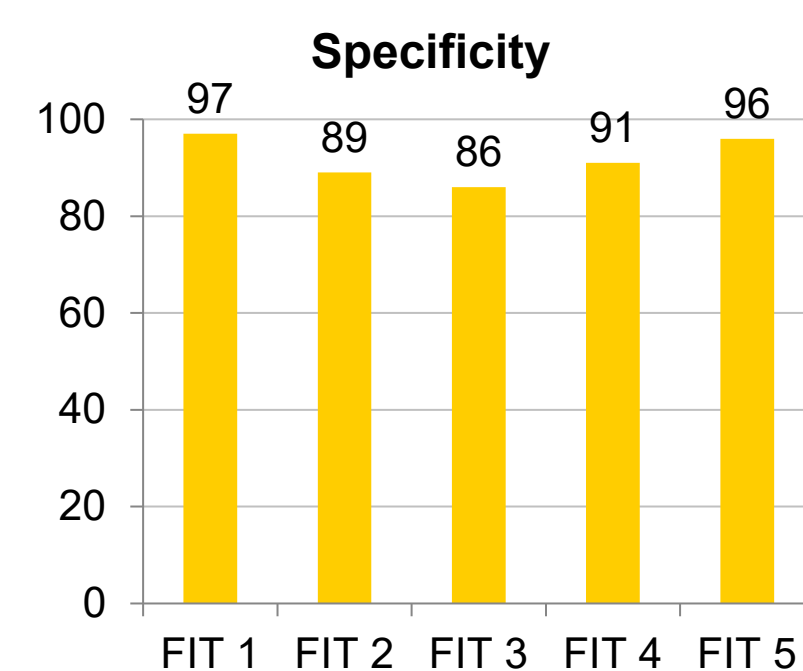
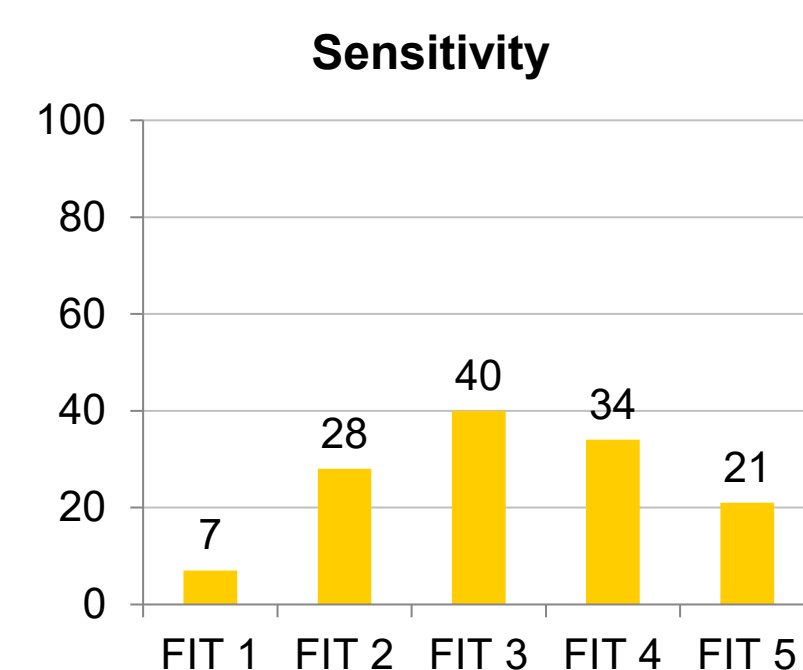
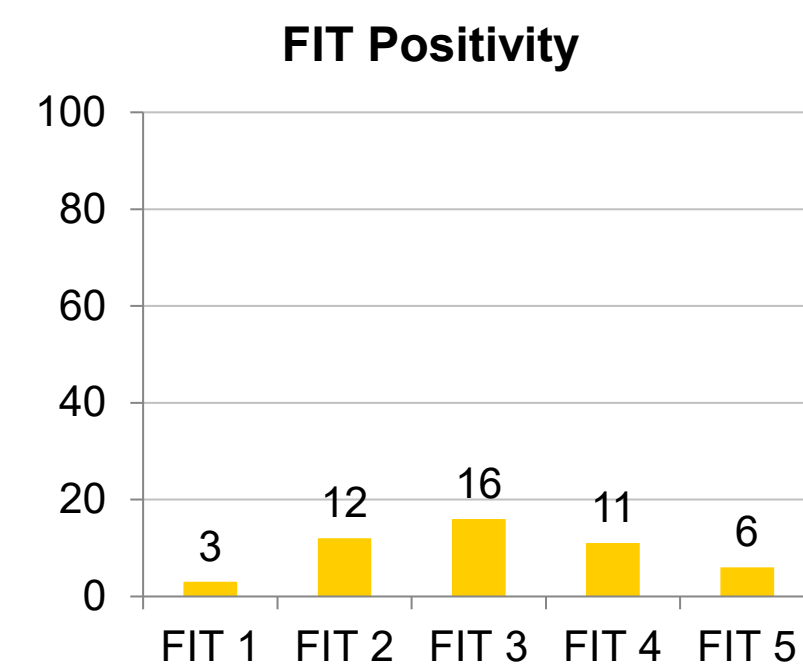
Goal: 3600 subjects over 3.5 years
 Database
 • Health Questionnaire
 • FIT results
 • Product Questionnaire
 • Colonoscopy results
 • Pathology results

Results (n=2792 participants)

Participant Characteristics	n (%)
Age, mean (SD), y	62.0 (7.8)
Gender (Female)	1746 (62.5)
Race	
White	2416 (86.5)
Black	142 (5.1)
Asian	36 (1.3)
Latino	865 (31.1)
Education	
8 th grade or less	246 (8.9)
High school	660 (23.8)
College or higher	1862 (67.3)
Income	
< \$40,000	1084 (40.4)
\$40,000 - < \$80,000	590 (22.0)
≥ \$80,000	1012 (37.7)
Medications	
Daily aspirin	841 (30.5)
NSAID use > 3 times per week	248 (8.9)
Any blood thinner use	121 (4.3)
Colonoscopy type	
Screening	2002 (71.7)
Surveillance	790 (28.3)

Colonoscopy Results	n (%)
Polyps	
Tubular adenoma	1188 (42.6)
Tubulovillous	39 (1.4)
Villous	2 (0.1)
Sessile serrated	203 (7.3)
Traditional serrated	7 (0.3)
Hyperplastic	551 (19.7)
Colorectal cancer	6 (0.2)
Advanced adenoma or cancer	210 (7.5)

Test Characteristics (%)



Discussion

- Preliminary results have been presented on five FITs collected from a diverse sample of 2792 subjects recruited from 3 academic health centers.
- FIT positivity, sensitivity, and PPV varied widely across the five FITs.
 - FIT positivity: 3% to 16%
 - Sensitivity: 7 to 40%
 - Positive predictive value: 17 to 28%
- Specificity ranged from 86 to 97%.
- FITs have the potential to reduce the burden of CRC, but test characteristics need to be understood.

Strengths & Limitations

- This study will allow head-to-head comparisons across five of the most commonly used FITs.
- FITs are delivered to UI by U.S. mail and analyzed the day they are delivered.
- We have a large, ethnically diverse sample.
- Our data will not provide information on how well these FITs work for population-based CRC screening where FIT is recommended every year to two years, depending on the country. Programmatic sensitivity will always be higher than single-sample sensitivity.



Conclusions

- Preliminary results suggest substantial variation in test characteristics among different FIT brands when used for single-sample stool testing.
- Understanding comparative test characteristics could impact regulatory policy and FIT brand selection by healthcare organizations, since certain characteristics may be desirable given healthcare constraints.

References

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