

Improving Fecal Immunochemical Test Collection for Colorectal Cancer Screening During the COVID-19 Pandemic

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Background: Colonoscopy is a first-line method for colorectal cancer (CRC) screening. However, cost-effective noninvasive tests, such as high-sensitivity guaiac-based fecal occult blood test (gFOBT) and fecal immunochemical test (FIT), are also used. The COVID-19 pandemic had a substantial negative impact on CRC screening rates. The James A. Haley Veterans Affairs Hospital (JAHVAH) continued socially distant CRC screening using FITs, but encountered inefficiencies due to high rates of incorrectly collected FIT samples. A quality improvement (QI) project was conducted to increase correctly collected and testable FIT kits upon initial laboratory submission.

Observations: The ambulatory QI project sought out root causes for incorrectly returned FITs and proposed Plan-Do-Study-Act (PDSA) cycles based on a series of approved action plans. A multidisciplinary team of laboratory, nursing,

administrative, and primary care staff worked together to discover 6 major root causes. Our multipronged PDSA cycle attempted to set up redundant patient reminders, centralize the FIT dispersal process, and make the patient-FIT interface more user-friendly. All PDSA solutions were implemented over 4 months. Lack of collection date was the most common reason for incorrectly returned FIT kits and the focus of PDSA improvements. The rate of FITs with missing collection dates dropped from 24% prior to PDSA to 14% in April 2021. The rate of correctly returned FIT kits rose from 38% before the project to 72% afterwards, surpassing the 20% improvement goal.

Conclusions: FIT is a useful method for CRC screening that can be particularly helpful when in-person visits are limited, as seen during the COVID-19 pandemic. The increase in demand for FITs during the pandemic revealed process deficiencies and gave JAHVAH an opportunity to improve workflow.

Colorectal cancer (CRC) is the third-most common cancer worldwide and accounts for almost 11% of all cancer diagnoses, with > 1.9 million cases reported globally.^{1,2} CRC is the second-most deadly cancer, responsible for about 935,000 deaths.¹ Over the past several decades, a steady decline in CRC incidence and mortality has been reported in developed countries, including the US.^{3,4} From 2008 through 2017, an annual reduction of 3% in CRC death rates was reported in individuals aged ≥ 65 years.⁵ This decline can mainly be attributed to improvements made in health systems and advancements in CRC screening programs.^{3,5}

US Preventive Services Task Force (USPSTF) recommends CRC screening in individuals aged 45 to 75 years. USPSTF recommends direct visualization tests, such as colonoscopy and flexible sigmoidoscopy for CRC screening.⁶ Although colonoscopy is commonly used for CRC screening, it is an invasive procedure that requires bowel preparation and sedation, and has the potential risk of colonic perforation, bleeding, and infection. Additionally, social determinants—such as health care costs, missed work, and geographic location (eg, rural communities)—may

limit colonoscopy utilization.⁷ As a result, other cost-effective, noninvasive tests such as high-sensitivity guaiac-based fecal occult blood test (gFOBT) and fecal immunochemical test (FIT) are also used for CRC screening. These tests detect occult blood in the stool of individuals who may be at risk for CRC, helping direct them to colonoscopy if they screen positive.⁸

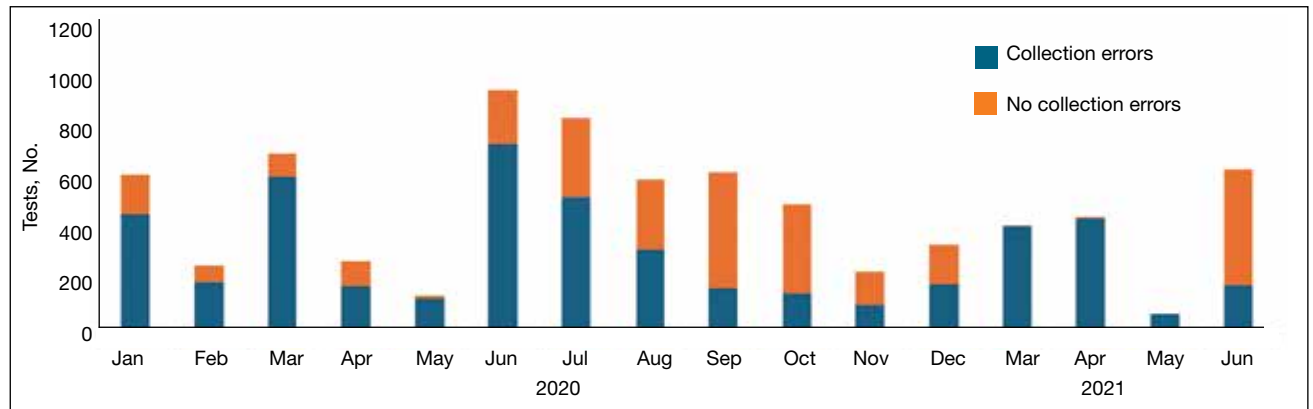
The gFOBT relies on simple oxidation and requires a stool sample to detect the presence of the heme component of blood.⁹ If heme is present in the stool sample, it will enable the oxidation of guaiac to form a blue-colored dye when added to hydrogen peroxide. It is important to note that the oxidation component of this test may lead to false-positive results, as it may detect dietary hemoglobin present in red meat. Medications or foods that have peroxidase properties may also result in a false-positive gFOBT result. Additionally, false-negative results may be caused by antioxidants, which may interfere with the oxidation of guaiac.

FIT uses antibodies, which bind to the intact globin component of human hemoglobin.⁹ The quantity of bound antibody-hemoglobin complex is detected and measured by a variety of automated quantitative techniques. This

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FIGURE 1 Fecal Immunochemical Tests Collected^a

^aData missing for January and February 2021.

testing strategy eliminates the need for food or medication restrictions and the subjective visual assessment of change in color, as required for the gFOBT.⁹ A 2016 meta-analysis found that FIT performed better compared with gFOBT in terms of specificity, positivity rate, number needed to scope, and number needed to screen.⁸ The FIT screening method has also been found to have greater adherence rates, which is likely due to fewer stool sampling requirements and the lack of medication or dietary restrictions, compared with gFOBT.^{7,8}

The COVID-19 pandemic had a drastic impact on CRC preventive care services. In March 2020, elective colonoscopies were temporarily ceased across the country and the US Department of Veterans Affairs (VA) deferred all elective surgeries and medical procedures, including screening and surveillance colonoscopies. In line with these recommendations, elective colonoscopies were temporarily ceased across the country.¹⁰ The National Cancer Institute's Population-Based Research to Optimize the Screening Process consortium reported that CRC screening rates decreased by 82% across the US in 2020.¹¹ Public health measures are likely the main reason for this decline, but other factors may include a lack of resource availability in outpatient settings and public fear of the pandemic.¹⁰

The James A. Haley Veterans Affairs Hospital (JAHVAH) in Tampa, Florida, encouraged the use of FIT in place of colonoscopies to avoid delaying preventive services. The initiative to continue CRC screening methods via FIT was scrutinized when laboratory personnel reported that in fiscal year (FY) 2020, 62% of the FIT kits that patients returned to the laboratory were missing

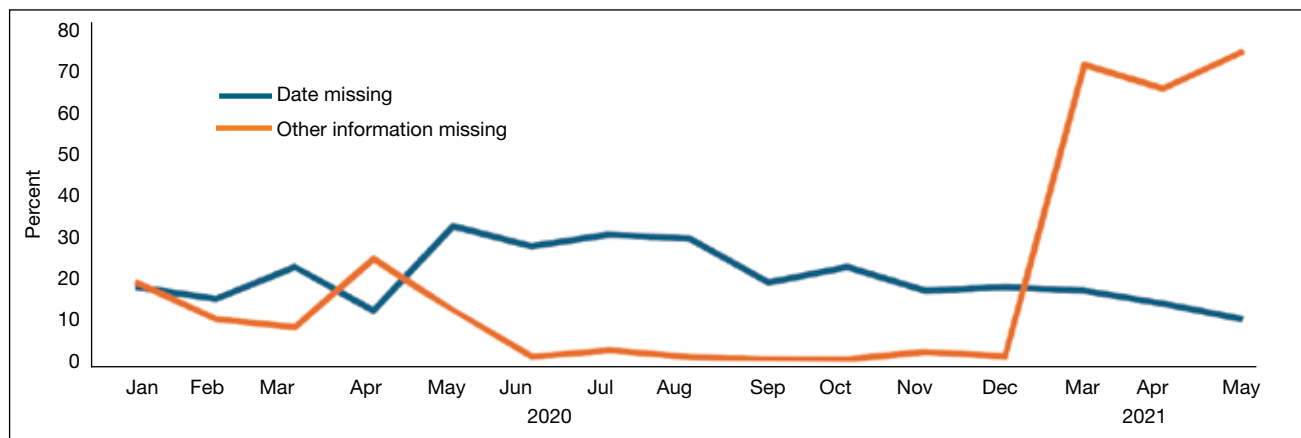
information or had other errors (Figure 1). These improperly returned FIT kits led to delayed processing, canceled orders, increased staff workload, and more costs for FIT repetition.

Research shows many patients often fail to adhere to the instructions for proper FIT sample collection and return. Wang and colleagues reported that of 4916 FIT samples returned to the laboratory, 971 (20%) had collection errors, and 910 (94%) of those samples were missing a sample collection date.¹² The sample collection date is important because hemoglobin degradation occurs over time, which may create false-negative FIT results. Although studies have found that sample return times of ≤ 10 days are not associated with a decrease in FIT positive rates, it is recommended to mail completed FITs within 24 hours of sample collection.¹³

Because remote screening methods like FIT were preferred during the COVID-19 pandemic, we conducted a quality improvement (QI) project to address FIT inefficiency. The aim of this initiative was to determine the root cause behind incorrectly returned FIT kits and to increase correctly collected and testable FIT kits upon initial laboratory arrival by at least 20% by the second quarter of FY 2021.

QUALITY IMPROVEMENT PROJECT

This QI project was conducted from July 2020 to June 2021 at the JAHVAH, which provides primary care and specialty health services to veterans in central and south Florida. The QI was designed based on the Plan-Do-Study-Act (PDSA) model of health care improvement. The QI team consisted of physicians, nurses, administrative staff, and laboratory

FIGURE 2 Reasons for Incorrect Fecal Immunochemical Test Return^{a,b}

^aBeginning in December 2020, order numbers were not inserted by the new administrative group when the process pathway changed hands; this error was rectified and documented in the short-term follow-up.

^bData missing for January and February 2021.

personnel. A SIPOC (Suppliers, Input, Process, Output, Customers) map was initially designed to help clarify the different groups involved in the process of FIT kit distribution and return. This map helped the team decide who should be involved in the solution process.

The QI team performed a root cause analysis using a fishbone diagram and identified the reasons FIT kits were returned to the laboratory with errors that prevented processing. The team brainstormed potential change ideas and created an impact vs effort chart to increase the number of correctly returned and testable FIT kits upon initial arrival at the laboratory by at least 20% by the second quarter of FY 2021. We identified strengths and prioritized change ideas to improve the number of testable and correctly returned FIT kits to the hospital laboratory. These ideas included centralizing FIT kit dispersal to a new administrative group, building redundant patient reminders on kit completion and giving patients more accessible places for kit return.

Patients included in the study were adults aged 50 to 75 years seen at the JAHVAH outpatient clinic who were asked to undergo FIT CRC screening. FIT orders for other facilities were excluded. The primary endpoint of this project was to improve the number of correctly returned FITs. The number of correct and incorrect returned FITs were measured from July 2020 to June 2021. FITs returned with errors were categorized by the type of error, including: no order on file in the electronic health record (EHR), canceled test, expired test, unable to identify test, missing information, and missing collection date.

We attempted to calculate costs of FITs that were returned to the laboratory but could not be analyzed and were discarded. In FY 2020, 1568 FITs were discarded. Each FIT cost about \$7.80 to process for an annualized expense of \$12,230 for discarded FITs.

Root Cause Analysis

Root causes were obtained by making a fishbone diagram. From this diagram, an impact vs effort chart was created to form and prioritize ideas for our PDSA cycles. Data about correctly and incorrectly returned kits were collected monthly from laboratory personnel, then analyzed by the QI team using run charts to look for change in frequency and patterns.

To improve this process, a swim lane chart for FIT processing was assembled and later used to make a comprehensive fishbone diagram to establish the 6 main root cause errors: missing FIT EHR order, cancelled FIT EHR order, expired stool specimen, partial patient identifiers, no patient identifiers, and no stool collection date. Pareto and run charts were superimposed with the laboratory data. The most common cause of incorrectly returned FITs was no collection date.

PDSA Cycles

Beginning in January 2021, PDSA cycles from the ideas in the impact vs effort chart were used. Organization and implementation of the project occurred from July 2020 to April 2021. The team reassessed the data in April 2021 to evaluate progress after PDSA initiation. The mean rate of missing collection date dropped

from 24% in FY 2020 prior to PDSA cycles to 14% in April 2021; however, the number of incorrectly returned kits was similar to the baseline level. When reviewing this discrepancy, the QI team found that although the missing collection date rate had improved, the rate of FITs with not enough information had increased from 5% in FY 2020 to 67% in April 2021 (Figure 2). After discussing with laboratory personnel, it was determined that the EHR order was missing when the process pathway changed. Our PDSA initiative changed the process pathway and different individuals were responsible for FIT dispersal. The error was quickly addressed with the help of clinical and administrative staff; a 30-day follow-up on June 21, 2021, revealed that only 9% of the patients had sent back kits with not enough information.

After troubleshooting, the team achieved a sustainable increase in the number of correctly returned FIT kits from an average of 38% before the project to 72% after 30-day follow-up.

DISCUSSION

Proper collection and return of FIT samples are vital for process efficiency for both physicians and patients. This initiative aimed to improve the rate of correctly returned FIT kits by 20%, but its final numbers showed an improvement of 33.6%. Operational benefits from this project included early detection of CRC, improved laboratory workflow, decreased FIT kit waste, and increased patient satisfaction.

The multipronged PDSA cycle attempted to increase the rate of correctly returned FIT kits. We improved kit comprehension and laboratory accessibility, and instituted redundant return reminders for patients. We also centralized a new process pathway for FIT distribution and educated physicians and support staff. Sampling and FIT return may seem like a simple procedure, but the FIT can be cumbersome for patients and directions can be confusing. Therefore, to maximize screening participation, it is essential to minimize confusion in the collection and return of a FIT sample.^{14,15}

This QI initiative was presented at Grand Rounds at the University of South Florida in June 2021 and has since been shared with other VA hospitals. It was also presented at the American College of Gastroenterology Conference in 2021.

Limitations

This study was a single-center QI project and

focused mostly on FIT kit return rates. To fully address CRC screening, it is important to ensure that individuals with a positive screen are appropriately followed up with a colonoscopy. Although follow-up was not in the scope of this project, it is key to CRC screening in general and should be the subject of future research.

CONCLUSIONS

FIT is a useful method for CRC screening that can be particularly helpful when in-person visits are limited, as seen during the COVID-19 pandemic. This increase in demand for FITs during the pandemic revealed process deficiencies and gave JAHVAH an opportunity to improve workflow. Through the aid of a multidisciplinary team, the process to complete and return FITs improved and surpassed the goal of 20% improvement. Our goal is to continue to fine-tune the workflow and troubleshoot the system as needed.

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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.

Ethics and consent

This project did not require institutional review board approval.

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