

# High Rate of Inappropriate Fecal Immunochemical Testing at a Large Veterans Affairs Health Care System

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**Introduction:** Colonoscopies and fecal immunochemical tests (FITs) are the preferred modalities for colorectal cancer (CRC) screening. In addition to proper patient selection, appropriate fecal immunochemical testing requires that negative tests be repeated annually, positive tests lead to a diagnostic colonoscopy, and FIT not be performed within 5 years of a colonoscopy with adequate bowel preparation. We sought to study the frequency of inappropriate FITs at the Veterans Affairs Pittsburgh Health Care System in Pennsylvania.

**Methods:** A retrospective quality assurance study was undertaken of veterans undergoing FIT in a 3-year period (2015-2017). We calculated the rate of a negative initial FIT in 2015/2016 followed by a second FIT in 2016/2017 in a random selection of veterans (3% SE, 95% CI). Demographics were compared in an equal random number of veterans that did and did not have a follow-up FIT (5% SE, 95% CI of all negative FIT). We also calculated the rate of completing colonoscopy following a positive FIT in a random selection of veterans (3% SE, 95% CI). Finally, we investigated use of FIT following a colonoscopy for all veterans in the study period.

**Results:** A total of 6,766 FITs were performed; 4,391 unique veterans had at least 1 negative FIT, and 709 unique veterans

had a positive FIT. Of 1,742 veterans with at least 1 negative FIT, 870 were eligible for repeat testing during the study period, and only 543 (62.4%) underwent at least 2 FITs. There was no significant demographic difference in veterans that had only 1 or at least 2 FITs. Of 410 veterans with a positive FIT, 113 (27.5%) did not undergo a subsequent colonoscopy within 1 year due to patient refusal, or failure to schedule or keep a colonoscopy appointment. Of 832 veterans who had both a FIT and colonoscopy in the interval, 108 veterans underwent colonoscopy with a subsequent FIT (1.6% of total FITs performed). Of these, 95 (88%) were judged to be inappropriate. Thirteen instances of FIT following colonoscopy were appropriate based on patient preference to undergo fecal immunochemical testing for CRC screening modality after undergoing colonoscopy with an inadequate bowel preparation.

**Conclusions:** Veterans underwent inappropriate testing due to failure to undergo serial FIT after a negative result (37.6%), failure to complete colonoscopy following a positive FIT (27.5%), and undergoing inappropriate FIT following a recent colonoscopy (88%). Efforts are still required to improve both patient and provider education and adherence to appropriate fecal immunochemical testing and CRC screening guidelines.

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*Fed Pract.* 2021;38(6).  
Published online June 15.  
doi:10.12788/fp.0142

Colonoscopies and annual fecal immunochemical tests (FITs), are 2 of the preferred modalities for colorectal cancer (CRC) screening endorsed by the US Preventive Services Task Forces as well as the US Multi-Society Task Force of Colorectal Cancer, which represents the American Gastroenterological Association, American College of Gastroenterology, and the American Society of Gastrointestinal Endoscopy.<sup>1,2</sup> The recommendations include proper patient selection (patients aged 50 - 75 years with a life expectancy of at least 10 years), and a discussion with the patient regarding both options.

## BACKGROUND

It is known that patients with a positive FIT are at an increased risk for CRC. Lee and colleagues found that patients who do not undergo subsequent colonoscopy after a positive FIT have a 1.64 relative risk of death from colon cancer compared with those who undergo follow-up colonoscopy.<sup>3</sup> Studies also have shown that longer wait

times (10 months vs 1 month) between a positive FIT and colonoscopy also are associated with a higher risk of CRC.<sup>4</sup> FIT utilize antibodies specific for the globin moiety of human hemoglobin and measure the development of antibody-globin complexes using immunoassay techniques. FIT has largely replaced the fecal occult blood test (FOBT), which depends on the detection of heme in feces through oxidation.

A US Department of Veterans Affairs (VA) study found that a longer time to colonoscopy was associated with a higher risk of neoplasia in veterans with a positive FOBT (odds ratio [OR], 1.10).<sup>5</sup> It is thus crucial that a positive FOBT or FIT be investigated with follow-up colonoscopy. However, a retrospective study at a single safety-net hospital in San Francisco found that only 55.6% of patients with a positive FIT completed colonoscopy within 1 year.<sup>6</sup> Importantly, almost half the patients examined in this study lacked documentation of the result of the FIT or counseling regarding the significance of the positive FIT by the patient's primary care

**TABLE 1** Subgroup Demographics for Veterans Undergoing Single vs Multiple Negative FIT (5% SE, 95% CI)

Characteristics	Single FIT (n = 110)	Multiple FIT (n = 110)	P value
Age, mean (SD), y	64.1 (8.3)	65.4 (5.3)	.16
Race, No. (%)	92 (83.6)	98 (89)	.47
African American	14 (12.2)	10 (9)	
Hispanic	0 (0)	0 (0)	
Other	4 (3.6)	2 (1.8)	
Gender, No. (%)			
Male	103 (93.6)	108 (98.1)	.17
Female	7 (6.3)	2 (1.8)	

Abbreviation: FIT, fecal immunochemical test.

provider who ordered the test. A VA study looked at veterans aged > 70 years at 4 VA medical centers who did not receive a follow-up colonoscopy within 1 year and reported that 26% of patients studied had a documented refusal to undergo colonoscopy.<sup>7</sup>

It also is clear that FOBT is used inappropriately for colon cancer screening in some patients. A 2005 single-center VA study looked at inappropriate fecal occult blood tests and found that 18% of veterans for whom FOBTs were ordered had a severe comorbid illness, 13% had signs or symptoms of gastrointestinal (GI) blood loss, and 7% had a history of colorectal neoplasia or inflammatory bowel disease.<sup>8</sup> An additional national VA study looked at all veterans aged ≥ 50 years who underwent FOBT or screening colonoscopy between 2009 and 2011 and found 26% to be inappropriate (13.9% of veterans not due for screening, 7.8% with limited life expectancy, and 11% receiving a FOBT when colonoscopy was indicated).<sup>9</sup>

An often-misunderstood additional requirement in utilizing FIT for CRC screening is that negative tests should be repeated annually.<sup>2</sup> A study from Kaiser Permanente in California found that 75.3 to 86.1% of eligible patients underwent yearly FIT.<sup>10</sup> In this study, programmatic FIT detected 80.4% of all patients with CRC detected within 1 year of testing.

Since most of the VA-specific studies are based on inappropriate or inadequate use of FOBT, we feel it is essential that further data be gained on appropriate and inappropriate testing. The aim of this study is to determine the frequency at which improper FIT occurs because of failure to obtain serial FIT over time with a negative

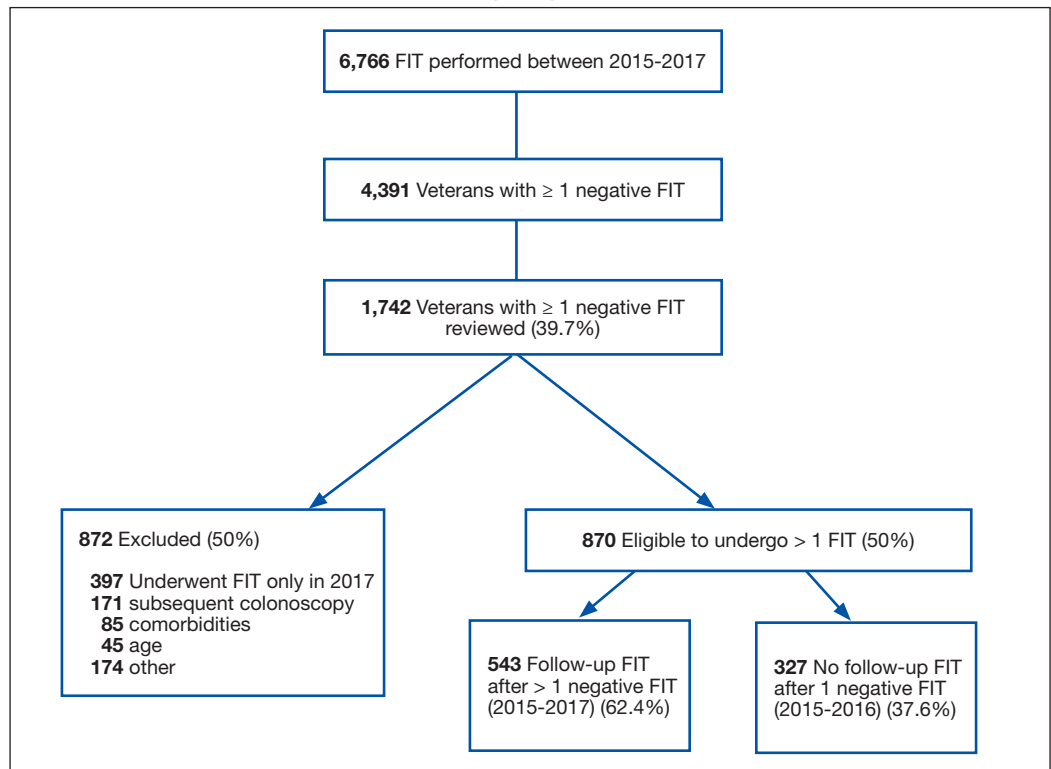
result, failure to follow-up a positive FIT result with a diagnostic colonoscopy, or performance of FIT in veterans undergoing a recent colonoscopy with adequate bowel preparation. This quality assurance study received an institutional review board exemption from the VA Pittsburgh Healthcare System (VAPHS) in Pennsylvania.

## METHODS

VAPHS has a data repository of all veterans served within the health care system, which was queried for all veterans who underwent a FIT in the system from January 1, 2015 through December 31, 2017 as well as the number and results of FITs during the interval. In addition, the data repository was also queried specifically for veterans who had at least 1 colonoscopy as well as FIT between 2015 and 2017. The ordering location for each FIT also was queried.

We made 3 calculations for this study. First, we measured the rate of a negative initial FIT in 2015 and/or 2016 followed by a second FIT in 2016 and/or 2017 in a random selection of veterans (3% SE, 95% CI). Demographics were compared in an equal random number of veterans who did and did not have a follow up FIT (5% SE, 95% CI of all negative FIT). Second, we measured the rate of completing colonoscopy following a positive FIT in a random selection of veterans (3% SE, 95% SI). Finally, we calculated FITs following a colonoscopy for all veterans.

Using a power analysis with a 3% SE and 95% CI for sample size calculation and accounting for the approximate 50% exclusion rate from the final eligible population of veterans with at least 1 negative FIT, a random sample of 1,742 patient charts with

**FIGURE** Flowchart of Veterans Undergoing FIT

Abbreviation: FIT, fecal immunochemical test.

a negative FIT in the interval were then reviewed to determine the frequency with which they underwent multiple FITs in the interval as well as for the presence of exclusionary factors. Because of the large number of veterans involved in this category, a more detailed demographics review was performed of a subset of these patients using a 95% CI and 5% SE. Using a 95% CI and 3% SE, 445 veterans with a positive FIT in the interval were reviewed to determine the frequency at which they underwent a follow-up diagnostic colonoscopy.

Because of a relatively small sample size, all 108 veterans who underwent a colonoscopy followed by a FIT were reviewed to determine the reason for follow-up FIT. In addition, in veterans who then went on to have a subsequent repeat colonoscopy, the examination findings were recorded.

## RESULTS

From January 1, 2015 to December 31, 2017, 6,766 FIT, were ordered at VAPHS. Of these, 4,391 unique veterans had at least 1 negative FIT during the period and 709 unique veter-

ans had a positive FIT. There were 832 veterans who had both a FIT and colonoscopy during the study period. Of these, 108 had a colonoscopy with a subsequent FIT (Figure).

Of 1,742 randomly selected veterans with at least 1 negative FIT in the study interval, 870 were eligible for multiple FITs during this period as they were in the appropriate screening age (50-75 years or 85 years based on an assessment of life expectancy by the ordering health care provider [HCP]), did not have exclusionary comorbidities to multiple FIT, were not lost to follow-up, and had at least 1 negative FIT collected from 2015 to 2016 (veterans who only had a FIT in 2017 were excluded from this aim to avoid confounding). Of these 870 veterans, 543 (62.4%) underwent at least 2 FITs during the study period. In a demographic comparison of 110 veterans with 1 FIT and 110 veterans with > 1 FIT, there were no statistically significant differences in demographics (Table 1).

In a random chart review of 410 veterans with a positive FIT, 113 (27.5%) veterans did not undergo a subsequent colonoscopy

within 1 year due to patient refusal, failure to schedule, or failure to keep colonoscopy appointment. There were no differences in demographics between those that underwent a diagnostic colonoscopy and those that did not (Table 2).

Of the 108 patients with a FIT following colonoscopy in the study interval, 97 FITs were negative. Ninety-five of the 108 FITs (88%) were judged to be inappropriate, having been performed for indications, including 38 for colon cancer screening, 23 for anemia, 32 for GI symptoms (eg, diarrhea, rectal bleeding, possible GI bleeding), and 2 for unclear indications. Thirteen FITs were deemed appropriate, as they were performed on veterans who refused to have a repeat colonoscopy following an examination with inadequate bowel preparation (Table 3). There was no difference in age or race between these 2 groups, although there was a statistically significant difference in gender (Table 4).

There were 19 patients who had a colonoscopy following a prior colonoscopy and subsequent positive FIT in the interval. Eight patients had no significant findings, 10 had nonadvanced adenomas, and 1 had an advanced adenoma (this patient had inadequate preparation with recommendation to repeat colonoscopy in 1 year).

While not a specific aim of the study we were able to identify certain HCPs by clinic location who systematically performed inappropriate or appropriate FIT. There were 47 separate ordering locations for the 95 inappropriate FIT following recent colonoscopy. Of these, 1 location was responsible for ordering 20 (21%) inappropriate FIT. Eight locations accounted for 51% of all the inappropriately ordered FIT. Two clinics seemed to be high performers in regard to overall appropriate vs inappropriate FIT use. The appropriate FIT rate for these locations was 30 of 33 (90.9%) and 26 of 28 (92.8%), respectively.

## DISCUSSION

In this retrospective study, we found that a large percentage of veterans eligible for colon cancer screening utilizing FIT did not undergo appropriate screening. Almost 40% of veterans in a 3-year interval received only 1 FIT. This seemed to occur due to a combi-

**TABLE 2** Colonoscopy Follow-Up for Veterans With a Positive Fecal Immunochemical Test<sup>a</sup>

Characteristics	Followed Up	Not Followed Up	P value
Total, No. (%)	297 (72.4)	1130 (27.6)	
Age, mean (SD), y <sup>a</sup>	65.4 (7.2)	66.4 (6.7)	.23
Race, No. (%)			.72
White	257 (86.5)	95 (84.1)	
African American	30 (10.1)	14 (12.4)	
Hispanic	1 (0.3)	1 (0.9)	
Other	9 (3.0)	3 (2.7)	
Gender, No. (%)			.63
Male	293 (98.7)	110 (97.3)	
Female	4 (1.3)	3 (2.6)	

<sup>a</sup>Subgroup based on 3% SE, 95% CI.

nation of patient refusal and inadequate education by HCPs regarding how to screen appropriately for CRC using FIT. This occurred despite a reminder in the VA Computerized Patient Record System regarding CRC screening.

There did not seem to be significant differences in demographics between those who were screened appropriately vs inappropriately. While there was a statistically significant difference in gender between those who had an appropriate FIT following recent colonoscopy (2 of 13 were female) and those who had an inappropriate FIT after recent colonoscopy (1 of 95 was a female), we are uncertain of the significance of this finding given the small number of female veterans in the analysis.

We do believe that the ratio of veterans in our study with a single FIT likely underestimates the true prevalence. To avoid confounding from factors such as inadequate prior follow-up in the study interval, we excluded veterans who underwent FIT only in 2017 for this analysis. As such, a significant percentage of these veterans were actually eligible to be screened throughout the study interval.

In spite of recommendations regarding the need for diagnostic colonoscopy following a positive FIT, we found that more than one-quarter of patients did not undergo colonoscopy. Although this number is an improvement over previously published literature that found almost half of patients at a safety-net hospital did not undergo

**TABLE 3** Indication for Fecal Immunochemical Test Ordered Following Recent Colonoscopy (n = 108)

Indications	Patients, No. (%)
Appropriate	
Refusal for follow-up colonoscopy	13 (12)
Inappropriate	95 (88)
Colon cancer screening	38 (35)
Anemia	23 (21)
Gastrointestinal symptoms <sup>a</sup>	32 (30)
Unclear/undocumented indication	2 (2)

<sup>a</sup>Diarrhea, rectal bleeding, possible gastrointestinal bleeding

**TABLE 4** Fecal Immunochemical Tests Following Recent Colonoscopies

Characteristics	Appropriate (n = 13)	Inappropriate (n = 95)	P value
Age, mean (SD), y	65.6 (8.8)	65.8 (7.6)	.95
Race, No. (%)			
White	10 (76.9)	87 (91.6)	.25
African American	3 (23.1)	8 (8.4)	
Gender, No. (%)			
Male	11 (84.6)	94 (98.9)	.04
Female	2 (15.3)	1 (1.1)	

diagnostic colonoscopy following a positive FIT, this is still clearly suboptimal.<sup>6</sup>

VAPHS has a mandate that all patients with a positive FIT be scheduled for colonoscopy within 30 days, either at VAPHS or in the community. An alert is sent to both ordering HCP regarding the positive FIT as well as to the GI department. In addition to contact from the ordering HCP, all veterans also are contacted by either a physician or nurse practitioner GI provider to provide test results and an explanation of its clinical significance and to facilitate colonoscopy scheduling. If a patient cannot be reached by telephone, the patient is sent a certified letter from the GI department regarding the significance of a positive FIT and instructions for scheduling a colonoscopy.

Despite this outreach, 27.5% of veterans did not have a diagnostic colonoscopy following a positive FIT. This suggests that there may be inadequate education and counseling of veterans at the time of the FIT order about the subsequent series of events and need for diagnostic colonoscopy following a positive FIT. If a patient refuses to

undergo a colonoscopy under any circumstances (including after a positive FIT), the utility of placing a FIT order is questionable.

There is also a need for more education of ordering HCPs on appropriate indications for FITs. We found that 35% of FIT ordered after a recent colonoscopy were done for the purpose of CRC screening, despite clear guidelines recommending against this. In addition, another 50% of FIT ordered after recent colonoscopy was done either for evaluation of GI symptoms like diarrhea and rectal bleeding or in the evaluation of anemia, both of which are inappropriate uses for FIT. Since FIT is an antibody test against globin, the protein component of hemoglobin that degrades during passage through the small bowel, it is not a useful test for the evaluation of upper GI or small bowel bleeding. A relatively recent database study in the Netherlands looking at the diagnosis of upper GI malignancies within 3 years of a positive FIT found a < 1% rate.<sup>11</sup>

In our study, albeit limited by the small number of veterans undergoing a repeat colonoscopy following a prior colonoscopy and subsequent positive FIT, there were few significant findings. Only 1 veteran had an advanced adenoma detected, and this veteran had already been recommended a repeat colonoscopy in 1 year due to an inadequate bowel preparation on the last examination.

Lastly, we found that certain HCPs (based on ordering clinic location) systematically performed improper FIT compared with other HCPs. This presumably is due to a lack of education on appropriate FIT usage and suggests opportunity for educational and/or systems interventions.

### Limitations

While our study strengths include a relatively large number of veterans and detailed review of individual patient data, it has multiple limitations. As a retrospective chart review-based study, incomplete or inaccurate data are a possibility. It is possible that patients underwent repeat FIT or underwent colonoscopy outside of the VA system and never recorded into the VA records. In addition, there is likely a sampling bias in this study as only veterans who underwent at least 1 FIT in the interval were included. These patients may be different from those who choose to undergo



colonoscopy for CRC screening or from those who do not undergo screening at all.

## CONCLUSIONS

A large percentage of patients underwent improper FIT at a tertiary referral academic VA medical center. Additional education and systems interventions are necessary to improve both provider and patient adherence to appropriate CRC screening. For example, one measure may include providing HCPs with a list of their patients not up-to-date with CRC screening that was shown to increase patient participation in FIT screening compared with patients who received usual care in a 2017 study.<sup>12</sup> In addition, a 2018 study showed that a digital health intervention that allows patients to self-order tests (eg, on an iPad) can increase CRC screening rates.<sup>13</sup>

## Author Contributions

Adam Gluskin: Study concept and design; acquisition of data; analysis and interpretation of data; drafting of the manuscript. Jeffrey Dueker: Study concept and design; analysis and interpretation of data; statistical analysis; critical revision of the manuscript for important intellectual content. Asif Khalid: Study concept and design; analysis and interpretation of data; drafting of the manuscripts; critical revision of the manuscript for important intellectual content; study supervision.

## Author disclosures

The authors report no actual or potential conflicts of interest with regard to this article.

## Disclaimer

The opinions expressed herein are those of the authors and do not necessarily reflect those of *Federal Practitioner*, Frontline Medical Communications Inc., the US Government, or any of its agencies.

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