



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Colorectal Cancer Screening,
Timely Colonoscopies, and
Physician Coverage in the
Intensive Care Unit at the James
H. Quillen VA Medical Center
Mountain Home, Tennessee



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in 2016 to assess allegations of inadequate colorectal cancer (CRC) screening, timely performance of colonoscopies, and Intensive Care Unit (ICU) physician coverage at the James H. Quillen VA Medical Center (facility), Mountain Home, Tennessee. The OIG reviewed allegations that:

- Veterans were dying unnecessarily as a result of not getting adequate screening because the facility used fecal immunochemical tests (FIT) for routine CRC screening instead of colonoscopies.
- Colonoscopies that were not timely impacted patient care.
- The ICU was without physician coverage for multiple nights throughout a month.

During the healthcare inspection, OIG staff also identified deficiencies in the facility's FIT specimen labeling, tracking, and monitoring processes.

CRC Screening Using FIT

The OIG did not substantiate that veterans were dying because FIT was used for initial CRC screening instead of colonoscopies. Veterans Health Administration (VHA) recognizes multiple effective CRC screening methods, and FIT is an acceptable screening option.

Colonoscopies that were not Timely Impacted Patient Care

The OIG could not substantiate that a specific delay or timeframe interval impacted a particular patient's care for the patients OIG staff reviewed. VHA and medical literature does not identify a specific timeframe between the identification of the need for colonoscopy (such as a positive FIT) and completion of the colonoscopy that would impact patient care. However, of the 1,439 patients OIG staff reviewed, 15 patients had CRC or carcinoid and longer intervals between identification of a need for a colonoscopy and completion than other patients without cancer in the review group. Although OIG staff could not identify a specific or minimum delay interval, the OIG determined those patients who had CRC or carcinoid and the longest colonoscopy intervals were most likely impacted by the longer intervals.¹

¹ For this report, the OIG uses the terms untimely and not timely to describe the colonoscopies of patients who had CRC or carcinoid and the longest colonoscopy intervals.

To evaluate the facility's colonoscopy timeliness and resulting impact to patients, OIG staff analyzed two groups of patients.² In the first group, OIG staff evaluated the interval between patients' endoscopy or colonoscopy consults and completed colonoscopies. In the second group, OIG staff evaluated the interval between patients' positive FITs and completed colonoscopies.

During the healthcare inspection, the OIG also identified issues with the facility's labeling, tracking, and monitoring processes for FIT specimens.

Colonoscopy Consults to Colonoscopy Completions

To evaluate whether a colonoscopy consult delay of more than 30 days might be associated with patients' hospitalization, CRC, or death, OIG staff reviewed the 358 electronic health records (EHR) of patients who had at least one of these three health events. For this group (first group), OIG staff found eight patients who had untimely colonoscopy consults that impacted patient care. Of the 358 patients' EHRs reviewed, 335 had a colonoscopy. The interval between submission of the consult for a colonoscopy and the completion of the colonoscopy for these 335 patients varied between one–18 months; the average was about six months.

Seventeen patients had CRC or carcinoid. One of the 17 patients did not have a colonoscopy because the patient underwent surgery for CRC before a colonoscopy could be done. For the remaining 16 patients with CRC or carcinoid, the interval between the consult for a colonoscopy and colonoscopy completion was from one month to about 10 months. The average time from consult to colonoscopy was about five months; one month shorter than for patients who did not have CRC.

Delays in Surveillance Colonoscopies

In the group of 335 patients who received colonoscopies, the OIG found that 11 patients had a delay in surveillance colonoscopy. The delays in surveillance colonoscopy ranged from one year to 10 years. Four of the 11 patients did not have CRC.³ Six of the patients with CRC had colonoscopy delays of 34 days (also a 10-year surveillance delay), 65 days (also a five-year surveillance delay), 217 days (also a 2.5-year surveillance delay), 227 days (also two-year surveillance delay), 293 days (also a three-year surveillance delay), and 295 days (also a nine-year surveillance delay). The seventh patient with CRC, who had a one-year delay in surveillance colonoscopy, was scheduled for a colonoscopy but had surgery for a CRC before the

² For these two groups, OIG staff reviewed 1,439 unique patients. The first group had 358 patients, and the second group had 1,168 patients for a total of 1,526 patients. However, 87 patients were common to both groups, which resulted in 1,439 total unique patients reviewed.

³ For the four patients who did not have CRC, delays in surveillance colonoscopy ranged from one year to four years.

colonoscopy could be done. The seven patients with a history of a previous abnormal colonoscopy finding should have been evaluated with a surveillance colonoscopy at an earlier time. Surveillance colonoscopies were delayed for a number of reasons. These documented reasons included patients who were not notified that they were due for a surveillance colonoscopy; colonoscopy consult delays; clinics that cancelled appointments; and patients who either cancelled appointments, did not show up for scheduled appointments, or deferred completion of the surveillance colonoscopy.

Positive FITs to Colonoscopy Completions

To further evaluate untimely colonoscopies and the impact on patient care, OIG staff reviewed the EHRs of 1,168 patients who had positive FITs in fiscal year (FY) 2015 (second group). The OIG found seven patients who had untimely colonoscopy completion after a positive FIT that impacted care.⁴ OIG staff identified issues with the facility's positive FIT follow-up that included delays in colonoscopy consult submissions, colonoscopy consults that were not submitted, delays in completion of colonoscopies, documentation of colonoscopy results/follow-ups missing from patients' EHRs, and conducting repeat FITs after a positive result rather than follow-up colonoscopies.

Colonoscopy Consult Submission Delays after a Positive FIT

Providers submitted colonoscopy or gastroenterology consults for 888 of the 1,168 patients. Medical providers submitted about 85 percent of the colonoscopy consults within 30 days of the positive FIT. However, 137 of the 888 patients had consults submitted more than 30 days after the patient was determined to have a positive FIT. CRC was diagnosed in four of these 137 patients.

Colonoscopy Consults not Submitted after a Positive FIT

Two hundred-eighty of the 1,168 patients with positive FITs did not have a consult entered for a colonoscopy or gastroenterology to follow up a positive FIT. Documented reasons for not placing a consult included: the patient elected to use a non-VA provider, facility staff were unable to contact the patient, the patient declined a consult, the patient had a recent colonoscopy, and the patient had comorbid medical conditions, which did not permit a colonoscopy at the time. Of the 280 patients who did not have a colonoscopy consult submitted, 45 had documentation of a completed colonoscopy in the EHR.

⁴ The OIG determined that the delay from positive FIT to colonoscopy impacted the care of 12 patients within the second group. However, five of these patients were also considered as impacted in the first group, consult to colonoscopy, resulting in seven unique patients in the second group whose clinical care was impacted.

Colonoscopy Completion after a Positive FIT

Six-hundred thirty-two of the 1,168 patients with positive FITs underwent diagnostic colonoscopies. The interval from positive FIT to colonoscopy for these patients varied widely, from days to years. Ten patients had a FIT performed after their colonoscopy; a colonoscopy was not repeated.⁵ These 10 patients were excluded from analysis of the interval between the positive FIT and the colonoscopy. The average time to colonoscopy for the 622 patients who had a colonoscopy after a positive FIT was just over five months. Twenty-seven patients had a CRC or carcinoid tumor. The interval from positive FIT to colonoscopy for these patients varied widely, with one patient undergoing colonoscopy about 15 months after the positive FIT. One patient with CRC had a FIT performed 17 days after colonoscopy; the colonoscopy was not repeated. The average time to colonoscopy for the remaining 26 patients with CRC was about five months. For 12 of these patients, longer intervals between FIT and completion of a colonoscopy most likely impacted patient care.⁶

Six hundred-five of the 632 patients who had a colonoscopy did not have CRC. Nine of these patients had a positive FIT just after their colonoscopy; colonoscopies were not repeated. For the remaining 596 patients who did not have CRC, the average time from positive FIT to colonoscopy was similar to those patients with CRC.

During the review of the positive FIT patients, OIG staff noted that there were five patients evaluated for a diagnostic colonoscopy who should have been categorized as patients needing follow-up surveillance colonoscopies for a previously identified abnormal finding. These five patients also had CRC or carcinoid and had delays in their surveillance colonoscopy ranging from two to nine years. These patients were among the highest risk patients for development of CRC due to the length of the surveillance colonoscopy delay.

Diagnostic Colonoscopy Results Not Documented in the EHR for Patients with a Positive FIT

Of the 1,168 patients with positive FITs, 536 (46 percent) did not have follow-up diagnostic colonoscopy results documented in their EHRs. However, as required by VHA policy,⁷ providers

⁵ Reasons for providers to order a FIT after a colonoscopy included a patient's report of bleeding after a colonoscopy, the medical provider being unaware of a recent colonoscopy, the patient not reporting a recent colonoscopy, or the medical provider ordering a FIT after receiving a CRC screening by an EHR reminder or alert.

⁶ The OIG determined that the delay from positive FIT to colonoscopy impacted the care of 12 patients within this second group. However, five of these patients were also considered as impacted in the first group, consult to colonoscopy, which resulted in seven unique patients in the second group whose clinical care was impacted.

⁷ VHA Directive 2007-004, *Colorectal Cancer Screening*, January 12, 2007. This directive was rescinded and replaced by VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014.

documented the reasons for the lack of follow-up, which included notations that patients cancelled or declined a colonoscopy; patients sought non-VA care and results were not documented in the EHR; patients could not be contacted; and colonoscopies could not be performed due to patients' personal or medical reasons. During the review, OIG staff communicated with facility managers about specific patients who had no EHR documentation of positive FIT follow-up, including completed colonoscopies. OIG staff asked the facility to supply a reason for non-completion/follow-up or to supply documentation of the procedure. Facility managers provided the OIG with the additional documentation.

Repeat of FIT Rather than Diagnostic Colonoscopy

Forty-two of the 1,168 patients (four percent) with a positive FIT underwent a repeat FIT rather than proceeding directly to a diagnostic colonoscopy. Documented reasons for these repeat FITs were patients and/or providers' requests. VHA recommends that patients receive colonoscopy follow-up after a positive FIT done as part of a CRC screening program.⁸

In summary, while most of the patients, in both the first and second groups, had a timely colonoscopy and did not have CRC or carcinoid, the OIG found 15 patients who had an untimely consult and/or colonoscopy and CRC or carcinoid. Many of these patients also had a delay in their surveillance colonoscopies. Almost one-half of the patients who had a positive test for blood in their stool, did not have the results of a colonoscopy in the EHR. Some of these patients declined a colonoscopy, some had medical reasons that justified not performing a colonoscopy, and some elected a non-VA colonoscopy but results were not consistently available or placed into the EHR.

FIT Specimen Process Deficiencies

During the review, OIG staff also identified deficiencies with the facility's FIT specimen labeling, tracking, and monitoring processes. Interviewees told OIG staff that patients returned FIT kit specimens to the facility's laboratory in spring 2016 with labelling deficiencies, such as illegible patient names. Illegible labels caused problems with the correct identification of patients' specimens and laboratory staff disposed of these specimens. At that time, approximately two–four specimens per day were not processed due to laboratory staff's inability to decipher patient information on the FIT specimen label. Although facility leaders took action to improve the labelling process, facility staff stated they were not well versed in the new process. Clinic nurses documented distributing a kit to the patient in his/her EHR; however, a process was not in place for facility-wide FIT specimen tracking and monitoring.

⁸ VHA Directive 2007-004; VHA Directive 1015.

ICU Physician Coverage

The OIG substantiated that the facility ICU had inconsistent attending physician coverage in May 2016; however, resident physicians, hospitalists, and intensivists were available for ICU coverage. Facility leaders implemented a plan that included ICU coverage by temporary physicians and hospitalists. If facility staff could not meet the needs of ICU patients, physicians arranged for patients to be transferred to a non-VA facility or diverted VA Emergency Department patients to a non-VA Emergency Department. In February 2017, the OIG received satisfactory updated information from facility leaders indicating that the issue of inconsistent physician coverage in the ICU had been resolved.

The OIG made seven recommendations related to clinical reviews/disclosures of reviewed patients, tracking patients' surveillance colonoscopies, tracking follow-up of positive FIT patients, availability of non-VA colonoscopy reports, providing a diagnostic colonoscopy after patients have a positive FIT rather than repeating the FIT, notifying patients if they need to re-submit FIT specimens, and tracking distribution of patients' FIT kits.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 32–38, for the full text of the comments. The OIG will follow up on the planned actions until they are completed.



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Contents

Executive Summary	i
Abbreviations	viii
Introduction.....	1
Scope and Methodology	10
Case Summaries.....	12
Inspection Results	14
Issue 1: CRC Screening using FIT	14
Issue 2: Colonoscopies that were not Timely Impacted Clinical Care	14
Issue 3: Physician Coverage in the ICU	25
Conclusion	26
Recommendations 1–7.....	31
Appendix A: VISN Director Comments	32
Appendix B: Facility Director Comments.....	34
OIG Contact and Staff Acknowledgments	39
Report Distribution	40

Abbreviations

CBOC	Community Based Outpatient Clinics
Choice	Veteran’s Access, Choice, and Accountability Act of 2014
CRC	colorectal cancer
ED	emergency department
EGD	esophagogastroduodenoscopy
EHR	electronic health record
facility	James H. Quillen VA Medical Center, Mountain Home, Tennessee
FIT	fecal immunochemical tests
FOBT	Fecal Occult Blood Test
FY	fiscal year
GI	gastroenterology
ICU	intensive care unit
NVCC	Non-VA Care Coordination
OIG	Office of Inspector General
RN	registered nurse
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations of inadequate colorectal cancer (CRC) screening, timely colonoscopies,⁹ and Intensive Care Unit (ICU) physician coverage at the James H. Quillen VA Medical Center (facility), Mountain Home, Tennessee.

Background

The facility is a tertiary care,¹⁰ teaching hospital that provides general medical and surgical services to more than 170,000 veterans living in 41 counties in Tennessee, Virginia, Kentucky, and North Carolina; and is part of Veterans Integrated Service Network (VISN) 9. The facility has 114 medical, surgical, and psychiatric beds; 120 Community Living Center beds; 150 domiciliary beds; and 10 outpatient clinics, which include community based outpatient clinics (CBOC) and rural outreach clinics. The facility has a Level 3 ICU¹¹ and an Emergency Department (ED). The facility is primarily affiliated with the James H. Quillen College of Medicine at East Tennessee State University and trains residents, interns, and students in multiple medical disciplines.

⁹ Colonoscopies are performed for different purposes. Indications for a colonoscopy include the monitoring of disease for progression, investigation for findings on other studies, and investigation for symptoms. For this report, OIG staff applied the following definitions to screening, diagnostic, and surveillance colonoscopies: (a) A screening colonoscopy is done to allow for early detection of pre-cancerous conditions in patients without symptoms who may be at risk for developing disease, (b) a diagnostic colonoscopy is done to determine the presence and/or extent of a disease process in a patient with signs, symptoms, or laboratory findings suggestive of disease (for example, a positive test for blood), and (c) a surveillance colonoscopy is done to evaluate a patient who needs monitoring for recurrence of disease.

¹⁰ Tertiary care occurs at hospitals where patients may be referred for specialty services and treatment. https://www.hopkinsmedicine.org/patient_care/pay_bill/insurance_footnotes.html. (This website accessed May 22, 2017.)

¹¹ Almenoff, P, et al., Intensive Care Services in the Veterans Health Administration, *Chest*, 2007 Nov132 (5), 1455-1462. doi:10.1378/chest.06-3083, <http://www.sciencedirect.com/science/article/pii/S0012369215512579>, website (This website accessed January 25, 2017). The authors established a four-level criteria for VA ICUs based on available resources such as specialty physicians, fellowship training programs, and ED, OR, laboratory, and radiology capabilities. Level 4 is basic, Level 3 is moderate, and Levels 2 and 1 are complex and require the facility to have the capability of providing additional resources.

CRC

CRC is the second leading cause of cancer-related deaths in the United States and the third most common cancer in men and women.¹² In 2017, the American Cancer Society estimated that 95,520 patients were diagnosed with colon¹³ cancer and 39,910 patients were diagnosed with rectal¹⁴ cancer.¹⁵ An estimated 50,260 deaths from CRC were expected to occur in 2017.¹⁶ However, since 1990, the incidence¹⁷ of CRC deaths has been decreasing by about three percent per year.¹⁸

After colon or rectal cancer has been diagnosed, the stage of the disease must be determined to guide patients' treatment decisions and estimate survival rates. The type of cancer cells, the size of the primary tumor, the extension of the cancer to local tissues, the number of lymph nodes involved, and the spread of the cancer to areas or organs outside of the colon (metastasis) are all considered in staging of the cancer.¹⁹ Determination of the extent of disease (stage) may involve the findings at surgery, specialized radiologic tests, and biopsy results.²⁰

CRCs usually develop over a period of several years. The cancer usually begins as a precancerous lesion, most commonly an adenoma.²¹ The progression from adenoma to CRC is

¹² <https://www.cdc.gov/cancer/colorectal/statistics/index.htm>. (This website accessed January 25, 2017.)

¹³ The colon, also known as the large intestine, is part of the digestive system and consists of the cecum; the ascending, transverse, descending, and the sigmoid colon; and the rectum. It is tubular in structure, about five feet long and three inches in diameter. One of the primary purposes of the colon is to remove water from the material entering the large intestine, resulting in the formation of a solid or semi-solid stool, which is stored at the end of the large intestine (the rectum) before it is expelled from the body through the anus.

¹⁴ The rectum is the final portion of the large intestine, or colon. It is a straight segment about six to eight inches in length, and serves the function of storing stool.

¹⁵ Cancer Statistics, 2017. Siegel RL, Miller KD, Jemal ASO, CA Cancer J Clin. 2017;67(1):7.

<http://onlinelibrary.wiley.com/doi/10.3322/caac.21387/full>

UpTo Date® Website: <https://www.uptodate.com/contents/clinical-presentation-diagnosis-and-staging-of-colorectal-cancer>. (This website accessed January 25, 2017.)

¹⁶ Cancer Statistics, 2017. Taken from the CA Cancer J Clin 2017;67:7-30.doi: 10.3322/caac.21387.

¹⁷ In this setting, incidence refers to the rate of newly diagnosed cancers each year.

¹⁸ UpTo Date® Website: <https://www.uptodate.com/contents/clinical-presentation-diagnosis-and-staging-of-colorectal-cancer>. (This website accessed January 25, 2017.)

¹⁹ A pathologist reviews the specimens taken at colonoscopy or at surgery by a gross inspection and under the microscope to classify and stage the cancer.

²⁰ The selection of these modalities typically depends on the findings at colonoscopy or surgery, but it may be determined by the clinical presentation of the patient or incidental findings on other studies.

²¹ An adenoma is an abnormal growth of tissue that is not cancer.

estimated to take at least 10 years on average. CRC screening recognizes this slow progression to cancer.²²

CRC Screening

CRC screening detects early cancers and improves mortality rates.²³ Removal of pre-cancerous polyps can prevent cancer, and removal of localized cancer may prevent CRC-related death.²⁴

Multiple tests are available for CRC screening. Two of the most commonly employed screening strategies are the collection of the patient's stool for the assessment of blood or blood products and colonoscopy.²⁵

The presence of blood in the stool can be indicative of an abnormal colon lesion (such as cancer and polyps). This is because an abnormal lesion is more likely to bleed than the surface of a normal colon. The Fecal Immunochemical Test (FIT) screening test has a high sensitivity for CRC.²⁶ To conduct a FIT, the patient is given a collection device with a label that includes patient information. The patient is instructed to place a stool sample into the collection device and return it to a laboratory for processing. FIT has a sensitivity of 80 percent for detecting CRC, and a sensitivity of 20–30 percent for detecting advanced neoplasia (new growth that may be cancerous).²⁷ If a FIT is positive (blood was detected in the stool), the patient is typically advised to have a colonoscopy for diagnostic purposes.²⁸ More patients may be willing to have CRC screening with the FIT test than other methods. FIT testing requires no modification of diet or colonic preparation, is easy to perform in the home, and avoids the risks inherent to an invasive procedure, such as a colonoscopy (including the risk of bowel perforation and the risks associated with sedation).

²² Screening is undertaken to diagnose disease in people with no symptoms but who have a risk factor for the disease being screened. Various medical societies have published guidelines regarding recommended screening tests for individuals at risk for disease. This contrasts with surveillance, which refers to a program of regular monitoring for a known disease process.

²³ UpTo Date® Website: <https://www.uptodate.com/contents/clinical-presentation-diagnosis-and-staging-of-colorectal-cancer>, (This website accessed January 25, 2017.)

²⁴ UpTo Date® Website: <https://www.uptodate.com/contents/tests-for-screening-for-colorectal-cancer-stool-tests-radiologic-imaging-and-endoscopy>, (This website accessed January 26, 2017.)

²⁵ A colonoscopy is a test, usually performed by a physician that permits visualization of the inside of the large intestine and rectum. The test uses a four-foot long flexible tube that is inserted through the anus and optimally progressed to the cecum, the beginning of the large intestine. Typically, the inside of the large intestine is inspected for abnormalities as the colonoscope is withdrawn.

²⁶ Sensitivity in this context refers to the ability of a test to correctly identify those patients with disease.

²⁷ UpTo Date® Website: <https://www.uptodate.com/contents/tests-for-screening-for-colorectal-cancer-stool-tests-radiologic-imaging-and-endoscopy>, (This website accessed January 26, 2017.)

²⁸ VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014.

For screening purposes, colonoscopy has become the most commonly used test in the United States.²⁹ Colonoscopy has the benefit of high sensitivity and high specificity.³⁰ The entire large intestine and rectum can be visualized using an endoscope, and lesions can be removed or sampled during the colonoscopy. Lesions that are sampled or removed are sent to the laboratory to determine if a pre-cancerous or cancerous condition is present. The disadvantages of a colonoscopy are that it requires sedation, a vigorous bowel preparation, and carries the risks of bleeding and bowel perforation.³¹ If a lesion was detected on a screening colonoscopy, established guidelines suggest when a follow-up (surveillance) colonoscopy should occur.

CRC Screening in Veterans Health Administration

Screening options available in Veterans Health Administration (VHA) at the beginning of fiscal year (FY) 2015 under VHA Directive 2007-004 included: home Fecal Occult Blood Test (FOBT—that includes FIT), flexible sigmoidoscopy, double contrast barium enema, and colonoscopy.³² Eligible veterans at average risk (greater than or equal to (\geq) 50 years old) were to be offered screening. Because none of the screening methods had been shown to be superior, the provider and patient had the option of selecting the screening test best suited to the patient based on patient risk and preferences.³³

For positive screening results:

...the provider responsible for initiating follow-up must develop a follow-up plan or must document that no follow-up is indicated, within 14 calendar days of the screening test (day of laboratory receipt of FOBT, day of test for sigmoidoscopy, or DCBE [double contrast barium enema]). If a diagnostic colonoscopy is indicated, the colonoscopy must be performed within 60 calendar days of the positive screening test. If the patient desires colonoscopy more than 60 calendar days after positive screening, this must be documented in the medical record and

²⁹ UpTo Date® Website: <https://www.uptodate.com/contents/tests-for-screening-for-colorectal-cancer-stool-tests-radiologic-imaging-and-endoscopy>. (This website accessed January 26, 2017.)

³⁰ Specificity in this context refers to the ability of a test to properly identify those patients who do not have disease; UpTo Date® Website: <https://www.uptodate.com/contents/screening-for-colorectal-cancer-strategies-in-patients-at-average-risk>. (This website accessed January 25, 2017.)

³¹ UpTo Date® Website: <https://www.uptodate.com/contents/screening-for-colorectal-cancer-strategies-in-patients-at-average-risk>. (This website accessed January 25, 2017.)

³² VHA Directive 2007-004, *Colorectal Cancer Screening*, January 12, 2007. This Directive was rescinded and replaced by VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014.

³³ VHA Directive 2007-004.

the colonoscopy must be scheduled within 14 calendar days of the patient's requested date.³⁴

In 2007, VA initiated a national CRC diagnosis quality improvement effort. In this study, the median facility reported that the 60-day colonoscopy follow-up rate for positive screening FOBTs was 24.5 percent. Constraints on gastroenterology (GI) service capacity (the number of individuals and resources available to perform colonoscopy) were often cited as a barrier to timely colonoscopy in this study.³⁵

A study published in 2009 examined the records of 231 patients who received a colonoscopy within 18 months of a positive FOBT. While the mean time to colonoscopy in that study was 236 days, the authors concluded that a longer interval to colonoscopy after a positive FOBT was associated with an increased risk of neoplasia. While no optimal interval between a positive FOBT and colonoscopy was proposed, the authors concluded that the risk of colorectal neoplasia per day of delay is minimal, and the risk of neoplasia becomes more pronounced "...when large delays are encountered."³⁶

A VHA Evidence-based Synthesis Program examining *Patients with Positive Screening Fecal Occult Blood Tests* published in 2013 concluded that the evidence to draw conclusions about the effects of time between positive screening by FOBT and colonoscopy in terms of critical survival outcomes and CRC stage was insufficient.³⁷

A 2016 study of four VA health care systems identified over 60,000 patients with a positive FIT. Most patients who received a follow-up colonoscopy did so within six months, and the median days to colonoscopy ranged from 41 to 174 days in the four systems. Across the four health care systems, the percent of patients who had a diagnostic colonoscopy ranged from 58.1 percent to 83.8 percent.³⁸

³⁴ VHA Directive 2007-004, *Colorectal Cancer Screening*, January 12, 2007. This directive was rescinded and replaced by VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014.

³⁵ Powel, AA, Gravely, AA, Ordin, DI et al. Timely follow-up of positive fecal occult blood tests: strategies associated with improvement. *Am. J. Prev. Med.* 2009; 37(2):87-93.

³⁶ Ziad, F, et.al. Time from Positive Screening Fecal Occult Blood Test to Colonoscopy and Risk of Neoplasia. *Dig Dis Sci.* 2009 November; 54(11): 2497–2502. Doi: 10.1007/s10620-008-0653-8.

³⁷ VA Health Services Research & Development Services, Evidence-Based Synthesis Program, Quality Enhancement Research Initiative, *Patients with Positive Screening Fecal Occult Blood Tests: Evidence Brief on the Relationship between Time Delay to Colonoscopy and Colorectal Cancer Outcomes*. April 2013. One limitation of this study was that it examined the fecal occult blood test and not the FIT, which was used to screen most patients in the population for the OIG review.

³⁸ Chubak, J, Garcia, MP, Burnett-Hartman, A. et al. Time to colonoscopy after positive fecal blood test in four US health care systems. *Cancer Epidemiol Biomarkers Prev.* 2016; 25(2); 344-50.

The 2007 VHA CRC Directive was rescinded December 30, 2014 and replaced with VHA Directive 1015.³⁹ Directive 1015 included guidance regarding the selection of screening options for eligible patients similar to the previous Directive.

Prior to performing non-colonoscopy screening, Veterans should be informed that colonoscopy is recommended if the test is positive. The VHA National Center for Health Promotion and Disease Prevention states that “there are multiple acceptable methods of CRC screening that have similar efficacies.” There is insufficient evidence to recommend one screening strategy over another as each strategy has certain advantages and disadvantages...Veterans are informed about the different options available for CRC screening, including the option of no screening, **NOTE:** Veterans should make a shared decision with their primary care provider.⁴⁰

The provider who orders a non-colonoscopy screening test is responsible for informing the patient of the result, and if the test is positive, initiating follow-up, or documenting that no follow-up is indicated. While the 2014 Directive does not include a timeframe for completing the diagnostic colonoscopy after a positive screening test, it does include a requirement for tracking patients for whom a diagnostic colonoscopy is indicated but not performed.⁴¹

CRC Screening in Non-VHA Medical Literature

Consistent with the VHA’s 2014 rescission of the 60-day diagnostic colonoscopy requirement after a positive screening test, the medical literature OIG staff reviewed does not recommend a specific time interval between a positive FIT and a diagnostic colonoscopy. However, clinical consensus is that a longer interval to colonoscopy after a positive FIT is associated with an increased risk of neoplasia.⁴² A study examining data that compared patients who underwent a colonoscopy 12 months after a positive FIT compared to two weeks after a positive FIT found a four percent increase in CRC risk and a 16 percent increase in mortality risk in the 12-month group compared to the 2-week group.⁴³

³⁹ VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014.

⁴⁰ VHA Directive 1015.

⁴¹ VHA Directive 1015. The tracking process should help to determine barriers to completion such as patient refusal, patients who do not come to appointments without cancelling them (no show), cancellations, and lack of endoscopic capacity.

⁴² Gellad, Z. et al. *Time from Positive Screening Fecal Occult Blood Test to Colonoscopy and Risk of Neoplasia*. *Dig Dis Sci*. November 2009; 54(11): 2497-2502. Doi:10.1007/s10620-008-0653-8.

⁴³ Meester RG, Zauber AG, Doubeni CA, et al. Consequences of Increasing Time to Colonoscopy Examination Following Positive Result From Fecal Colorectal Cancer Screening test. *Clin Gastroenterol Hepatol*. 2016; Could 19. Pii: S1542-3565 (16)30204-X. doi: 1016/j.cgh.2016.05.017.

In 2017, an electronic health record (EHR) study of 70,124 patients in a non-VA health system with positive FIT tests examined the time to colonoscopy after a positive FIT, and its association with CRC. The authors concluded that compared with colonoscopy follow up at eight to 30 days, follow up at 10 months was associated with a higher risk of CRC and more advanced stage disease at the time of diagnosis.⁴⁴ In an editorial to this study, no optimal positive FIT to colonoscopy interval was supported. However, the author of the editorial opined that “...sooner is probably better...” for the follow up of a positive FIT with a colonoscopy.⁴⁵

Surveillance: Follow-Up of Abnormal Colonoscopies

If a patient’s initial or index colonoscopy is normal, the patient does not require another colonoscopy for 10 years in the absence of other risk factors. However, if polyps or other abnormalities are identified on colonoscopy, the patient generally requires more frequent follow-ups.⁴⁶ A colonoscopy done to follow up on the findings of a previous colonoscopy is referred to as a surveillance colonoscopy. The interval between an index colonoscopy, and its associated surveillance colonoscopy, is determined by the findings at the index colonoscopy.

Clinical Reminders

VHA established a national clinical reminder program that directs providers to perform certain tests or provide treatments for specific populations via an automated electronic message when it is time for the provider to take action.⁴⁷ The clinical reminder for CRC screening has a default setting of 10 years, which is generally appropriate for a patient without abnormal findings. However, the 10-year timeframe may be too long for patients with increased CRC risk or who require diagnostic or surveillance colonoscopies.⁴⁸

Consult Management

A consult is a document in the EHR that facilitates and details communication of consultative service requests and related activities. In general, a physician or other health care staff member

⁴⁴ Corley DA, Jensen CD, Quinn VP, et al. Association between time to colonoscopy after a positive fecal test result and risk of colorectal cancer and cancer stage diagnosis. *JAMA*.2017;317(16):1631-1641:DOI:10100/JAMA.2017.3634

⁴⁵ [Rutter CM, Inadomi JA. Follow up of positive fecal test results sooner is better, but how much better? *JAMA*.2017;317\(16\):1627-1628.](#)

⁴⁶ Liberman, David A, Rex, Douglas K. et at. Guidelines for Colonoscopy Surveillance After Screening and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer AGA. 2012; 143:844.

⁴⁷ VA National Clinical Reminders, <http://vista.med.va.gov/reminders/>. (This website accessed February 19, 2015.)

⁴⁸ VA National Clinical Reminders; Ten-year time frame to colonoscopy for some patients may expose patients to additional risk. This statement was based on expert medical opinion.

provides a response to requesting providers seeking a clinical consultation opinion or expertise regarding evaluation and/or management of a specific patient's problem.⁴⁹ In the case of a positive FIT, a medical provider would typically enter a consult request into the EHR requesting an additional evaluation of the positive FIT. This consult might request that a physician (the consultant) perform a colonoscopy, or it might request an opinion from the consultant regarding the optimal course of action for the positive FIT given the patient's comorbid conditions. The 2008 Consult Directive required that "all requests for clinical consultation be clinically completed with results consistent with VHA timeliness standards and resolved efficiently taking into account individual health needs."⁵⁰

On May 23, 2013, VHA issued a memorandum to all VISN Directors and VA Central Office Program Offices that announced the standardization of certain aspects of the electronic consultation process.⁵¹ VHA Directive 1232, *Consult Processes and Procedures*, August 23, 2016, Appendix B outlines similar business rules as issued in 2013. National efforts are underway to ensure that patients' appointments are within 30 days of the clinically indicated date⁵² or patients' preferred dates⁵³ for services.⁵⁴

ICU Structure and Staffing

ICU patients receive critical care for a range of complex medical issues. Due to the medical complexity of patients and the various organizational ICU infrastructures, VHA defined criteria for ICU Levels at individual facilities.^{55 56 57 58} In 2016, the facility's ICU was designated as a Level 3 ICU.

⁴⁹ VHA Directive 2008-056, *VHA Consult Policy*, September 16, 2008. This policy was in effect during the timeframe of the events discussed in this report. It was rescinded and replaced by VHA Directive 1232(1), *Consult Processes and Procedures*, August 24, 2016, amended September 23, 2016, which contains the same or similar definition of a consult. Both the 2008 and 2016 Consult Directives require that action be taken by the receiving service within seven days of the request.

⁵⁰ VHA Directive 2008-056.

⁵¹ Under Secretary for Health, "Consult Business Rule Implementation" memorandum, May 23, 2013.

⁵² The clinically indicated date is the date an appointment is deemed clinically appropriate by a medical provider and documented in the EHR.

⁵³ The preferred date is the date the patient prefers to be seen for care or services.

⁵⁴ http://www.va.gov/HEALTH/docs/VA_Report_Section101-PL_113-146-Final.pdf. Report to Congress on the Veterans Choice Program Authorized by Section 101 of the Veterans Access, Choice, and Accountability Act of 2014, October 3, 2014, (This website accessed March 16, 2017.)

⁵⁵ Almenoff, P, et al. Intensive Care Services in the Veterans Health Administration. *Chest*, 2007 Nov 132 (5), 1455-1462. doi:10.1378/chest.06-3083.

⁵⁶ VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010. This VHA Directive expired May 31, 2015 and has not yet been updated.

VHA defines four Levels of intensive care. The higher Levels (1 and 2) are associated with tertiary care, academic affiliated medical centers. A Level 3 ICU provides a moderate level of services that typically does not include a dedicated ICU attending physician or coverage by an intensivist. Specialty care is provided through consultation. A Level 3 ICU is supported by moderate levels of pharmacy, laboratory, and radiology services.⁵⁹

Physicians who care for patients in the facility's ICU setting include intensivists, hospitalists, and resident physicians. VHA requires that attending (supervising) physicians document resident supervision in the EHR.⁶⁰ Because of the unstable nature of ICU patients, attending physicians must be frequently involved in a patient's care with documentation of this involvement in the EHR.

Allegations

The OIG received allegations in March and April of 2016 regarding the adequacy of CRC screening, timely performance of colonoscopies, and ICU physician coverage at the facility. Specifically, the complainant(s) alleged that:

- Veterans were dying unnecessarily as a result of not getting adequate screening because the facility used FITs for routine CRC screening instead of colonoscopies.
- Colonoscopies that were not timely impacted patient care.
- The ICU was without physician coverage for multiple nights throughout a month.

The OIG also received allegations of intimidation and retaliation as well as complaints regarding physician competence, workloads, and panel sizes. These issues were discussed with OIG leaders and referred to the OIG Hotline for further review; and therefore, will not be a part of this Healthcare Inspection.

⁵⁷ Medical Centers and VISNs need to meet established ICU criteria that would establish their level of care from highly complex (Level 1) to basic (Level 4). Updates to the level of ICU care can be made anytime during the year in collaboration with the National Program Director for Pulmonary/Critical Care. ICU Levels: 1-Complex, 2-Complex, 3-Moderate or 4-Basic are based on the results of the FY 2007–2008 HAIG ICU Level Survey and ongoing updates through the VA Inpatient Evaluation Center.

⁵⁸ [2012 VHA Facility Quality and Safety Report, September 2012](#), (This website accessed November 21, 2016.)

⁵⁹ Almenoff P. Sales A, et al. Intensive Care Services in the Veterans Health Administration. *Chest* (132).November 2007:1455-1462.

⁶⁰ VHA Handbook 1400.01, *Resident Supervision*, December 19, 2012.

Scope and Methodology

The OIG initiated a healthcare inspection in April 2016, and conducted announced site visits to the facility May 24–26, 2016 and August 16, 2016. On August 15, 2016, OIG staff conducted an unannounced evening ICU site visit.

OIG Staff interviewed the facility Director; Chief of Staff; Patient Advocate; ICU and primary care physicians; ICU and GI Nurse Managers; ICU, GI, and CBOC staff nurses; respiratory staff assigned to the ICU; ED staff; and laboratory staff. The OIG also conducted interviews with the Non-VA Care Coordination (NVCC) Coordinator, Scheduling Coordinator for Colorectal Consults and procedures, Chief of Quality Management, Patient Safety Officer, and Nurse Executive.

To evaluate the facility’s methods for CRC screening, the OIG reviewed VHA recommendations for CRC screening for the timeframe that coincided with the patients OIG staff reviewed. OIG staff performed a literature review of past and current national recommendations for CRC screening, specifically focusing on FIT and colonoscopies.

To evaluate the facility’s colonoscopy timeliness and possible resulting impact to patients, OIG staff analyzed two groups of patients.⁶¹ In the first group, OIG staff evaluated the interval between patients’ endoscopy⁶² consults and completed colonoscopies. In the second group, OIG staff evaluated the interval between patients’ positive FITs and completed colonoscopies.

The first group consisted of 358 patients; who had at least one outpatient colonoscopy consult from March 2015 through January 2016; whose consult was delayed greater than (>) 30 days; and who had at least one of the following health events: hospitalization, CRC, or death. The OIG chose this approach to capture patients who may have had a delay in colonoscopy, not necessarily attributed to a positive FIT, and who may have had a health care event related to the delay in colonoscopy.⁶³ For these patients, OIG staff examined the consult to colonoscopy

⁶¹ For these two groups OIG staff reviewed 1,439 unique patients. The first group had 358 patients, and the second group had 1,168 patients for a total of 1,526 patients. However, 87 patients were common to the two groups, which resulted in 1,439 total unique patients reviewed.

⁶² OIG staff evaluated patients who had an “endoscopy outpatient consult.” Because general surgeons and gastroenterologists both performed colonoscopy at the facility, this strategy helped to ensure that OIG staff were obtaining the proper population of patients. Throughout the report, unless otherwise indicated, the OIG used the term “colonoscopy” to describe the consult or identify the procedure the patients underwent.

⁶³ The OIG sent facility managers the names of patients who did not have documented EHR evidence of completed colonoscopies or other positive FIT follow up. A set of 39 patient identifiers was sent to facility managers in October 2016. A second set of 39 patient identifiers was sent to facility managers on August 8, 2017. The facility provided documented evidence of follow-up for both sets of patients.

interval as the primary interest because many of the patients had colonoscopy consults submitted for abnormal signs or symptoms.

The second group consisted of 1,168 patients who had a positive FIT in FY 2015. OIG staff reviewed the facility's follow-up actions from the beginning of FY 2015 through September 8, 2017. OIG staff reviewed patients' EHRs to determine if a consult to evaluate the positive FIT was submitted, the time from the positive FIT to colonoscopy consult submission, the time from the positive FIT to the colonoscopy completion, and documentation of colonoscopy results and providers' follow-up plans.

To evaluate issues related to ICU physician coverage, OIG staff reviewed relevant current and previous VHA and facility policies and procedures related to ICU staffing, coverage, and resident supervision. OIG staff also reviewed ICU physician and hospitalist coverage schedules from March 2016 through September 2016. To determine if attending (supervising) physicians could be contacted by residents and nursing staff; OIG staff made anonymous calls to the ICU during the day, evening, and night shifts. OIG staff also reviewed updated ICU physician coverage schedules in February 2017.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to substantiate or not substantiate an allegation when the available evidence is insufficient to determine whether or not an alleged event or action took place.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Case Summaries

For in-depth EHR reviews, the OIG selected 15 patients who had CRC or carcinoid and the longest delays in colonoscopy. Table 1 provides an overview of these 15 patients.

Fourteen patients had CRC. One patient had a carcinoid tumor. OIG staff determined that delayed colonoscopies impacted the care of these 15 patients, especially the eight patients who had between a one and 10-year delay in surveillance colonoscopy. Two patients had Stage IV⁶⁴ colon cancer; one of these patients died approximately nine months after the diagnosis (cause of death was not documented in the EHR). Nine patients required removal of a portion of their colon due to colon cancer, and one of these patients had this procedure prior to colonoscopy. Ten patients had some role (such as appointment postponement, travel difficulties, or contact difficulties) in the delay of their colonoscopy. For all of these patients, and especially those with a delay in surveillance colonoscopy, there may have been a relationship between the delay in colonoscopy and risk of CRC.

⁶⁴ Colon cancer is graded from Stage 0 (the least advanced stage) to stage IV (the most advanced stage). Generally the more the advanced the stage of the cancer, the lower the chances of the patient being alive in five years.

Table 1. Summary of 15 Patients who had CRC or Carcinoid and the Longest Colonoscopy Delays.

ID	Group	Delay in Days for Consult to Colonoscopy or from Positive FIT to Colonoscopy	Delay in Years for Surveillance Colonoscopy	Reason for Colonoscopy	Did the Patient Have CRC	Did the Patient Require Cancer Surgery	Was the Colonoscopy Delayed by the Patient	Was the Colonoscopy Delayed by the Colonoscopy Clinic	Was the Colonoscopy Delayed by Patient's Medical Conditions	Was there Difficulty in Contacting the Patient	Was the Colonoscopy Done at the VA or at a Non-VA Facility
#1	Delayed Consults	293	3	Survey	yes	yes	yes			yes	VA
#2	Positive FITs	464		FIT	yes	yes			yes		VA
#3	Positive FITs	209		FIT	yes	yes	yes	yes			Non-VA
#4	Both Groups	295/297	9	FIT and Survey	yes	yes	yes	yes			Non-VA
#5	Positive FITs	349		FIT	yes	yes	yes				Non-VA
#6	Both Groups	65/60	5	FIT and Survey	yes	no					VA
#7	Positive FITs	258	7	FIT and Survey	yes	yes					Non-VA
#8	Both Groups	217/210	2.5	FIT and Survey	Carcinoid	no					VA
#9	Positive FITs	280		FIT	yes	no	yes				VA
#10	Both Groups	230/231		FIT	yes	no	yes				Non-VA
#11	Positive FITs	208		FIT	yes	no	yes				Non-VA
#12	Both Groups	227/227	2	FIT and Survey	yes	yes	yes			yes	VA
#13	Delayed Consults	No colonoscopy done: surgery	1	Survey	yes	yes	yes				No colonoscopy done
#14	Delayed Consults	34 (*previous FIT)	10+	Anemia, weight loss, Survey	yes	no	yes				Non-VA
#15	Positive FITs	200		FIT	yes	yes			yes		VA

Source: VA OIG EHR review and analysis *Previous FIT = this positive FIT was done in 2012, prior to the review timeframe.

Inspection Results

Issue 1: CRC Screening using FIT

The OIG did not substantiate that veterans were dying unnecessarily as a result of inadequate screening because the facility used FIT for routine screening instead of colonoscopies. VHA recommends using several types of CRC screening methods without choosing one method over the others.⁶⁵ FIT is a VHA acceptable method of CRC screening.

OIG staff reviewed VHA recommendations for CRC screening for the timeframe of the events discussed in the report and performed a literature review of current, national recommendations for CRC screening, specifically focusing on FIT and colonoscopy.⁶⁶

Since 2007, VHA has approved the use of FOBT as an appropriate CRC screening tool. VHA requires that any positive CRC screening tool must be followed by a colonoscopy.⁶⁷ In December 30, 2014, VHA included FIT as an approved FOBT screening method and stated that no screening method is considered to be superior to any other. According to VHA, the provider and patient should confer and select the preferable screening method.⁶⁸ Facility providers who offered patients FIT as a CRC screening option were in compliance with VHA policy.

Issue 2: Colonoscopies that were not Timely Impacted Clinical Care

The OIG could not substantiate that a specific delay or timeframe interval impacted a particular patient's care for the patients reviewed. VHA and medical literature does not identify a specific timeframe between the identification of the need for colonoscopy (such as a positive FIT) and completion of the colonoscopy that would impact patient care. However, of the 1,439 unique patients reviewed, OIG staff identified 15 patients who had CRC or carcinoid and longer intervals between identification of a need for a colonoscopy and completion than other patients without cancer in the review group. Although OIG staff could not identify a specific or minimum delay interval, the OIG determined that patients who had CRC or carcinoid and the longest colonoscopy intervals were most likely impacted by the longer intervals.⁶⁹

⁶⁵ VHA Directive 2007-004, *Colorectal Cancer Screening*, January 12, 2007. This Directive was rescinded and replaced by VHA Directive 1015 *Colorectal Cancer Screening*, December 30, 2014.

⁶⁶ VHA Directive 2007-004.

⁶⁷ If the initial CRC screening tool is a colonoscopy, a follow-up colonoscopy is not required unless abnormalities are found and the patient needs a surveillance colonoscopy done within a provider suggested timeframe.

⁶⁸ VHA Directive 2007-004. Both the 2007 and 2014 directives stated that selection of the screening method is a provider/patient decision.

⁶⁹ For this report, the OIG uses the terms untimely and not timely to describe the colonoscopies of patients who had CRC or carcinoid and the longest colonoscopy intervals.

To evaluate the facility's colonoscopy timeliness and resulting impact to patients, OIG staff analyzed two groups of patients. In the first group, OIG staff evaluated the interval between patients' colonoscopy consults and completed colonoscopies. In the second group, OIG staff evaluated the interval between patients' positive FITs and completed colonoscopies. During the review, the OIG also identified issues with the facility's processing and management of FIT specimens.

Colonoscopy Consults to Colonoscopy Completions

The OIG determined that outpatient colonoscopy consults that were not timely impacted care for eight of the patients reviewed for the first group. OIG staff reviewed the EHRs of 358 patients who had an outpatient colonoscopy consult for any reason from March 2015 through January 2016; who had a consult delay > 30 days; and who had at least one of the following health events: hospitalization, CRC, or death.

The OIG determined that 335 of the 358 patients, who had untimely completion of their consults, underwent a colonoscopy. The interval between the placement of the outpatient colonoscopy consult and the completion of the colonoscopy for these 335 patients varied. The average time to colonoscopy for these patients was about six months. For the 319 patients who had a colonoscopy and did not have CRC or carcinoid, the average time from consult to colonoscopy was about one month longer than the interval for patients who had CRC.

Seventeen patients had CRC or carcinoid tumor (carcinoid). One of the 17 patients did not have a colonoscopy because surgery was required for CRC before the colonoscopy could be done; this patient also had a one-year delay in surveillance colonoscopy. For the remaining 16 patients with CRC or carcinoid who had a colonoscopy, the interval between the identification of a need for colonoscopy and the completion of the colonoscopy was from one month to about 10 months. The average time to colonoscopy for these 16 patients was about five months; one month less than for those patients without CRC or carcinoid. (See Table 2 for a summary of the patients.)

Table 2. Consult to Colonoscopy Intervals for 358 Patients (First Group).

Patients who had a Delayed Outpatient Colonoscopy Consult Completion	Number of Patients who had a Colonoscopy	Average Number of Days, Consult to Colonoscopy	Range of Days, Consult to Colonoscopy
CRC or Carcinoid	16	144.6	34–295
No CRC	319	173.2	32–529
All Patients	335*	171.8	32–529

Source: VA OIG EHR review and analysis

* For this analysis, OIG staff excluded the 23 patients who did not have a colonoscopy.

Figure 1 illustrates the number of patients who received a colonoscopy, in 30-day intervals, from the date of the consult to the colonoscopy completion (blue boxes). About half of the patients had their colonoscopy within 180 days. The red line is the cumulative percentage of patients who received a colonoscopy, at each 30-day interval from the time of the consult. About 90 percent of patients received a colonoscopy within 240 days of the consult. The average time from consult to colonoscopy was about 30 days shorter for patients with CRC (diamond shapes in the gray boxes on the right graph). Variability in the time to colonoscopy (vertical lines above and below the gray boxes) increased for patients without cancer. The gray boxes represent the consult to colonoscopy range (in days) in which 50 percent of the patients received a colonoscopy. This range is broader for patients with CRC. The horizontal lines inside the gray boxes represent the median number of days from consult to colonoscopy; this is about 60 days shorter for patients with CRC.

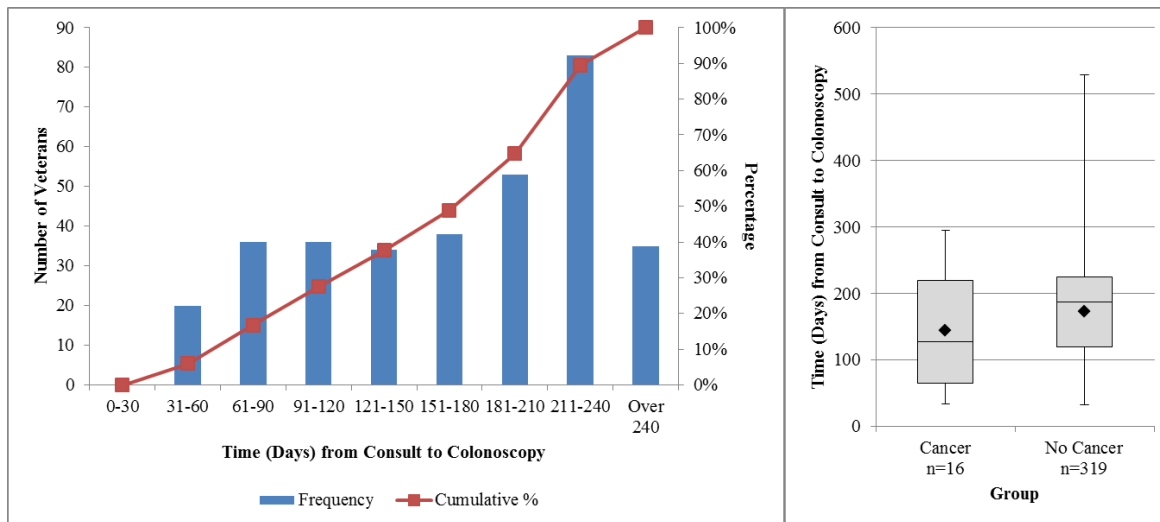


Figure 1. Cumulative Colonoscopy Completion for Reviewed Patients (First Group) after Submission of Consult at 30-day Intervals.

Source: OIG staff EHR reviews and analyses of 358 reviewed patients

Note: For this analysis, the OIG excluded the 23 patients who did not have a colonoscopy.

For the 23 patients who did not have a colonoscopy completed (see Figure 2), the EHR documented reasons for non-completion:

- Fourteen patients declined, cancelled, or could not be contacted for a colonoscopy.
- Five patients underwent an esophagogastroduodenoscopy (EGD).⁷⁰
- One patient's GI provider determined that a colonoscopy was not indicated.
- One patient had comorbid conditions that contraindicated a colonoscopy.
- One patient had surgery for CRC before a colonoscopy could be done.
- One patient had a non-VA colonoscopy (colonoscopy results were not available/documented in the EHR).

Of the 335 patients who underwent colonoscopy, 16 (5 percent) had CRC (see bottom row of Figure 2) and one patient had a carcinoid tumor. The 16 CRC patients include six patients who had a delayed surveillance colonoscopy. The patient with carcinoid also had a delay in surveillance colonoscopy. (See Table 1, Patient 8.)

⁷⁰ EGD is a procedure where a thin flexible tube with a light, a camera, and another portal for suctioning and procedures is passed into the mouth and then through the esophagus, stomach, and upper intestine to examine the surfaces of these structures. Procedures can be done through this instrument.

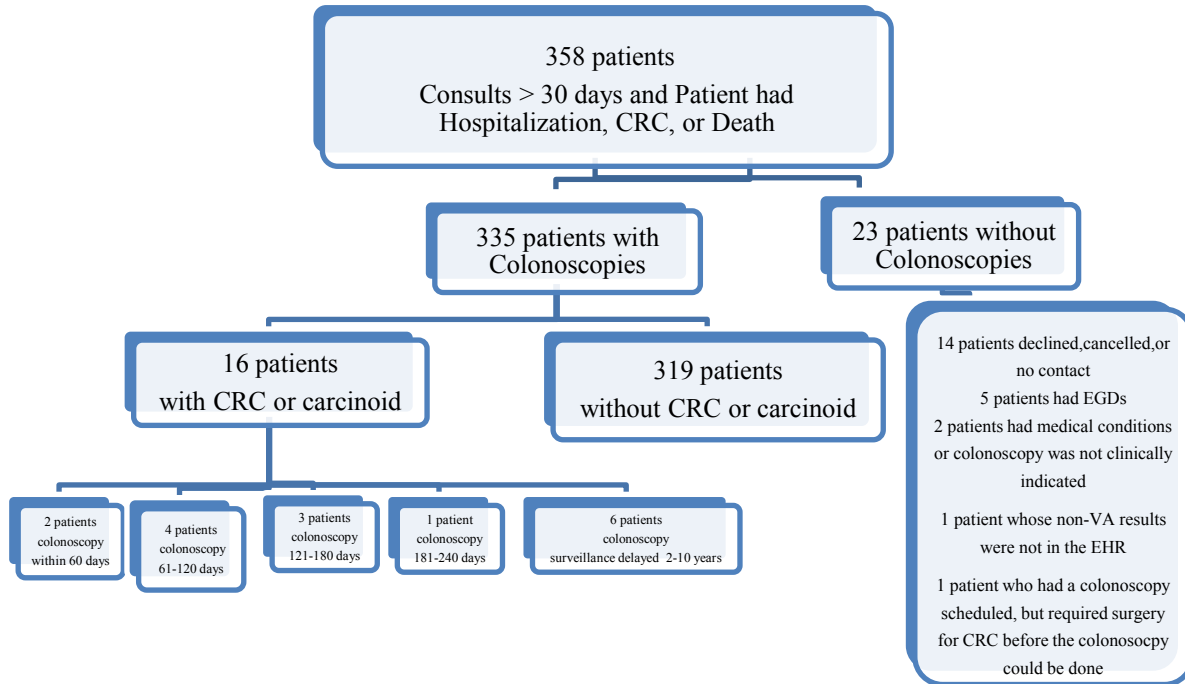


Figure 2: Consults > 30 Days Submitted Between March 1, 2015–January 30, 2016 for Reviewed Patients with Hospitalization, CRC, and/or Death (First Group).
Source: OIG staff Analysis

Delays in Surveillance Colonoscopies

For the 335 patients who had delayed consults and colonoscopies, OIG staff found that 11 patients also had a delay in surveillance colonoscopy. The delays in surveillance colonoscopy ranged from one year to 10 years. Four of the patients with a delay in surveillance colonoscopy did not have CRC. See Table 1 for summaries of the remaining seven patients (Patients 1, 4, 6, 8, 12, 13, and 14). These seven patients had CRC or carcinoid and a history of a previous abnormal finding on colonoscopy. Their surveillance colonoscopies were delayed from one to 10 years.⁷¹ These patients were at high-risk for the development of CRC due to the surveillance colonoscopy delay. An earlier surveillance colonoscopy should have been done for these seven patients.

Surveillance colonoscopies were delayed for a number of reasons. These documented reasons included patients who were not notified that they were due for a surveillance colonoscopy; colonoscopy consult delays; clinics that cancelled appointments; and patients who either

⁷¹ The patient who had a one-year delay did not have a colonoscopy performed because he required surgery for CRC before he could undergo a colonoscopy.

cancelled appointments, were “no shows” for scheduled appointments,⁷² or deferred the surveillance colonoscopy. As of April 13, 2016, facility managers were in the process of implementing steps to address the identified contributing factors.

Positive FITs to Colonoscopy Completions

To further evaluate untimely colonoscopies and the possible impact on patient care, OIG staff reviewed a second group that consisted of the EHRs of 1,168 patients who had positive FITs in FY 2015. The OIG substantiated that colonoscopy completions that were not timely impacted clinical care for seven of the patients OIG staff reviewed for the second group.⁷³ VHA policy states that if the FIT is positive, a diagnostic colonoscopy is recommended.⁷⁴ OIG staff identified issues with the facility’s positive FIT follow-up that included delays in colonoscopy consult submissions, colonoscopy consults that were not submitted, delays in completion of colonoscopies, missing documentation of colonoscopy results and follow-up, and repeat FITs conducted after positive FITs rather than follow-up colonoscopies.

Colonoscopy Consults Submission Delays after a Positive FIT

From October 1, 2014 through August 2, 2016, OIG staff found that providers submitted colonoscopy consults for 888 of the 1,168 patients with positive FITs. About 85 percent (751 of the 888 patients) of the consults were submitted within 30 days of the positive FIT. However, 137 of the 888 consults were submitted > 30 days after the positive FIT.⁷⁵

Four of the 137 patients were diagnosed with CRC; they had consult submission delays of 72, 83, 182, and 372 days. Three patients required surgery to remove the cancer and a portion of the colon. One of these three patients incurred a delay in CRC diagnosis related to the treatment of an underlying medical condition. One patient (see Table 1, Patient 9), whose cancer was entirely removed during the colonoscopy, required periodic surveillance colonoscopy.

Colonoscopy Consults not Submitted after a Positive FIT

The OIG found that 280 of the 1,168 patients with positive FITs did not have a consult entered to follow up the positive FIT. Documented reasons for not placing a consult included: the patient

⁷² VHA Directive 1230, *Outpatient Scheduling Processes and Procedures*, July 15, 2016. “A no show occurs when a patient does not present for a scheduled appointment by the time the appointment was scheduled to start.” This directive was issued in 2016 and did not encompass the entire study period for this inspection. It was used in this context only to provide a definition of the term “no show” which was formerly referred to as a missed opportunity.

⁷³ The OIG determined that the delay from positive FIT to colonoscopy impacted the care of 12 patients within the second group. However, five of these patients were also considered as impacted in the first group, consult to colonoscopy, resulting in seven unique patients in the second group whose clinical care was impacted.

⁷⁴ VHA Directive 2007-004.

⁷⁵ The interval range was 31–488 days.

elected to use a non-VA provider, facility staff were unable to contact the patient, the patient declined a consult, the patient had a recent colonoscopy, and the patient had comorbid medical conditions (which did not permit a colonoscopy at the time). Although 45 of the 280 patients did not have EHR documentation that a colonoscopy consult was submitted, they did have EHR documentation that a colonoscopy was completed.

Colonoscopy Completion after a Positive FIT

The OIG found that 632 of the 1,168 patients who had positive FITs in FY 2015 had results of associated diagnostic colonoscopies in their EHRs. Ten patients had a FIT performed after their colonoscopy; a colonoscopy was not repeated. These 10 patients were excluded from analysis of the interval between the positive FIT and the colonoscopy. The average time to colonoscopy (excluding the 10 patients) was about five months. Twenty-seven patients were diagnosed with CRC or carcinoid. The interval from positive FIT to colonoscopy for these patients varied widely; one patient had a positive FIT 17 days after the colonoscopy. The average time to colonoscopy for the 26 patients with cancer or carcinoid who had a colonoscopy after a positive FIT was about five months. Five of the 27 patients with CRC or carcinoid also had delays in surveillance colonoscopy ranging from two to nine years. These five patients were among the highest risk patients for development of CRC due to the length of the surveillance colonoscopy delay. Six hundred-five patients, who had a colonoscopy, did not have CRC or carcinoid. Nine of these patients had a colonoscopy prior to the positive FIT; therefore, their colonoscopies were not repeated. For the remaining 596 patients who did not have CRC, the average time from positive FIT to colonoscopy completion was similar to patients who had CRC. The interval from positive FIT to colonoscopy for these patients varied widely. (See Table 3 for a summary of the results of positive FIT to colonoscopy completion intervals.)

Table 3: Positive FIT to Colonoscopy Completion Intervals (Second Group).

Patients who had a Colonoscopy after a Positive FIT	Number of Patients who had a Colonoscopy*	Average Number of Days, Positive FIT to Colonoscopy	Range of Days, Positive FIT to Colonoscopy
CRC or Carcinoid	26	151.5	1–464
No CRC	596	153.4	0–992
All Patients	622	153.3	0–992

Source: OIG staff EHR reviews and analysis

**For this analysis, OIG staff excluded the 10 patients whose colonoscopies were done prior to their positive FITs.*

Figure 3 illustrates the number of reviewed patients who received a colonoscopy, in 30-day intervals, from the date of patients’ FY 2015 positive FIT (blue boxes). About one-half of the patients had a colonoscopy within 120 days. The red line shows the cumulative percent of patients who received a colonoscopy at each 30-day interval from a positive FIT. About

80 percent of patients received a colonoscopy within 240 days of a positive FIT. While the average time from a positive FIT to colonoscopy was nearly identical for patients with and without cancer (diamond figures in the gray boxes on the right graph) variability in the time to colonoscopy (vertical lines above and below the gray boxes) was greater for those without cancer. The gray boxes represent the positive FIT to colonoscopy range (in days) in which 50 percent of the patients received a colonoscopy. This range is broader for those patients with CRC. The horizontal lines in the gray boxes represent the median number of days from positive FIT to colonoscopy; this is 17 days longer for patients with CRC.

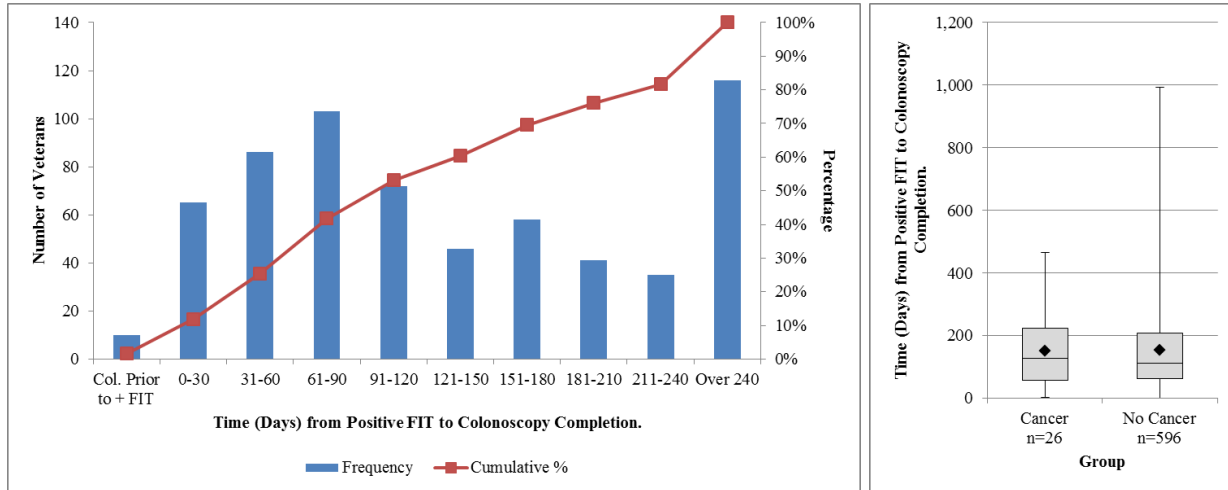


Figure 3. Cumulative Colonoscopy Completion after Positive FIT, at 30-Day Intervals, for 632 of 1,168 patients (Second Group).

Source: VA OIG EHR review and analysis

Note: For the box plot analysis, the OIG excluded the 10 patients whose colonoscopies preceded their positive FIT. The one patient who had a carcinoid was included in the cancer group.

Results of Diagnostic Colonoscopy not in the EHR for Patients with a Positive FIT

The OIG identified 536 of the 1,168 patients (46 percent) who had positive FITs in FY 2015 but did not have documented results of associated diagnostic colonoscopies and/or discussion of positive FIT follow-up in their EHRs. VHA requires that, when indicated, providers document why there is no follow-up for a positive FIT.⁷⁶ The documented reasons for no colonoscopy/follow-up are listed below.

- 190 patients declined the colonoscopy
- 67 patients planned to seek non-VA care and their non-VA colonoscopy results were not available/recorded in the EHR
- 27 patients could not be contacted to schedule a colonoscopy
- 252 patients had other documented reasons for why a follow-up colonoscopy was not performed after a positive FIT which included:
 - Comorbid conditions prohibited the safe performance of colonoscopy.
 - Clinical indications warranted a study other than colonoscopy.
 - Patients moved out of the area.
 - Patients were awaiting medical clearance.
 - Physicians were awaiting results of a prior colonoscopy before proceeding with another colonoscopy.
 - Patients or physicians desired a repeat FIT rather than a colonoscopy.

⁷⁶ VHA Directive 2007-004; VHA Directive 1015.

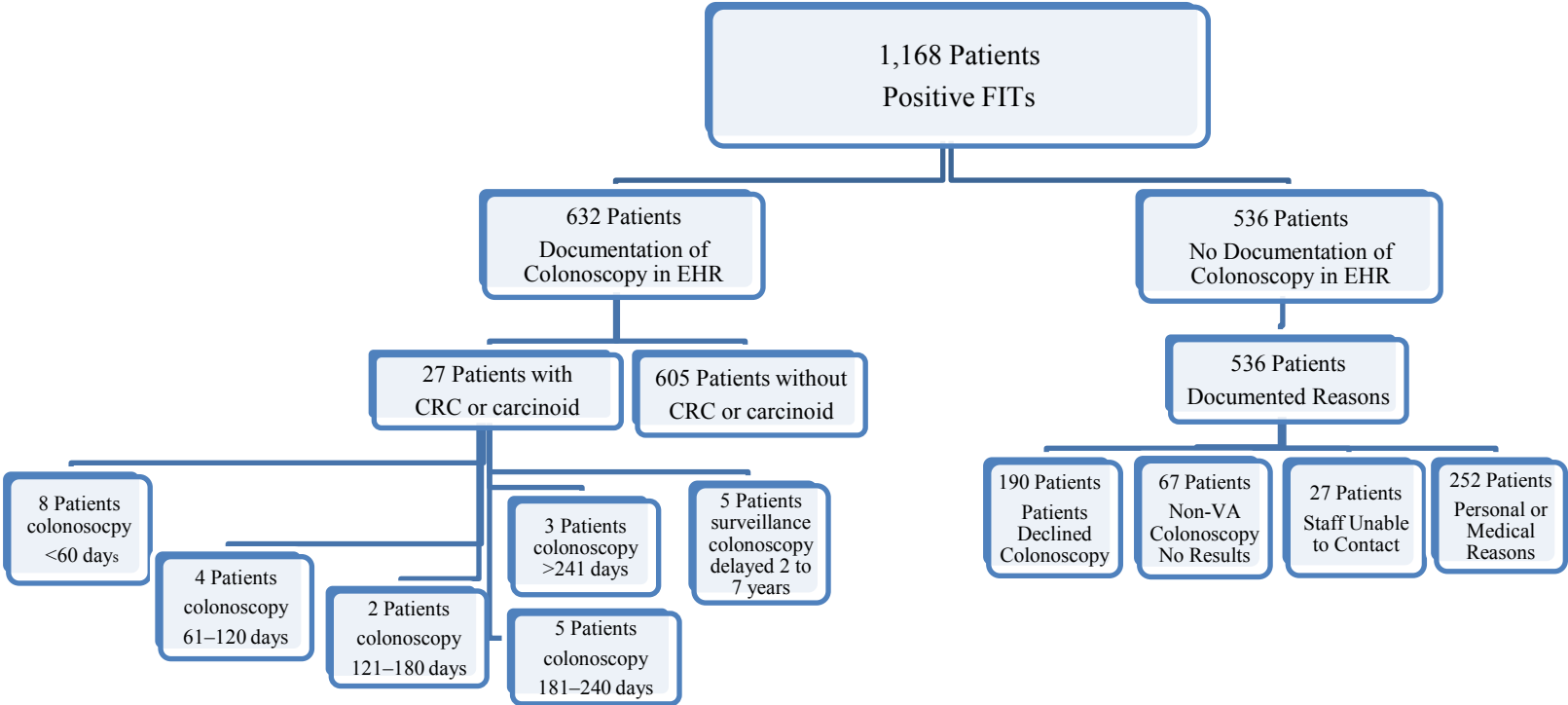


Figure 4. EHR Documentation for Patients with Positive FITs in FY 2015 (Second Group)
 Source: OIG Staff EHR analysis

Repeat of FIT Rather than Diagnostic Colonoscopy

The OIG determined that 42 of the 1,168 patients with an initial positive FIT had a repeat FIT rather than a colonoscopy. For 17 of the 42 patients, the patient requested a repeat FIT prior to proceeding with further evaluation. For 10 of the 42 patients, the provider made the decision to repeat the FIT. For the remaining 15 patients, OIG staff found no documentation in the EHR regarding why the FIT was repeated prior to commencing additional evaluation. Of these 42 patients, two patients underwent a colonoscopy after the repeat positive FIT. Both patients had non-cancerous polyps at colonoscopy.

The facility's process of repeating a positive FIT to confirm validity is not generally recommended as a part of CRC screening and could result in the delayed diagnosis of a clinically significant condition. However, the OIG realizes that this strategy might be indicated when initiated by medical providers.

FIT Specimen Process Deficiencies

During the healthcare inspection, OIG staff also identified deficiencies with the facility's FIT specimen labeling, tracking, and monitoring processes.

FIT Specimen Labelling, Tracking, and Monitoring

FIT is a home test kit that is given to the patient at the facility. The patient collects a fecal sample and returns the specimen to the facility laboratory for analysis. Interviewees told OIG staff that there were issues with illegible or missing labelling of FIT specimens returned to the facility laboratory and difficulties in tracking and monitoring the FITs.

Labelling

The FIT specimen should be appropriately labelled with patient identifiers and other pertinent information. Specimens with handwritten labels that were illegible or missing a label and could not be properly identified were discarded by laboratory staff. Laboratory technicians received approximately 800 FIT specimens per month with about 50 percent of the labels handwritten. Interviewees told OIG staff that laboratory technicians spent a lot of time trying to identify the patients' identification on the FIT kit labels; if technicians were unable to decipher the labels, they discarded the FIT kits. Approximately two–four specimens a day were discarded in May 2016. Facility managers had identified issues with illegible FIT specimen labels prior to the OIG site visit and implemented procedures to improve labelling.

During the OIG unannounced August 15, 2016 site visit, OIG staff interviewed facility and CBOC staff and observed the FIT process in two clinical areas. Facility managers had ordered additional label makers to improve the labelling process. Nursing staff confirmed they received emails regarding FIT problems; however, nurses told OIG staff that they did not consistently know the facility protocol that was implemented to improve the process. Laboratory staff

reported they tracked the FITs they received and sent alerts to physicians for positive FITs. Laboratory staff attempted to identify illegible patient labels by piecing together identifying information (such as pairing a legible first name and date of birth to determine a patient's illegible last name). According to quality management and laboratory staff, the number of illegible FIT kits decreased since the facility started using label makers and re-educated staff on the process. As of February 16, 2017, the facility's discarded FIT kits decreased to less than 0.8 percent and use of handwritten labels decreased to less than 15 percent. However, OIG staff could not determine if disposals of FIT kits were related to delays in care because the facility could not identify who received these kits.

Tracking and Monitoring

When a provider requested a FIT kit for a patient, a nurse provided the patient with a sampling kit, a pre-printed label, and instructions on how to collect a FIT specimen. Clinic nurses then documented distributing a kit to the patient in a nurse's note in the patient's EHR. Although the provider's order for the FIT kit was not entered in the EHR, a CRC screening clinical reminder remained active until FIT results were available to the provider. Other than the clinical reminder, the facility did not have a facility-wide tracking system to monitor distribution of FIT kits to patients.

Issue 3: Physician Coverage in the ICU

Although the OIG substantiated a lack of attending physician coverage in the ICU between March and September 2016, resident physicians, hospitalists, and intensivists were available for ICU coverage. OIG staff found that attending on-call physicians were consistently designated to be available to provide care for ICU patients during non-business hours (6 p.m.–7 a.m.) when necessary.

The facility ICU is classified as Level 3 or moderate complexity ICU.⁷⁷ Intensivists, hospitalists, and residents provide facility physician coverage. However, VHA policy does not require that Level 3 ICUs have 24-hour coverage by intensivists.⁷⁸ Residents are supervised by attending physicians both during regular and after-hours. After regular on-duty hours, the facility has an in-house hospitalist who can be called to the ICU and supervise residents as needed. Designated attending physicians are also available by phone or pager, who can come into the ICU. OIG staff

⁷⁷ Almenoff, P, et al. Intensive Care Services in the Veterans Health Administration. *Chest*, 2007 Nov 132 (5), 1455-1462. doi:10.1378/chest.06-3083, <http://www.sciencedirect.com/science/article/pii/S0012369215512579>, (This website accessed January 25, 2017.) Dr. Almenoff, et al., established a four-Level criteria for VA ICUs based on available resources such as specialty physicians, fellowship training programs, and ED, OR, laboratory, and radiology capabilities. Level 4 is basic, Level 3 is moderate, and Levels 2 and 1 are complex and require additional available resources.

⁷⁸ VHA Directive 2010-018.

reviewed the ICU attending physicians' call schedules from March through September 2016 and found coverage during the day tours, with the exception of one day. However, OIG staff found inconsistent coverage after-hours. During the timeframe reviewed, OIG staff found no intensivist⁷⁹ coverage in 108 of 214 tours (51 percent) although resident physicians were available onsite. Through staff interviews, OIG staff validated that hospitalists⁸⁰ provided coverage when intensivists were unavailable.

During the OIG initial site visit in May 2016, OIG staff interviewed facility staff who stated they had difficulty contacting hospitalists. OIG staff conducted calls to the ICU at different times in July 2016⁸¹ and conducted an unannounced evening site visit to the ICU in August 2016. OIG staff found that resident physicians and nursing staff were able to identify and contact the on-call attending physicians who were responsible for supervising resident physicians covering the ICU.

In addition, facility leaders were actively trying to fill pulmonary/critical care physician positions and had contracted with three locum tenens companies to provide ICU coverage and bridge provider gaps until they could hire full-time physicians. If the intensivist or locum tenens physicians were not available, facility managers told OIG staff that ICU patients, who became unstable or required expertise that hospitalists could not provide, were transferred to a non-VA hospital for critical care services. All requests from ED and admitting physicians to transfer their patients for non-VA critical care were granted and expedited. Because facility leaders implemented a comprehensive ICU physician coverage plan, the OIG made no recommendations regarding ICU physician coverage.

Conclusion

CRC Screening

The OIG did not substantiate that veterans were dying due to the use of FIT rather than colonoscopies for CRC screening. VHA recognizes multiple CRC screening methods and FIT is an acceptable option based on patient and provider preference.

⁷⁹ “An intensivist is a board-certified physician who provides special care for critically ill patients. Also known as a critical care physician, the intensivist has advanced training and experience in treating this complex type of patient.” Website <https://www.umassmemorialhealthcare.org/umass-memorial-medical-center/services-treatments/critical-care/what-intensivist>. (This website accessed May 8, 2017.)

⁸⁰ Hospitalists are “physicians whose primary professional focus is the general medical care of hospitalized patients.” Website, www.the-hospitalist.org/hospitalist/article/123072/what-hospitalist, (This website accessed May 8, 2017.)

⁸¹ Calls were conducted on day, night, and evening shifts including weekend and day shifts.

Colonoscopies that were not Timely Impacted Clinical Care

The OIG determined that outpatient colonoscopies that were not timely impacted care for 15 of the 1,439 unique patients reviewed. To evaluate the facility's colonoscopy timeliness and resulting impact to patients, OIG staff analyzed two groups of patients. In the first group, OIG staff evaluated the interval between patients' colonoscopy consults and completed colonoscopies. In the second group, OIG staff evaluated the interval between patients' positive FITs and completed colonoscopies.

Colonoscopy Consults to Colonoscopy Completions

To evaluate whether a colonoscopy consult delay of more than 30 days might be associated with patients' hospitalization, CRC, or death; OIG staff reviewed the 358 EHRs of patients who had at least one of these three health events. For this group, OIG staff identified eight patients who had untimely colonoscopy consults that impacted patient care. Of the 358 patients' EHRs reviewed, 335 had a colonoscopy. The interval between submission of the consult for a colonoscopy and the completion of the colonoscopy for these 335 patients varied between 1–18 months; the average was about six months. Seventeen patients had CRC or carcinoid. One of the 17 patients did not have a colonoscopy because the patient underwent surgery for CRC before a colonoscopy could be done. For the remaining 16 patients with CRC or carcinoid, the interval between the consult for a colonoscopy and colonoscopy completion was from one month to about 10 months. The average time from consult to colonoscopy was about five months; one month shorter than for patients who did not have CRC.

Seven of the patients with CRC had colonoscopy delays of 34 days (also a 10-year surveillance delay), 65 days (also a five-year surveillance delay), 217 days (also a 2.5-year surveillance delay), 227 days (also two-year surveillance delay), 293 days (also a three-year surveillance delay) and 295 days (also a nine-year surveillance delay). The seventh patient with CRC, who had a one-year delay in surveillance colonoscopy, was scheduled for a colonoscopy but had surgery for a CRC before the colonoscopy could be done.

Delays in Surveillance Colonoscopies

In the group of 335 patients who received colonoscopies, the OIG found that 11 patients had a delay in surveillance colonoscopy. The delays in surveillance colonoscopy ranged from one year to 10 years. Four of the 11 patients did not have CRC. The seven patients with a history of a previous abnormal colonoscopy finding should have been evaluated with a surveillance colonoscopy at an earlier time. Surveillance colonoscopies were delayed for a number of reasons. These documented reasons included patients who were not notified that they were due for a surveillance colonoscopy; colonoscopy consult delays; clinics that cancelled appointments; and patients who either cancelled appointments, did not show up for scheduled appointments, or deferred completion of the surveillance colonoscopy.

Positive FITs to Colonoscopy Completions

To further evaluate untimely colonoscopies and the impact on patient care, OIG staff reviewed the EHRs of 1,168 patients who had positive FITs in FY 2015. The OIG determined that colonoscopy completions that were not timely impacted care for seven of the patients reviewed for this first group.⁸² The OIG identified issues with the facility's positive FIT follow up which included delays in colonoscopy consult submissions, colonoscopy consults that were not submitted, delays in completion of colonoscopies, documentation of colonoscopy results/follow-ups missing from patients' EHRs, and conducting repeat FITs after a positive result rather than follow-up colonoscopies.

Colonoscopy Consult Submission Delays After a Positive FIT

Providers submitted colonoscopy or gastroenterology consults for 888 of the 1,168 patients. Medical providers submitted about 85 percent of the colonoscopy consults within 30 days of the positive FIT. However, 137 of the 888 patients had consults submitted more than 30 days after the patient was determined to have a positive FIT. CRC was diagnosed in four of these 137 patients.

Colonoscopy Consults Not Submitted After a Positive FIT

Two hundred-eighty of the 1,168 patients with positive FITs did not have a consult entered for a colonoscopy or gastroenterology to follow up a positive FIT. Documented reasons for not placing a consult included: the patient elected to use a non-VA provider, facility staff were unable to contact the patient, the patient declined a consult, the patient had a recent colonoscopy, and the patient had comorbid medical conditions which did not permit a colonoscopy at the time. Of the 280 patients who did not have a colonoscopy consult submitted, 45 had documentation of a completed colonoscopy in the EHR.

Colonoscopy Completion After a Positive FIT

Six hundred thirty-two of the 1,168 patients with positive FITs underwent diagnostic colonoscopies. The interval from positive FIT to colonoscopy for these patients varied widely, from days to years. Ten patients had a FIT performed after their colonoscopy; a colonoscopy was not repeated. These 10 patients were excluded from analysis of the interval between the positive FIT and the colonoscopy. The average time to colonoscopy for the 622 patients who had a colonoscopy after a positive FIT was just over five months. Twenty-seven patients had a CRC or carcinoid tumor. The interval from positive FIT to colonoscopy for these patients varied widely,

⁸² OIG staff determined that the delay from positive FIT to colonoscopy impacted the care of 12 patients within this group. However, five of these patients were also considered as impacted in the first group, consult to colonoscopy, resulting in seven unique patients whose clinical care was impacted.

with one patient undergoing colonoscopy about 15 months after the positive FIT. One patient with CRC had a FIT performed 17 days after colonoscopy; the colonoscopy was not repeated. The average time to colonoscopy for the remaining 26 patients with CRC was about five months. For 12 of these patients, longer intervals between FIT and completion of a colonoscopy most likely impacted patient care. Six hundred-five of the 632 patients who had a colonoscopy did not have CRC. Nine of these patients had a positive FIT just after their colonoscopy; colonoscopies were not repeated. For the remaining 596 patients who did not have CRC, the average time from positive FIT to colonoscopy was similar to those patients with CRC.

During the OIG review of the positive FIT patients, OIG staff noted that there were five patients evaluated for a diagnostic colonoscopy who should have been categorized as patients needing follow-up surveillance colonoscopies for a previously identified abnormal finding. These five patients also had CRC or carcinoid and had delays in their surveillance colonoscopy ranging from two to nine years. These patients were among the highest risk patients for development of CRC due to the length of the surveillance colonoscopy delay.

Diagnostic Colonoscopy Results Not Documented in the EHR for Patients with a Positive FIT

Of the 1,168 patients with positive FITs, 536 (46 percent) did not have follow-up diagnostic colonoscopy results documented in their EHRs. However, as required by VHA policy,⁸³ providers documented the reasons for the lack of follow-up, which included notations that patients cancelled or declined a colonoscopy; patients sought non-VA care and results were not documented in the EHR; patients could not be contacted; and colonoscopies could not be performed due to patients' personal or medical reasons. During the OIG review, OIG staff communicated with facility managers about specific patients who had no EHR documentation of positive FIT follow-up, including completed colonoscopies. Facility managers provided the OIG with the documentation of the reasons for non-completion/follow-up or completion of the procedure.

Repeat of FIT Rather than Diagnostic Colonoscopy

Forty-two of the 1,168 patients (four percent) with a positive FIT underwent a repeat FIT rather than proceeding directly to a diagnostic colonoscopy. Documented reasons for these repeat FITs were patients and/or providers' request. VHA recommends that patients receive colonoscopy follow-up after a positive FIT done as part of a CRC screening program.⁸⁴

⁸³ VHA Directive 2007-004; VHA Directive 1015.

⁸⁴ VHA Directive 2007-004; VHA Directive 1015.

In summary, while most of the patients had a timely colonoscopy and did not have CRC or carcinoid, the OIG had concerns about the 15 patients who were diagnosed with CRC or carcinoid and had the longest delays in colonoscopies identified from the two groups of patients. Colonoscopy delays exposed these patients to a greater risk of developing CRC or developing CRC at a more advanced stage than patients who did not have delayed colonoscopies.

FIT Specimen Process Deficiencies

In spring 2016, patients returned FIT kit specimens to the facility's laboratory with labelling deficiencies, such as illegible names. The label deficiencies caused problems with the correct identification of patients' specimens and laboratory staff disposed of these specimens. Approximately 2–4 specimens per day could not be processed due to staff's inability to decipher information on the FIT kit label. Although facility leaders took action to improve the labelling process, facility staff were not well-versed in the new process. Clinic nurses documented distributing a kit to the patient in his/her EHR, but a process was not in place for facility-wide FIT specimen tracking and monitoring.

ICU Physician Coverage

The OIG substantiated that the facility ICU had inconsistent ICU intensivist and attending physician coverage in May 2016; however, resident physicians, hospitalists, and/or intensivists were available for ICU coverage as needed. Facility leaders implemented a plan that included ICU coverage by temporary physicians and hospitalists. If facility staff could not meet the needs of ICU patients, physicians arranged for the patients' transfers to a non-VA facility or diverted facility ED patients to a non-VA ED. In February 2017, the OIG received updated facility information verifying that the inconsistent physician coverage in the ICU was resolved; therefore, the OIG made no recommendations related to ICU physician coverage.

Recommendations 1–7

- 1.** The Veterans Integrated Service Network 9 Director ensures that clinical reviews are completed on the patients discussed in this report to determine whether delays adversely affected patients' clinical care, notifies patients of lapses in care as needed, and/or takes other action as appropriate.
- 2.** The James H. Quillen VA Medical Center Director improves and monitors mechanisms to track and recall patients who require surveillance colonoscopies.
- 3.** The James H. Quillen VA Medical Center Director improves and monitors mechanisms to track patients for whom a diagnostic colonoscopy after a positive fecal immunochemical test is indicated as required by Veterans Health Administration and James H. Quillen VA Medical Center policy.
- 4.** The James H. Quillen VA Medical Center Director improves efforts to ensure non-VA colonoscopy reports are available for viewing in patients' VA electronic health records.
- 5.** The James H. Quillen VA Medical Center Director ensures that processes are in place to monitor providers' compliance with Veterans Health Administration Colorectal Cancer Screening policy including the referral of the patient for a diagnostic colonoscopy after a positive fecal immunochemical test rather than a repeat fecal immunochemical test.
- 6.** The James H. Quillen VA Medical Center Director takes action to identify patients who submitted fecal immunochemical test kits that could not be processed and notifies these patients of a need to re-submit fecal immunochemical test specimens.
- 7.** The James H. Quillen VA Medical Center Director ensures that processes are strengthened to track and monitor the distribution of fecal immunochemical test kits to patients.

Appendix A: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: April 11, 2018

From: Director, VA MidSouth Healthcare Network (10N9)

Subj: Healthcare Inspection—Colorectal Cancer Screening, Timely Colonoscopies, and Physician Coverage in the Intensive Care Unit, James H. Quillen VA Medical Center, Mountain Home, Tennessee

To: Director, Dallas Office of Healthcare Inspections (54DA)
Director, Management Review Service (VHA 10E1D MRS Action)

1. I have reviewed and concur with the findings and recommendations in the OIG Report entitled, Healthcare Inspection—Colorectal Cancer Screening, Timely Colonoscopies, and Physician Coverage in the Intensive Care Unit, James H. Quillen VA Medical Center, Mountain Home, Tennessee.
2. Should you require additional information, please contact Quality Management Officer, VA MidSouth Healthcare Network, VISN 9, at (615) 695-2143

(Original signed by:)

Cynthia Breyfogle, FACHE
Network Director

Comments to OIG's Report

Recommendation 1

The Veterans Integrated Service Network 9 Director ensures that clinical reviews are completed on the patients discussed in this report to determine whether delays adversely affected patients' clinical care, notifies patients of lapses in care as needed, and/or takes other action as appropriate.

Concur.

Target date for completion: June 1, 2018

Director Comments

The Chief of Staff and Chief Quality Management and Improvement at James H. Quillen VAMC conducted a comprehensive evaluation of each of the 15 cases discussed in this report. They analyzed reasons for delays and identified areas of concerns and impact on patient care. Steps have been taken at numerous levels to improve timeliness of the colorectal cancer screening process. Centralized and organized surveillance, management and tracking systems have been implemented. Non-VA care staff have been integrated in the Gastrointestinal (GI) service to improve tracking of patients and completeness of medical record for the non-VA care colonoscopy patients. Basic distribution and labeling of the FIT kits was revised in conjunction with communication pathways for follow up with patients, nurse, or provider for any issues. These measures have been taken to avoid future delays in colorectal cancer screening. The Chief of Staff is personally contacting those patients noted in this report whose care were adversely impacted due to a delay to conduct an Institutional Disclosure and take action as indicated.

Appendix B: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: April 4, 2018

From: Director, James H. Quillen VA Medical Center (621/00)

Subj: Healthcare Inspection—Colorectal Cancer Screening, Timely Colonoscopies, and Physician Coverage in the Intensive Care Unit, James H. Quillen VA Medical Center, Mountain Home, Tennessee

To: Director, VA MidSouth Healthcare Network (10N9)

1. I have reviewed and concur with the findings and recommendations in the OIG Report entitled, Healthcare Inspection—Colorectal Cancer Screening, Timely Colonoscopies, and Physician Coverage in the Intensive Care Unit, James H. Quillen VA Medical Center, Mountain Home, Tennessee
2. Should you require additional information, please contact Chief Quality Management and Improvement, Mountain Home VA Healthcare System, at 423-979-3617.

(Original signed by:)

Dean B. Borsos, MHSA
Medical Center Director

Comments to OIG's Report

Recommendation 2

The James H. Quillen VA Medical Center Director improves and monitors mechanisms to track and recall patients who require surveillance colonoscopies.

Concur.

Target date for completion: March 30, 2018

Director Comments

An improved tracking mechanism was developed to include specific patients who require surveillance colonoscopies, target dates and compliance. A dedicated Registered Nurse (RN), provides oversight for maintaining the tracker and ensuring all surveillance colonoscopies are scheduled, completed and recall dates are obtained. A Nurse Practitioner Care Manger was hired to provide oversight for this process and all tracking and recall occurs through GI clinic staff.

Recommendation 3

The James H. Quillen VA Medical Center Director improves and monitors mechanisms to track patients for whom a diagnostic colonoscopy after a positive fecal immunochemical test is indicated as required by Veterans Health Administration and James H. Quillen VA Medical Center policy.

Concur.

Target date for completion: March 30, 2018

Director Comments

A dedicated individual generates daily reports of all positive Fecal Immunochemical Tests (FIT), and arranges patient contact to schedule timely diagnostic colonoscopies. Patients are followed via the tracker spreadsheet to ensure colonoscopies are scheduled, completed and recall dates are obtained. The evidence of compliance is being tracked and shared monthly with the Chief of Staff and Chief, Medicine Service.

Recommendation 4

The James H. Quillen VA Medical Center Director improves efforts to ensure non-VA colonoscopy reports are available for viewing in patients' VA electronic health records.

Concur.

Target date for completion: March 30, 2018

Director Comments

Non-VA Care Staff were also relocated to Gastrointestinal (GI) service to provide comprehensive follow up of non-VA colonoscopy reports. Patients are tracked through the Excel tracker and monitored weekly for colonoscopy reports. Regular follow up calls are placed to the community until final reports are obtained and placed into the patient's EHR. In addition, Tri-West portal status information is accepted by Non-VA Community Care staff. Most up to date reports and status changes can be obtained through this portal. If status information is unavailable through this site, staff make verbal or written contact with the outside provider, as explained, requesting updated information. The evidence of compliance is being monitored and reported to Chief of Staff and Chief, Medicine Service.

Community providers are aware that we need the patient's records from the initial visit/procedure and any recommendations for follow up (i.e. recall, surveillance, etc.).

Non-VA Colonoscopy providers are expected to send the patient's records within 14 days after the patient's appointment/procedure. If not received within 14 days, calls are made by the Claims Assistants or other personnel. If there are several patients' records required, a fax grouping the names is sent to the Non-VA Colonoscopy provider.

For patients sent to the community through Tri-West, it is expected Mountain Home VA Healthcare System will receive the records within 21 days of the patient's appointment/procedure. If not received within 21 days, calls are made by the Claims Assistants or other personnel. If there are several patients' records required, a fax grouping the names is sent to the Non-VA Colonoscopy provider.

Currently, the average time it is taking to obtain records following a patient's appointment/procedure in the community (Non-VA Care and Tri-West) is 14 to 30 days. Attempts continue until the records are received.

Recommendation 5

The James H. Quillen VA Medical Center Director ensures that processes are in place to monitor providers' compliance with Veterans Health Administration Colorectal Cancer Screening policy including the referral of the patient for a diagnostic colonoscopy after a positive fecal immunochemical test rather than a repeat fecal immunochemical test.

Concur.

Target date for completion: March 30, 2018

Director Comments

Practice changes were implemented so all positive fecal immunochemical tests are now managed by GI staff rather than the ordering provider. Dedicated GI staff contact each patient within

seven (7) days of a positive FIT. Patients are informed of the positive results with recommendations that a diagnostic colonoscopy be scheduled. No repeat FIT kits are offered or provided. GI schedule procedure notes are entered in the EHR initiating the colonoscopy if the patient agrees to screening. Patients that decline scheduling colonoscopy are encouraged to notify their primary care provider if they later decide to proceed with the endoscopy procedure. Patients unable to be reached by phone receive a mailed letter explaining the positive FIT results with a recommended colonoscopy procedure and a contact to reach. The evidence of compliance is being monitored and reported monthly to Chief, Medicine Service, and Chief of Staff.

Recommendation 6

The James H. Quillen VA Medical Center Director takes action to identify patients who submitted fecal immunochemical test kits that could not be processed and notifies these patients of a need to re-submit fecal immunochemical test specimens.

Concur.

Target date for completion: March 30, 2018

Director Comments

A Root Cause Analysis was completed to address FIT kits that cannot be processed. Procedure was changed to only have clinic RNs dispense FIT kits. Each nurse has a label maker on their desk and completes, prints and attaches a label to the cartridge during the patient education process. This labeling procedure also occurs when the FIT kit is mailed to the patient. Smaller labels were obtained to properly adhere to the FIT cartridges. Educational handouts were developed and distributed to staff with detailed education provided to ensure compliance. This procedure continues, and all FIT kits that cannot be processed are identified in the laboratory during accessioning and are tracked back to the provider and nurse for correction. The evidence of compliance is being monitored and reported to Chief, Quality Management and Improvement Service, Chief, Medicine Service, and Chief, Pathology and Laboratory. The actions taken on any case fall-outs will be included.

Recommendation 7

The James H. Quillen VA Medical Center Director ensures that processes are strengthened to track and monitor the distribution of fecal immunochemical test kits to patients.

Concur.

Target date for completion: March 30, 2018

Director Comments

FIT kit distribution is monitored via the Clinical Reminders. Documentation can be tracked and pulled on patients who have received FIT kits through the Clinical reminders. Nursing staff do not close the Clinical Reminders until the FIT results are noted in CPRS. In addition, positive FIT results are tracked by GI staff via reports generated in VISN Field Reporting through the Data Warehouse.

The facility has plans in place to implement the new VHA Colorectal Cancer screening Clinical Reminder to promote cancer screening. Prompts follow up after a positive FIT and prompts follow up after a colonoscopy, resetting the reminders to include reminders if future screening recommendations have not been documented. The evidence of compliance is being monitored and reported to Chief, Medicine Service, and Chief of Staff.

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OIG Contact and Staff Acknowledgments

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