# Variation in quality of approved colorectal cancer screening options: FIT positivity from the STOP CRC pragmatic trial

Amanda F. Petrik[1]
Carrie M. Nielson[1]
Lorie Jacob[2]
William M. Vollmer[1]
Erin M. Keast[1]
Jennifer L. Schneider[1]
Jennifer S. Rivelli[1]
Tanya J. Kapka[1]
Beverly B. Green[3]
Gloria D. Coronado[1]

1 Kaiser Permanente Center for Health Research, Portland, Oregon, USA
2 OCHIN, Portland, Oregon, USA
3 Kaiser Permanente Washington Health Research Institute, Seattle, Washington, USA

## OVERVIEW

The Strategies and Opportunities to STOP Colon Cancer in Priority Populations (STOP CRC) study evaluated the effectiveness of a direct-mail fecal immunochemical test (FIT) intervention at Federally Qualified Health Centers (FQHCs).

The FIT is a cost-effective method used for colorectal cancer screening; however, approved tests vary in quality, and differences between them are not clear to consumers. In practice, FIT positivity rates and positive predictive value (PPV) can vary substantially, such that false-positive results add to colonoscopy burden without improving detection of colorectal cancer or pre-cancerous lesions. We determined the PPV of cancer and advanced adenoma per FIT kit type and factors associated with a true-positive result among patients from FQHCs with a FIT-positive result in STOP CRC, a large community-based pragmatic trial.

## PATIENT ELIGIBILITY & ANALYTIC SAMPLE

In STOP CRC clinics, patients were:

- 50–75 years old
- Had attended a clinic visit in the previous year
- Were due for CRC screening

Additionally:

- All tests were mailed or distributed in the clinic from February 2014–February 2016
- Patients were excluded if they had EHR evidence of any of several health conditions that made them poor candidates for fecal testing (e.g., history of CRC, inflammatory bowel disease, or renal failure)
- Patients were included in the analyses of PPV if they had a positive FIT result using an OC-Micro, InSure FIT, or Hemosure test, completed a follow-up colonoscopy within 12 months of their positive FIT result, and had a colonoscopy procedure report, pathology report, or colonoscopy provider notes with sufficient detail to determine the result

## FECAL TEST

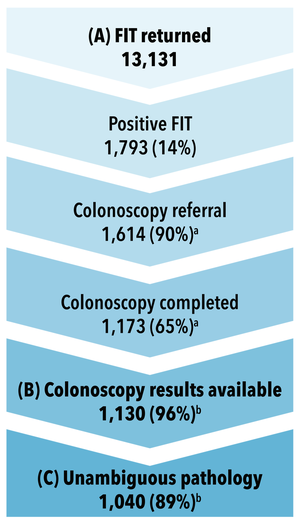
All but 2 of the 26 clinics used 1 of 3 FIT kits:

- The **OC-Micro** single-sample, automated quantitative test (PolyMedco, Inc., Cortland Manor, New York), was processed by 1 lab for all 3 health centers, using a threshold for positivity of 20 µg hHb/g feces.
- The **InSure** double-sample qualitative visual test (Enterix, Inc., Edison, New Jersey), which has a lower limit of detection of 50 µg hHb/g, was processed by lab technicians at a single lab for 2 health centers and in-house for 1 health center.
- The **Hemosure** single-sample test, a qualitative visual test (Hemosure, Inc., Irwindale, California), was employed in 1 health center, using a threshold for positivity of 50 µg hHb/g.

## CHART ABSTRACTION

Colonoscopy results were determined through chart abstraction, based on pathology or procedure reports when available, or on health center clinician notes.

**Figure 1. Analytic sample for report of FIT positivity rate (A); descriptive results of colonoscopy, by FIT kit (B); and PPV and factors associated with a FP FIT (C)**




[a] Percent of FIT-positives
[b] Percent of colonoscopies completed

**TABLE 1. Characteristics of patients in the STOP CRC evaluation of FIT positivity (left column) & PPV (right column)**

| | FIT returned (N=13,131) | Colonoscopy results available (N=1,130) |
|---|---|---|
| **Age** | | |
| 50-64 | 10,670 (81%) | 939 (83%) |
| 65-74 | 2,461 (19%) | 191 (17%) |
| **Female** | 7,435 (57%) | 578 (51%) |
| **Hispanic** | 2,244 (17%) | 124 (11%) |
| **Non-white** | 2,032 (16%) | 185 (16%) |
| **Language** | | |
| English | 9,410 (72%) | 894 (79%) |
| Spanish | 1,942 (15%) | 92 (8%) |
| Other | 1,779 (14%) | 144 (13%) |
| **Insurance status** | | |
| Medicaid | 5,344 (41%) | 477 (42%) |
| Medicare | 2,149 (16%) | 197 (17%) |
| Uninsured | 3,437 (26%) | 300 (27%) |
| Commercial | 1,767 (14%) | 131 (12%) |
| Other/Unknown | 434 (3%) | 25 (2%) |
| **Federal Poverty Level** | | |
| <100% | 5,353 (41%) | 479 (42%) |
| 100-150% | 2,216 (17%) | 192 (17%) |
| >150% | 2,686 (21%) | 209 (19%) |
| Unknown | 2,876 (22%) | 250 (22%) |
| **Co-morbidities** | | |
| Diabetes | 3,167 (24%) | 311 (28%) |
| Hypertension | 6,584 (50%) | 653 (58%) |
| Diverticulum | 244 (2%) | 29 (3%) |
| Hemorrhoids or anal fissures | 435 (3%) | 50 (4%) |
| Anticoagulant use | 226 (2%) | 35 (3%) |
| NSAIDs use | 2,360 (18%) | 243 (22%) |
| **Tobacco use** | | |
| Never | 5,966 (45%) | 411 (36%) |
| Former | 3,064 (23%) | 298 (26%) |
| Current | 2,830 (22%) | 301 (27%) |
| Unknown | 1,271 (10%) | 120 (11%) |
| **Season of FIT return** | | |
| Winter | 3,318 (25%) | 325 (29%) |
| Spring | 4,090 (31%) | 367 (33%) |
| Summer | 2,875 (22%) | 201 (18%) |
| Fall | 2,848 (22%) | 237 (21%) |

*Includes only patients with 3 FIT tests

**Figure 2. Proportion positive (95% CL) by health center (HC) and FIT brand**

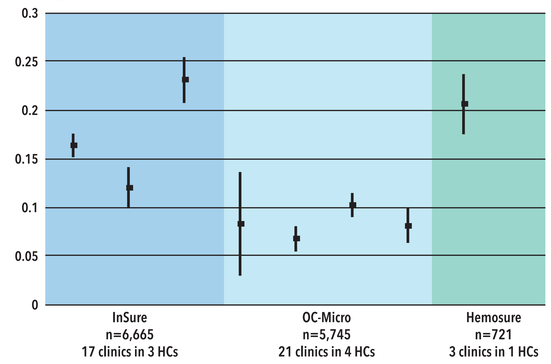



**Table 2. Most advanced colonoscopy result by FIT kit type, among those with a positive FIT result and completed colonoscopy (N=1,130)[a]**

| | Hemosure (n=83) | InSure (n=718) | OC-Micro (n=329) |
|---|---|---|---|
| **Advanced neoplasia** | **12 (14%)** | **177 (25%)** | **95 (29%)** |
| Colorectal cancer | 1 (1%) | 12 (2%) | 11 (3%) |
| Advanced adenoma | 11 (13%) | 165 (23%) | 84 (26%) |
| **No advanced neoplasia** | **87 (72%)** | **491 (68%)** | **225 (64%)** |
| Non-advanced adenoma | 16 (19%) | 176 (25%) | 45 (14%) |
| Non-adenomatous polyp | 10 (12%) | 65 (9%) | 32 (10%) |
| No polyp or adenoma | 34 (41%) | 246 (34%) | 132 (40%) |
| **Incomplete ascertainment[b]** | **12 (13%)** | **54 (8%)** | **29 (8%)** |
| Ambiguous adenoma | 0 (0%) | 9 (1%) | 1 (0.3%) |
| Polyp of unknown pathology | 11 (13%) | 45 (6%) | 24 (7%) |
| **PPV** for advanced neoplasia (95% CI)[c] | **0.17 (0.09-0.27)** | **0.27 (0.23-0.30)** | **0.31 (0.26-0.37)** |

[a] Sample consists of patients with an abnormal FIT result who were referred for a follow-up colonoscopy and whohad evidence of colonoscopy completion in their electronic medical record.
[b] Pathology report was unavailable in patient's health record; therefore, presence of adenoma or polyp was determined through provider notes. Not included in PPV calculations.
[c] p for $\chi^2$ = 0.04

## DISCUSSION

We observed a broad range of FIT positivity rates in health centers, each of which used 1 of 3 types of FIT kit. This variability has implications for the evaluation and planning of FIT screening strategies, including resources for follow-up diagnostic colonoscopy for FIT-positive patients. Despite large differences in FIT positivity, the frequencies of colonoscopy results were similar across centers and FIT kit types. Therefore, PPV for advanced neoplasia (including CRC or AA) also varied substantially.

The quality of fecal test results is important to health centers. However, given the lack of test performance data, the need for better population-based test performance information and communication of that information to providers is apparent. The ability to forecast colonoscopy burden accurately depends on reliable estimates of expected positivity rate.

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## IMPLICATIONS

Clinics, health plans, and decision makers will benefit from a greater understanding of variation in performance characteristics in diverse settings as data become available. By selecting appropriate FIT kits and thus minimizing false-positive rates, they may substantially reduce patient distress and colonoscopy burden on health centers and among FQHCs.

Data can be used to examine the use of FITs in community clinic settings by examining FIT-positive results and PPV for CRC or advanced adenoma.

## POTENTIAL IMPACT

Clinics, health plans, and decision-makers are responsible for determining which FIT best optimizes efforts and investments in colorectal cancer screening. Federal policy has allowed a variety of tests to be marketed in the US; further clarifying performance characteristics could help decision- and policy-makers optimize efforts to reduce cancer deaths.

**Amanda Petrik, MS**
3800 N Interstate Avenue
Portland, OR 97227-1098
amanda.f.petrik@kpchr.org

503-335-2483 | P