Systems-based Strategies Improve Positive Screening Fecal Immunochemical Testing Follow-up and Reduce Time to Diagnostic Colonoscopy

Brett W. Sadowski, MD, FACP; Allison M. Bush, MD, MPH; Ross Humes, MD; Priscilla Cullen, RN, MS; Ida Hopkins, RN; Yen-Ju Chen, RN; John McCarthy, MD; Adam M. Tritsch, MD; Jeffrey T. Laczek, MD, FACP, FACG

ABSTRACT

Introduction: Fecal immunochemical testing (FIT) is the most commonly used colorectal cancer (CRC) screening tool worldwide and accounts for 10% of all CRC screening in the United States. Potential vulnerabilities for patients enrolled to facilities within the military health system have recently come to light requiring reassessment of best practices. We studied the impact of a process improvement initiative designed to improve the safety and quality of care for patients after a positive screening FIT given previously published reports of poor organization performance.

Methods: During a time of increased utilization of nonendoscopic means of screening, we assessed rates of colonoscopy completion and time to colonoscopy after positive FIT after a multi-faceted process improvement initiative was implemented, compared against an institutional control period. The interventions included mandatory indication labeling at the time of order entry, as well as utilization of subspecialty nurse navigators to facilitate rapid follow-up even the absence of a referral from primary care.

Results: Preintervention, 34.8% of patients did not have appropriate follow-up of a positive FIT. Those that did had a variable and prolonged wait time of 140.1 ± 115.9 days. Postintervention, a standardized order mandating test indication labeling allowed for proactive gastroenterology involvement. Colonoscopy follow-up rate increased to 91.9% with an average interval of 21.9 ± 12.3 days.

Conclusion: The addition of indication labels and patient navigation after positive screening FIT was associated with 57.1% absolute increase in timely diagnostic colonoscopy. Similar highly reliable systems-based solutions should be adopted for CRC screening, and further implementation for other preventative screening interventions should be pursued.

INTRODUCTION

Fecal immunochemical testing (FIT) is the most commonly used colorectal cancer (CRC) screening tool worldwide and accounts for 10% of all CRC screening in the United States. The U.S. Multi-Society Task Force (MSTF) ranks FIT and colonoscopy as tier 1 screening tests for CRC, partly because of growing evidence demonstrating comparable test performance.1–4 The impact of screening FIT is dependent upon prompt follow-up of positive tests with colonoscopy. The MSTF recommends a quality metric goal of 80% completion rate of a diagnostic colonoscopy following a positive screening FIT.5 Despite this, approximately 40% to 45% of patients with a positive FIT do not have a diagnostic colonoscopy within 1 year.6,7 Potential vulnerabilities for patients enrolled in facilities within the military health system have recently come to light requiring reassessment of best practices.8 Delaying colonoscopy after positive FIT impacts CRC-related morbidity.9 Expanding upon combinations of previously reported systems and provider-level strategies,10,11 we sought to implement steps to identify and follow-up positive FIT screening tests in our institution encompassed in a direct to colonoscopy (DTC) program.

METHODS

Before project implementation, institutional rates of colonoscopy follow-up and time to colonoscopy after positive FIT had been retrospectively assessed from April 2018 to March 2020. This coincided with a period in which providers could order FIT for any purpose (i.e., screening or not), but that indication for the test was not linked to the result. Further, linkage between primary and subspecialty services for

*Division of Gastroenterology/Hepatology, Department of Medicine, Walter Reed National Military Medical Center, Bethesda, MD 20814, USA
†Division of Gastroenterology/Hepatology, Department of Medicine, Naval Medical Center Portsmouth, Portsmouth, VA 23708, USA

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confirmatory colonoscopy was not automated and depended on traditional referral based systems. We prospectively assessed patients who received FIT after a series of process improvement initiatives. Exclusion criteria included performance of an FIT for an indication other than screening, as determined by indication labeling at order entry. The postintervention study period was from April to July 2020, correlating with a rapid increase in the utilization of FIT because of reduced endoscopic screening capacity. No financial support from testing manufacturers was utilized during this study.

In response to wide variability in clinical practice regarding FIT utilization, we developed a standardized ordering process that required indication labeling (i.e., cancer screening or other clinical indication) for all providers, which enabled easy identification of screening test results. The second component of our program was to develop a weekly procedure in which gastrointestinal (GI) nurse navigators would generate a list of patients with newly positive screening FIT results from the electronic medical record. Based on a medical record review and brief screening by a clinic nurse, these patients would be directed through the process to directly schedule a procedure or, if necessary, have a preprocedural clinic visit scheduled regardless of referral status. The steps required to link primary and subspecialty clinics at our institution before and after our intervention are listed in Table I.

The primary outcome was time to colonoscopy after positive FIT. Additional observations in the postintervention group included colonoscopy findings and low-value clinic visit avoidance. This initiative was deemed exempt by the institutional review board. Statistically analysis was performed using the Student’s t-test to compare the means of the pre- and postintervention groups.

### TABLE I. Steps Required to Obtain Appropriate Follow-up for a Positive FIT Performed for Screening, Before and After Interventions

| Steps required to follow-up a positive screening FIT | Preintervention | Postintervention |
|------------------------------------------------------|----------------|-----------------|
| Test order without indication labeling                | Test order with indication labeling |               |
| Patient completes test<sup>a</sup>                    | Patient completes test<sup>a</sup>   |               |
| Ordering provider interprets results                  | GI clinic identifies positive results |               |
| Referral to gastroenterology                          | Colonoscopy scheduled<sup>b</sup>  | Colonoscopy completed |
| Patient arranges GI clinic appointment<sup>a</sup>    | Colonoscopy scheduled<sup>a</sup>  | Colonoscopy completed |
| Patient attends GI clinic appointment<sup>a</sup>     | Colonoscopy scheduled<sup>a</sup>  | Colonoscopy completed |
| Colonoscopy scheduled                                 | Colonoscopy completed               |               |
| Colonoscopy completed                                 | Colonoscopy completed               |               |

Abbreviations: FIT, fecal immunochemical testing; GI, gastrointestinal.

<sup>a</sup>Steps requiring significant patient responsibility.

<sup>b</sup>Patients deemed to require a preclinic assessment after initial phone screening may be directly offered an appointment.

### RESULTS

#### Preintervention

During the control period, the rate of inadequate follow defined as the absence of a documented colonoscopy or clearly defined alternative follow-up was 34.8% (69/198). A significant limitation was the lack of clear documentation of the indication for the FIT. Of patients who had a colonoscopy after a positive FIT (n = 58, average 2.4/month), the average time to colonoscopy was 140.1 ± 115.9 days with wide variability throughout the period of observation (Fig. 1). The findings included 18 normal colonoscopies, 17 cases of low-risk adenomas, 17 cases of high-risk adenomas, 1 CRC, and 5 colonoscopies with nonadenomatous findings.

#### Postintervention

During a time of significantly increased reliance on FIT for CRC screening, 511 tests were performed, 411 of which had the indication of screening (80.4%). A total of 349 screening tests returned negative (84.9%) with the remaining 62 being positive (average 15.5/month). Of these positive screens, 91.9% (57/62) either had their colonoscopy (43) or are scheduled (14). The average time to colonoscopy (completed or scheduled) from positive screening FIT is 21.9 ± 12.3 days, which is statistically significant and observed to be less than the preintervention rate (P < .0001). There was still some variability in the intervals, as was the case in the preintervention period, which is a limitation of our observation. A preprocedural clinic visit was not required for 69.4% (43/62) of these patients, circumventing multiple barriers in the linkage of care process and allowing access to care for other nonscreening GI patients. The results included 20 colonoscopies with high-risk adenomas (1 requiring surgical resection), 13 with low-risk adenomas, 1 large inflammatory polyp, 1 large lipoma, and 8 normal colonoscopies. Trends in the average times to colonoscopy are shown in Fig. 1.

### DISCUSSION

Colonoscopy after a positive FIT is an essential component of a stool-based CRC screening program, yet inadequate follow-up of positive FIT remains a challenge for healthcare systems. During a period of reduced endoscopy with the COVID-19 pandemic, the use of FIT for CRC screening increased in our organization and highlighted the need for a highly reliable system to address positive FITs while minimizing barriers. We identified percentage of follow-up and time to colonoscopy as quality metrics to address when developing our program.

#### Follow-up Colonoscopy

Accurately measuring the rate of follow-up for positive screening FIT had been limited by a lack of a clear indication for the test. Informed by large retrospective programmatic screening experiences from multiple healthcare systems, the MSTF has recommended a target of 80%
Improving Highly Reliable Follow-up of Positive FIT

By adapting the electronic medical record to include indication labeling, we were able to reliably identify positive screening FITs and direct those patients to colonoscopy. The percentage of patients with a follow-up colonoscopy within 3 months of our intervention was over 90%. Previous work by May et al. showed that one of the main reasons patients did not receive a colonoscopy after a positive screening FIT was due to patients declining the procedure. We did not observe this in our highly insured patient population, who in our postintervention cohort all agreed to the procedure. We hypothesize that our preintervention data are the result of a process that relied heavily on patient effort to arrange follow-up, as noted in Table I. This study occurred during a time of drastic reduction in the availability of alternative screening modalities, and it is possible that many of the patients who had these FITs would have been willing to undergo an invasive screening examination from the start had it been offered. Still, having the ability to identify these patients and prioritize their diagnostic examination helped identify many high-risk lesions, which may not have been found in a timely manner because of COVID-19-related endoscopic backlogs. Indication labeling can allow health systems using stool-based testing to reliably measure follow-up rates and provide higher quality care for patients. While we await randomized controlled trial data regarding FIT versus colonoscopy, including a large U.S. study, we anticipate that FIT will continue to grow in prominence as a modality for screening for colorectal cancer as we continue to grapple with variably reduced endoscopic capacity during the pandemic, the infusion of millions of screening aged patients with the new draft recommendation from the U.S. Preventative Services Task Force, and the overdue desire to more formally address racial healthcare disparities in multiple healthcare settings, including CRC screening. For these reasons, using all available screening options is critical.

Time to Colonoscopy

Time to colonoscopy following a positive FIT directly correlates with prognosis, with a more advanced stage at diagnosis and increased risk of CRC when follow-up colonoscopy is delayed. Traditionally, an ordering provider would need to receive and interpret FIT results and place a referral while the patient would need to make an appointment for a preprocedural visit before scheduling colonoscopy (Table I). By altering or removing several of the steps, specifically those dependent on patient coordination, the DTC program reduces patient vulnerability to being lost to follow-up and, when compared to the referral-based system, significantly reduces the time to colonoscopy after a positive screen.
CONCLUSION
FIT is a top-tier CRC screening tool with many advantages, including the ability to be performed during times of reduced endoscopy. With burgeoning data that FIT is noninferior to colonoscopy, it is likely that utilization of FIT will increase in the future, particularly as efforts to address healthcare disparities in CRC screening in underscreened, vulnerable populations gather momentum and younger average risk screening age thresholds are considered. These factors make the establishment of follow-up programs critically important, particularly in the MHS as we make strides toward becoming a more highly reliable organization. Our initial prospective experience with a multi-faceted program including indication labeling for noninvasive CRC screening tools and a DTC program after a positive screening demonstrates feasibility and sustainability that can be modeled broadly in other healthcare systems.

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CONFLICT OF INTEREST STATEMENT
None declared.

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