Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 15-05328-373

Healthcare Inspection

Colorectal Cancer Screening Practices
Charlie Norwood VA Medical Center
Augusta, Georgia

September 22, 2016

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review to assess the merit of allegations involving colorectal cancer (CRC) screening practices at the Charlie Norwood VA Medical Center (facility) in Augusta, GA. A confidential complaint alleged that:

- Patients over the age of 50 were only being scheduled for preventative [screening] colonoscopies if blood was detected in their stools.
- Patients had been diagnosed with colon cancer because they had not received appropriate preventative [screening] colonoscopies.

We substantiated that patients over the age of 50 were only being scheduled for preventative [screening] colonoscopies if blood was detected in their stools; however, we did not substantiate the implied inappropriateness of the process for patients with average risk for developing CRC. Veterans Health Administration (VHA) and the Centers for Disease Control and Prevention (CDC) have identified several effective CRC screening methods, including a fecal occult blood test, for patients at average risk. However, we found that facility staff did not fully comply with VHA guidelines on shared decision-making for patients who preferred screening colonoscopies rather than fecal occult blood tests.

Facility managers have since revised the screening colonoscopy consult process. However, facility providers did not have a common understanding about the current local process for requesting screening colonoscopies for average risk patients.

We did not substantiate the allegation that patients have been diagnosed with CRC because they did not receive appropriate preventative [screening] colonoscopies. We found that, in general, the patients included in our sample received fecal occult blood tests in accordance with VHA and Veterans Integrated Service Network 7 guidance and CDC guidelines.

We recommended that the Facility Director: (1) ensure compliance with shared decision-making and patient preference requirements, and (2) define and communicate current local processes for obtaining screening colonoscopies for average risk patients.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided acceptable action plans. (See Appendixes A and B, pages 7–9 for the Directors' comments.) We consider the recommendations closed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review to assess the merit of allegations involving colorectal cancer (CRC) screening practices at the Charlie Norwood VA Medical Center (facility) in Augusta, GA.

Background

The facility is a two-division medical center in Veterans Integrated Service Network (VISN) 7 that provides tertiary care in medicine, surgery, neurology, psychiatry, rehabilitation medicine, and spinal cord injury.

CRC occurs in the colon or rectum[1] and is the second leading cause of cancer deaths for men and women in the United States.[2] The risk for developing CRC increases with age with greater than 90 percent of cases occurring in individuals who are 50 years of age or older. Other risk factors include inflammatory bowel disease, Crohn's disease, ulcerative colitis, a personal or family history of CRC or colorectal polyps (abnormal growths), and genetic syndromes such as familial adenomatous polyposis or hereditary non-polyposis CRC (Lynch syndrome).[3] In almost all cases, CRC develops from pre-cancerous polyps in the colon or rectum. Screening tests can detect polyps and/or bleeding from polyps, so that they may be removed before they develop into cancer.[4]

Veterans Health Administration (VHA) policy is to recommend CRC screening for average risk[5] individuals and to assure that positive screening tests are followed up with appropriate evaluation. VHA acknowledges that multiple methods of CRC screening with similar efficacies are available and acceptable. For individuals at average risk for CRC, VHA recommends using one of the following screening methods for adults age 50–75:

- Fecal Occult Blood Test (FOBT) is an annual exam. The two types of FOBTs are:
  - Guaiac-based FOBT (gFOBT), which uses chemical guaiac to detect blood that is not visible in a stool sample.

[1] The colon is also called the large intestine or large bowel. The passageway that connects the colon to the anus is called the rectum. http://www.cdc.gov/cancer/colorectal/basic_info/what-is-colorectal-cancer.htm, accessed June 8, 2016.
[2] http://www.cdc.gov/vitalsigns/CancerScreening/ColorectalCancer/index.html, accessed June 8, 2016.
[3] http://www.cdc.gov/cancer/colorectal/basic_info/risk_factors.htm, accessed June 8, 2016.
[4] http://www.cdc.gov/cancer/colorectal/basic_info/screening/index.htm, accessed June 8, 2016
[5] Average risk patients are between the age of 50–75 with neither a family history of CRC nor other risk factors or symptoms that warrant surveillance or diagnostic colonoscopy. VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014.

  - Fecal Immunochemical Test (FIT), which uses antibodies to find blood in a stool sample.[6]

- Flexible sigmoidoscopy examination every 5 years with or without mid-interval FOBT, which allows physicians to visually inspect the interior walls of the rectum and the lower part of the colon using a thin, flexible, lighted tube called a sigmoidoscope.
- Colonoscopy examination every 10 years, which allows physicians to visually inspect the interior walls of the rectum and the entire colon using a thin, flexible, lighted tube called a colonoscope. Samples of tissue or cells may be collected for closer examination, and most polyps may be removed.

For adults age 76 through 85, VHA recommends offering CRC screening only if other considerations support providing screening to the individual patient. For adults older than 85 years of age, VHA recommends against screening for CRC. Additionally, VHA recommends that individuals with certain family histories should have a colonoscopy at an earlier age.

Timeline of Events

In December 2007, VISN 7 issued the *CRC Screening Policy Memorandum,* which stated that colonoscopy was to be reserved for patients at high risk for CRC, patients with a positive FOBT screening, and patients with physical disabilities that would prevent them from completing FOBT. Routine screening for other patients would be accomplished by FOBT.

In August 2012, facility leaders identified a backlog of screening, surveillance, and diagnostic colonoscopies;[7] screening colonoscopies accounted for approximately 60 percent of the backlog. At that time, the facility's in-house endoscopy suite was primarily performing surveillance and diagnostic colonoscopies.

In October 2012, the facility's former Deputy Chief of Staff sent an email instruction to discontinue the use of screening colonoscopy consults and to "turn off" the screening colonoscopy option within the electronic health record consult package. The plan was to develop a modified consult "in the near future"; however, facility managers did not implement the modified consult until April 2014, approximately 18 months later. Because of this action, the Primary Care and Gastroenterology (GI) Services established an unwritten agreement that primary care providers (PCPs) would contact the GI Service directly if a patient requested a screening colonoscopy.

[6] VHA Directive 2007-004, *Colorectal Cancer Screening*, January 12, 2007, was in effect until late 2014. This Directive did not specifically reference FIT testing but did include FOBT, sigmoidoscopy, and colonoscopy as acceptable screening methods. The current VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014, specifically discusses FIT as an acceptable screening method.

[7] Facility managers conducted systematic reviews and by December 30, 2012, had case managed and ensured that all patient care needs were resolved. Facility managers defined the resolution of patient care needs as completed, care refused, care provided in the community, or determined that care was no longer required.

During this timeframe, PCPs were also able to order screening colonoscopies when addressing clinical reminders associated with the OncWatch set.[8]

In April 2013, VISN 7 rescinded the December 2007 memorandum and issued the VISN 7 Clinical Preventative Services Policy, which instructed VISN 7 facility managers to "design and maintain Clinical Preventative policies and Clinical Reminders for Clinical Preventative Services that are aligned with VHA regulations and guidance…"

Allegations

On May 7, 2015, OIG received a confidential complaint alleging that:

- Patients over the age of 50 were only being scheduled for preventative [screening] colonoscopies if blood was detected in their stools.
- Patients had been diagnosed with colon cancer because they had not received appropriate preventative [screening] colonoscopies.

Scope and Methodology

We conducted our review from September 17, 2015, through February 3, 2016. The scope included CRC screening practices for the patients included in our sample.

We interviewed the complainant, the facility Director, Chief of Staff, Chief of GI Service, FOBT Coordinator, Non-VA Care Coordination Nurse Manager, Chief of Ambulatory Medicine, Chair of the Consult Management Committee, PCPs, a GI Service provider, and other staff knowledgeable about the issues.

We reviewed relevant VHA and facility policies and procedures, Consult Management Committee meeting minutes, Clinical Executive Board meeting minutes, patient advocate reports, GI consult data for the facility and Non-VA Care, FOBT data for fiscal years 2014 and 2015, and staffing levels for GI Service. We also reviewed the electronic health records of the 46 patients whose names were provided to us as examples to support the allegations.

In the absence of current VA/VHA policy, we considered previous guidance to be in effect until superseded by an updated or re-certified Directive, Handbook, or other policy document on the same or similar issue(s).

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts

[8] Clinical reminders are a decision support tool to furnish clinicians with timely information about preventive health maintenance schedules of their patients. The software looks for specified criteria such as diagnoses, procedures, or demographic variables (for example, age or gender) and then prompts the user to take an action through a reminder dialog box. The clinical reminders that are part of the OncWatch set specifically look for criteria relating to CRC screening. The OncWatch set is a locally created reminder.

showed the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

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

Inspection Results

Issue 1: Patients over the age of 50 were only being scheduled for preventative [screening] colonoscopies if blood was detected in their stools.

We substantiated that patients over the age of 50 were only being scheduled for preventative [screening] colonoscopies if blood was detected in their stools, but we did not substantiate the implied inappropriateness of this process for patients with average risk for developing CRC. VHA and the Centers for Disease Control and Prevention (CDC) have identified several effective CRC screening methods, including FOBT, for patients at average risk for developing CRC. As such, the facility's past practice of promoting FOBT for average risk patient populations did not diverge from VHA and VISN guidance or clinical practice guidelines. However, the VISN's 2007 instructions and the facility's actions did not fully comply with VHA guidelines on shared decision-making.

VHA's Directives on CRC screening (both Directive 2007-004 and its successor, Directive 1015) require(d) that average risk patients be informed about the different options available for CRC screening, including the option of no screening, and that selection of a particular CRC screening method should be the result of a shared decision-making process between the patient and the PCP.

While reviewing the electronic health records of the 46 patients referred to us, we identified 14 instances where it appeared that both the PCP and the patient agreed upon the choice of screening colonoscopy as the preferred method of CRC screening. However, all 14 screening colonoscopy consults were discontinued with a statement notifying PCPs to "…assure that FOBT/FIT testing is performed annually on all appropriate patients." Twelve of the 14 consults were discontinued between October 2012 and April 2014 when the facility was promoting FOBT for average risk patients, essentially to the exclusion of other CRC screening options.

Facility managers have since made changes to the screening colonoscopy consult template to allow PCPs to select asymptomatic, average risk as an indication for the procedure. The various processes for requesting screening colonoscopies have evolved over time, and facility providers did not have a common understanding about the current process to request screening colonoscopies for average risk patients.

Issue 2: Patients have been diagnosed with colon cancer because they did not receive appropriate preventative [screening] colonoscopies.

We did not substantiate the allegation. The confidential complainant provided the names of 46 patients in support of the claim. We conducted extensive reviews of these cases but did not identify patients diagnosed with colon cancer because they did not

receive a screening[9] colonoscopy.[10,11] We found that patients generally received, or were offered, FOBT in accordance with VHA, VISN, and CDC guidance.

Conclusions

We substantiated the allegation that patients over the age of 50 were only being scheduled for preventative [screening] colonoscopies if blood was detected in their stools, but we did not substantiate the implied inappropriateness of this process for patients with average risk for developing CRC. VHA and CDC have identified several effective CRC screening methods, including FOBT, for patients at average risk. However, we found that facility staff did not fully comply with VHA guidelines on shared decision-making for patients who preferred screening colonoscopies rather than FOBT.

Facility managers have since revised the screening colonoscopy consult process. However, facility providers did not have a common understanding about the process to request screening colonoscopies for average risk patients.

We did not substantiate the allegation that patients have been diagnosed with CRC because they did not receive appropriate preventative [screening] colonoscopies. We found that, in general, the patients included in our sample received FOBT in accordance with VHA and VISN 7 guidance and CDC guidelines.

Recommendations

1. We recommended that the Facility Director ensure that the selection of a colorectal cancer screening method is based on a shared decision-making process between a patient and his/her provider and that the patient's preference is honored.

2. We recommended that the Facility Director define and communicate current local processes for obtaining screening colonoscopies.

[9] A screening test is used to look for a disease when a person does not have symptoms. When a person has symptoms, diagnostic tests are used to find out the cause of the symptoms. CDC website, http://www.cdc.gov/cancer/colorectal/basic_info/screening/index.htm, accessed March 23, 2016.

[10] We identified two patients who were at *higher* than average risk for developing CRC. In both cases, a screening colonoscopy was appropriately ordered but was subsequently discontinued and annotated with "…assure that FOBT/FIT testing is performed annually on all appropriate patients." We referred the first case to the facility for review and confirmed that the patient has now received his screening colonoscopy and continues to be followed by the facility. In the second case, the patient's PCP entered a subsequent screening colonoscopy order, which was completed.

[11] We identified a patient from the list of names provided by to us whose PCP failed to order a diagnostic colonoscopy after the patient reported occasional bloody stools. The patient was later diagnosed with CRC. We referred this case to the facility for appropriate follow-up and actions.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: April 11, 2016

From: Director, VA Southeast Network (10N7)

Subj: Healthcare Inspection—Colorectal Cancer Screening Practices, Charlie Norwood VA Medical Center, Augusta, Georgia

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

1. In reference to Healthcare Inspection – Colorectal Cancer Screening Practices, Charlie Norwood VA Medical Center, Augusta, Georgia, VISN 7 would like to submit the attached response to recommendations 1-2.

2. If you have any questions or concerns, please contact Dr. Oladipo Kukoyi, Chief of Staff at 706-733-0188, extension 2145.

Director, VA Southeast Network

Appendix B

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: April 7, 2016

From: Director, Charlie Norwood VAMC, Augusta, GA (509/00)

Subj: Healthcare Inspection—Colorectal Cancer Screening Practices, Charlie Norwood VA Medical Center, Augusta, Georgia

To: Director, VA Southeast Network (10N7)

1. Please find the response to the Office of the Inspector General Healthcare Inspection, entitled Colorectal Cancer Screening Practices Charlie Norwood VA Medical Center, August, Georgia.

2. If you have any questions or concerns, please contact Dr. Oladipo Kukoyi, Chief of Staff at 706-733-0188, extension 2145.

Maria R. Andrews

Maria R. Andrews, MS, FACHE
Director, Charlie Norwood VAMC

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the Facility Director ensure that the selection of a colorectal cancer screening method is based on a shared decision-making process between a patient and his/her provider and that the patient's preference is honored.

Concur

Target date for completion: Closed, based on additional information provided by the facility on September 13, 2016

Facility response: The Primary Care providers were re-educated by the Deputy Chief of Staff on December 9, 2015, on the benefits of colon cancer screening and the options for screening for colon cancer as recommended by the American Society for Gastrointestinal Endoscopy (ASGE). Shared decision-making processes between the patient and his/her provider were emphasized. The facility is currently working on a documentation template that will track this education and performance will be monitored through medical executive committee.

Recommendation 2. We recommended that the Facility Director define and communicate current local processes for obtaining screening colonoscopies.

Concur

Target date for completion: Closed, based on additional information provided by the facility on September 13, 2016

Facility response: In January, 2016, the Primary Care providers were reeducated by the ACOS PC on the process for ordering and follow-up of colon cancer screening tests. At the April 21, 2016, Primary Care General Staff Meeting the Chief, GI will review the local process for colon cancer screening including the processes for obtaining screening colonoscopies and patient follow-up. New providers will be given this information in orientation. A revised colon cancer screening consult template was implemented in December, 2015 that streamlines the process for ordering screening colonoscopies.

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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