Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 15-00018-349

Healthcare Inspection

Lack of Follow-Up Care for Positive Colorectal Cancer Screening New Mexico VA Health Care System Albuquerque, New Mexico

September 27, 2016

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by an anonymous complainant concerning the lack of follow-up care for patients with positive colorectal cancer screenings at the New Mexico VA Health Care System (facility), Albuquerque, NM. Specifically, the complainant alleged that laboratory staff had a list of 300 patients who tested positive for the presence of fecal occult blood, but no follow-up had been done.

We did not substantiate that laboratory staff had a list of 300 patients who had tested positive for fecal occult blood, but no follow-up had been done. We determined that laboratory personnel do not keep lists of patients with positive fecal occult results. However, we found that laboratory staff flagged positive results in patients' electronic health records, which generated a "view alert" to providers, and that providers did not consistently notify patients of positive fecal immunochemical tests (used to determine presence of occult blood) in fiscal years (FYs) 2013 and 2014. As a result, some patients did not receive timely follow-up care. Although we recognize that providers may receive hundreds of "view alerts," it is the providers' responsibility to follow up on tests ordered to ensure positive results are communicated to patients and appropriate and timely follow-up care initiated.

We identified nine patients diagnosed with colorectal cancer who experienced delays and, in some instances, significant delays that may have affected the patients' clinical outcomes. Such delays placed patients at unnecessary risk for adverse outcomes.

In addition, we determined that during FY 2013 and FY 2014, the facility did not have a process in place to monitor provider compliance with colorectal cancer screening. In 2012, facility leaders had assigned a registered nurse to follow up on positive fecal immunochemical tests and report to the Chief of Staff monthly. However, the employee transferred from the facility, and the position had been vacant for over 2 years. We found that facility leaders did not institute another process for monitoring provider compliance with colorectal cancer screening and reporting to ensure that patients with a positive fecal immunochemical tests received timely notification of results and appropriate follow-up care.

We recommended that the Facility Director ensure that:

- Patients who experienced delays in notifications of positive fecal immunochemical tests are assessed to determine if appropriate follow-up care was rendered and whether the delays adversely affected the patients' clinical outcomes.

- The Office of Chief Counsel (formerly known as Regional Counsel) is consulted regarding the care of the four patients described in this report and any additional patients identified in further review who may have been adversely affected, to determine the appropriate action to take, if any.

- Providers communicate positive colorectal cancer screening test results to patients and document notifications in electronic health records according to Veterans Health Administration test notification policy.

- Processes are in place to monitor providers' compliance with Veterans Health Administration colorectal cancer screening policy.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the findings and recommendations and provided acceptable action plans. (See Appendixes A and B, pages 9–12 for the Directors' comments.) We consider recommendations 1 and 2 closed. We will follow up on the planned actions for recommendations 3 and 4 until they are completed.

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 an inspection to assess the merit of allegations made by an anonymous complainant concerning the lack of follow-up care for patients with positive colorectal cancer (CRC) screening at the New Mexico VA Health Care System (facility), Albuquerque, NM.

Background

Facility Profile. The facility is a 310-bed tertiary care hospital that provides comprehensive health care services in medicine, surgery, rehabilitation, mental health, and spinal cord injury. It serves patients in New Mexico, southwest Colorado, and Nevada through its main medical facility in Albuquerque, NM, and at 13 community based outpatient clinics. The facility is affiliated with the University of New Mexico in Albuquerque, NM, and is part of Veterans Integrated Service Network 18.

Clinical Overview. CRC is the third most common cancer in men and women and the second leading cause of cancer death in the United States. CRC screening detects early-stage cancer and adenomatous polyps[1] and has also been proven to reduce CRC mortality.[2]

According to current Veterans Health Administration (VHA) policy, the provider who orders the screening tests such as the fecal occult blood test[3] or fecal immunochemical test (FIT)[4] is responsible for informing the patient of the results and, if the test is positive, initiating follow-up or documenting that no follow-up is indicated.[5] During fiscal years (FYs) 2013 and 2014, the time of the events discussed in this report, VHA required VA facility staff to communicate all test results to patients no later than 14 days from the date on which the results were available to the ordering practitioner.[6] In October 2015, VHA published new guidance that requires communication of test results

[1] Adenomatous polyps are abnormal growths rising from the lining of the large intestine (colon) that protrude into the intestinal canal. Http://www.ameripath.com/adenomatous-polyps, accessed April 20, 2016.
[2] VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014. The previous version of this Directive that was in effect during the time frame of the events discussed in this report, VHA Directive 2007-004, Colorectal Cancer Screening, January 12, 2007 (corrected copy) did not delineate provider notification responsibilities as clearly as the current version.
[3] A fecal occult blood test is a laboratory test used to check stool samples for hidden (occult) blood. Http://www.mayoclinic.org/tests-procedures/fecal-occult-blood-test/basics/definition, accessed April 20, 2016.
[4] A FIT is an improved fecal occult blood test with higher sensitivity and specificity when compared to fecal occult blood test. FIT has accuracy rates near those of a colonoscopy. Http://www.ncbi.nlm.nih.gov/pmc/articles, accessed April 20, 2016.
[5] VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014.
[6] VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009. This VHA Directive was current during the time frame of the events discussed in this report; it expired March 31, 2014 and was rescinded and replaced by VHA Directive 1088 in October 2015.

to patients within 7 days for results requiring action and 14 days for those that do not require any action.[7]

In addition, VHA requires VA providers to follow up on any positive screening tests with a full colonoscopy, if not contraindicated, unless the primary screening method is a colonoscopy.[8] Until December 2014, VHA required that diagnostic colonoscopies be performed within 60 calendar days of the positive screening test, if indicated.[9]

Prior OHI Review. In 2012, OIG conducted an inspection of the facility and determined that positive CRC screening patient notification and timely follow-up care needed improvement. (See *Combined Assessment Program Review of the New Mexico VA Health Care System, Albuquerque, New Mexico,* Report No. 12-00881-203, June 19, 2012.) We recommended that processes be strengthened to ensure that patients are notified of positive CRC screening results, clinicians document notification and develop follow-up plans, and patients receive diagnostic testing and are notified of the results within the required timeframe. In 2013, the facility provided the OIG with documentation of processes that had been implemented to strengthen and improve CRC screening. The OIG reviewed the implemented processes and closed all four recommendations.

Allegation. In May 2014, the OIG's Hotline Division received an allegation concerning follow-up care for patients with positive CRC screening. Specifically, the complainant alleged that laboratory staff had a list of 300 patients who tested positive for the presence of fecal occult blood, but no follow up had been done.

At our request, the facility provided a response to the allegation in November 2014. After reviewing the response, we decided to conduct an inspection to evaluate the facility's compliance with VHA policy for CRC screening and follow-up care.

Scope and Methodology

We conducted this review from January 7, 2015 through April 2016. We made a site visit February 18–19, 2015. We interviewed the Acting Chief of Staff, the Acting Associate Chief of Staff Ambulatory Care, the Associate Chief Nurse Ambulatory Care, the Chief of Pathology and Laboratory, the Chief of Performance Improvement, the Registered Nurse (RN) Health Promotion Disease Prevention Coordinator, a Patient Advocate, a Health Information Specialist, a Nurse Informatics Specialist, and a laboratory manager. We reviewed the facility's tracking data for the 879 patients who facility staff determined had a positive FIT from January 2013 through November 2014.

[7] VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.
[8] VHA Directive 1015, *Colorectal Cancer Screening,* December 30, 2014. This requirement was also present in the previous version of the Directive that was in effect during the time frame of the events discussed in this report, VHA Directive 2007-004, *Colorectal Cancer Screening*, January 12, 2007 (corrected copy).
[9] VHA Directive 2007-004, *Colorectal Cancer Screening*, January 12, 2007 (corrected copy). This Directive was rescinded and replaced by VHA Directive 1015 in December 2014.

We reviewed 133 of the 879 electronic health records (EHRs) of patients for whom we could not clearly identify the status of notifications or follow-up care. In addition, out of the 879 patients, we identified and reviewed 24 EHRs of patients who were diagnosed with CRC.

We also reviewed current and previous VHA and facility policies related to CRC screening and notification of test results and other pertinent documents.

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 show 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: Follow-Up Care for Patients with Positive FITs

While we did not substantiate that laboratory staff had a list of 300 patients who tested positive for fecal occult blood, we substantiated that 879 patients had positive FITs from January 2013 through November 2014. We determined that the facility conducted a review of the 879 patients but did not notify all patients of positive FIT results and the need for follow-up care.

Laboratory List of Positive FITs. We interviewed staff in the Pathology and Laboratory Department who reported that they did not keep a list of patients' laboratory test results. Staff told us that FIT results were uploaded into the Veterans Health Information Systems and Technology Architecture[10] laboratory package in each patient's EHR. Laboratory personnel flagged all positive FITs as abnormal in the EHRs, which automatically triggered "view alerts"[11] to providers.

Facility List of Positive FITs. We found patients who had positive FITs and were not notified or provided follow-up care. In response to the OIG inquiry for this hotline, the facility's Information Technology Service generated a list of 879 patients who had positive FITs from January 2013 through November 2014. The data was pulled using the following criteria: (1) positive FIT testing date, (2) positive FIT letter, (3) gastroenterology (GI) or Non-VA Care Coordination[12] consult, (4) colonoscopy procedure, and (5) pathology results.

Facility staff reviewed the EHR of each patient on the list to screen for notification of a positive FIT and evidence of follow-up by the provider prior to our site visit. The RN Health Promotion Disease Prevention Coordinator in Ambulatory Care Service told us that GI Service staff completed a review of 261 EHRs, and Ambulatory Care Service staff completed a review of 206. The remaining 412 patients had follow-up colonoscopies completed. The Chief of Performance Improvement told us that patients who had not been previously notified were called between October and November 2014, during the facility's EHR review. The provider or RN completing the review documented the results of the telephone contacts or attempts made to contact the patients in the EHRs (for example, letter sent, patient refused colonoscopy, colonoscopy contraindicated, or patient moved out of state). Facility leaders provided us with the query results as well as documentation of the results from the completed EHR reviews.

[10] The Veterans Health Information Systems and Technology Architecture is an enterprise-wide information system built around an electronic health record used throughout the VA medical system.
[11] A view alert is a way to communicate abnormal diagnostic test results using the Computerized Patient Record System.
[12] Non-VA Care Coordination is healthcare service provided to the patient outside of the VA for emergent and non-emergent medical care when care cannot be provided at the facility.

We reviewed the data for all 879 patients and determined that providers who did notify patients of positive FITs did not consistently do so in a timely manner. Patients who received notification letters of positive FITs did not always receive the letters within 14 calendar days as required by the VHA Directive that was current at the time.[13]

Of the 467 patients whose EHRs were reviewed by the facility staff, we could not clearly identify the status of notifications or follow-up care for 133. We reviewed the 133 EHRs and determined that 25 EHRs did not contain documentation of completed colonoscopies, and 67 EHRs contained documentation that colonoscopies were completed, but 52 of the colonoscopies were not completed within 60 calendar days as required by VHA Directive that was current at the time.[14] VHA revised the CRC screening Directive in December 2014, and the current Directive does not specify a timeframe for completion of a colonoscopy after a positive FIT.[15] We found documentation of follow-up care for the remaining 41 patients (for example, patient had moved, unable to contact patient, patient refused colonoscopy, or high risk patient); however, the follow-up was not timely according to the VHA Directive that was current at the time follow-up should have occurred.

Issue 2. Patients Diagnosed with CRC

We determined that 24 of the 879 patients were diagnosed with CRC. We reviewed the EHRs of the 24 patients to determine if the facility provided timely notification of a positive FIT and timely follow-up care. We found 15 of the 24 patients reviewed had no delays in notification or follow-up care. The remaining nine patients had delays in notification of a positive FIT and/or completion of a colonoscopy procedure.[16] In five of the nine cases, the patients experienced delays that did not impact on the patients' clinical outcomes. The following four of the nine cases are patients who experienced delays that placed them at risk for adverse outcomes.

Case 1 — This patient was in his 60s who was found to be FIT positive in 2014. The patient was notified of his results approximately 3 months later. A colonoscopy was scheduled and completed; he was found to have a rectal mass. Pathology testing confirmed the mass was cancer. The patient underwent surgery to remove the mass in 2015. As of July 2016, the patient continued to have follow up and surveillance at the facility.

Case 2 — This patient was in his 70s and was found to be FIT positive in 2014. The EHR contains a notification of results letter addressed to the patient. A facility staff member contacted the patient in early 2015, 8 months after the positive FIT, to offer a

[13] VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009. This VHA Directive expired March 31, 2014 and was replaced by VHA Directive 1088 in October 2015. During FYs 2013 and 2014, the time of the events discussed in this report, VHA required VA facility staff to communicate all test results to patients no later than 14 days from the date on which the results were available to the ordering practitioner.
[14] VHA Directive 2007-004, *Colorectal Cancer Screening*, January 12, 2007 (corrected copy).
[15] VHA Directive 1015 (Transmittal Sheet), *Colorectal Cancer Screening*, December 30, 2014.
[16] VHA Directive 2009-019.

colonoscopy, and the patient accepted. A colonoscopy was performed and a large rectal mass was found. Pathology testing confirmed the mass was cancer. After receiving chemotherapy and radiation therapy, the patient underwent surgery to remove the mass. During the surgery, he was found to have unresectable metastatic disease and died a few months later.[17]

Case 3 — This patient was in his 50s and was found to be FIT positive in 2014. He was notified of the results 9 months later. A colonoscopy was performed and a large sigmoid mass was found. Pathology testing confirmed the mass was cancer. The patient underwent surgery to remove the mass followed by chemotherapy. A positron emission tomography[18] and a computed tomography[19] scan showed no evidence of metastatic disease. As of July 2016, the patient continued to have follow-up and surveillance at the facility.

Case 4 — This patient was in his 60s and was found to be positive FIT in 2014. The patient's EHR does not include documentation that he was notified of the results. Approximately 9 months later, the patient presented to his provider with complaints of rectal pain. General Surgery service was consulted, and the patient was seen on the same day. The patient was found to have a large anal/rectal mass. Pathologic findings from the biopsy revealed cancer. The patient received chemotherapy and radiation and died a few months later.

Issue 3. Monitoring and Reporting Compliance with VHA policy

We substantiated that although the facility had instituted a process in 2012 to ensure that patients with positive FITs received timely notifications of results and appropriate follow-up care, facility leaders failed to continue the process after the RN Population Health Coordinator left employment at the facility.

As previously discussed, laboratory personnel flagged all positive FITs as abnormal in the patients' EHRs, which automatically triggered "view alerts" to the providers who ordered the tests. When a provider acknowledged a "view alert," he/she had the option to check a "standard letter" box in the patient's EHR to generate a GI consult and send a letter to the ambulatory care clinic printer. The automated letter was formatted to show the patient's name, address, and an explanation of the positive FIT process. A secretary in the ambulatory care clinic would retrieve letters from the printer daily to mail to each patient.

A manager told us that providers receive hundreds of "view alerts" daily, and once the alert is viewed, the "view alert" disappears from the computer screen. If the provider

[17] Metastatic disease (or cancer) is a cancer that has spread from the part of the body where it started (the primary site) to other parts of the body.
[18] A positron emission tomography scan demonstrates how organs and tissues are functioning at a very early stage in a disease, often before structural changes take place.
[19] A computed tomography scan uses x-rays to create a three-dimensional picture of the inside of the body. It shows anything abnormal, including tumors.

does not check the "standard letter" box in the patient's EHR to generate a consult or a notification letter at the time he/she clears the view alert, the provider is not reminded and may fail to generate a notification letter when reviewing laboratory results in the EHR.

In response to the recommendations made in the OIG report, *Combined Assessment Program Review of the New Mexico VA Health Care System, Albuquerque, New Mexico,* (Report No. 12-00881-203, June 19, 2012), the facility's Information Technology Service developed a system to track patients with positive FITs. At the same time, an RN was assigned as the Population Health Coordinator and became responsible for monitoring patient notification of positive FITs and timely follow-up care and reporting this information to the Chief of Staff monthly. We found that the RN Population Health Coordinator position had been vacant since the end of 2012. Without a person assigned to this responsibility, patient notification and follow-up care reverted to the Patient Aligned Care Teams. However, monthly monitoring and reporting to the Chief of Staff did not occur.

Conclusions

We did not substantiate that laboratory staff had a list of 300 patients who had tested positive for fecal occult blood, but no follow up had been done. We determined that laboratory personnel do not keep lists of patients with positive fecal occult results. However, we found that laboratory staff flagged positive results in patients' EHRs, which generated a "view alert" to providers, and that providers did not consistently notify patients of positive FITs (used to determine presence of occult blood) in FYs 2013 and 2014.

We determined that 879 patients had positive FITs from January 2013 through November 2014. Facility staff conducted a review of the 879 patients but did not notify all patients of positive FIT results and the need for follow-up care. We identified and reviewed 133 EHRs of patients who may not have received appropriate notification and determined that 25 EHRs did not contain documentation of completed colonoscopies, and 67 EHRs contained documentation that colonoscopies were completed, but 52 of the colonoscopies were not completed within 60 calendar days as required by the VHA Directive that was current at the time.[20]

We identified nine patients diagnosed with colorectal cancer who experienced delays and, in some instances, significant delays that may have affected the patients' clinical outcomes. Such delays placed patients at unnecessary risk for adverse outcomes.

Although we recognized that providers may receive hundreds of "view alerts," it is each provider's responsibility to follow up on results of tests they order to ensure patients are notified of positive FITs and to initiate appropriate and timely follow-up care.

[20] VHA Directive 2007-004, *Colorectal Cancer Screening,* January 12, 2007 (corrected copy).

We substantiated that the facility did not have a process in place to monitor provider compliance with CRC screening after the RN responsible for monitoring compliance left employment in December 2012. Facility leaders did not institute another process to ensure that patients with a positive FIT received timely notification of results and appropriate follow-up care.

Recommendations

Recommendation 1. We recommended that the Facility Director ensure that all patients who experienced delays in notifications of positive fecal immunochemical tests are assessed to determine if appropriate follow-up care was rendered and whether the delays adversely affected the patients' clinical outcomes.

Recommendation 2. We recommended that the Facility Director confer with the Office of Chief Counsel (formerly known as Regional Counsel) regarding the care of the four patients described in this report and any additional patients identified in further review who may have been adversely affected, to determine the appropriate action to take, if any.

Recommendation 3. We recommended that the Facility Director ensure that providers communicate positive colorectal cancer screening results to patients and document notifications in electronic health records according to Veterans Health Administration test notification policy.

Recommendation 4. We recommended that the Facility Director ensure that processes are in place to monitor providers' compliance with Veterans Health Administration colorectal cancer screening policy.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: May 20, 2016

From: Director, VA Southwest Health Care Network (10N18)

Subj: Healthcare Inspection—Lack of Follow-Up Care for Positive Colorectal Cancer Screening, New Mexico VA Healthcare System, Albuquerque, New Mexico

To: Director, San Diego Office of Healthcare Inspections (54SD)
Director, Management Review Service (VHA 10E1D MRS Action)

1. I have reviewed and concur with the findings and recommendations in the draft OIG report entitled, "Healthcare Inspection—Lack of Follow-Up Care for Positive Colorectal Cancer Screening, New Mexico VA Healthcare System, Albuquerque, New Mexico."

2. If you have any questions or concerns, please contact Terri Elsholz, VISN 22 Deputy Quality Management Officer, at 480-397-278.

Marie L. Weldon, FACHE
Network Director

Appendix B

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: May 13, 2016

From: Director, New Mexico VA Healthcare System (501/00)

Subj: Healthcare Inspection—Lack of Follow-Up Care for Positive Colorectal Cancer Screening, New Mexico VA Healthcare System, Albuquerque, New Mexico

To: Director, VA Southwest Health Care Network (10N18)

1. In response to your Memo dated May 5, 2016, the facility concurs with the four recommendations.

2. Please find attached corrective action plan with target dates.

3. If you have any questions or require additional information, please contact Carol Moore, Chief, Performance Improvement, at 505-265-1711 (extension 3696).

Andrew M. Welch, MHA, FACHE
Director

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 all patients who experienced delays in notifications of positive fecal immunochemical tests are assessed to determine if appropriate follow-up care was rendered and whether the delays adversely affected the patients' clinical outcomes.

Concur

Target date for completion: Completed

Facility response: The facility has reviewed patients with positive fecal immunochemical tests (FIT) to ensure patients since 2013 have received appropriate follow-up care, to identify any delays and if there was a delay, determine if the delay adversely affected the patient's clinical outcome.

Recommendation 2. We recommended that the Facility Director confer with the Office of Chief Counsel (formerly known as Regional Counsel) regarding the care of the four patients described in this report and any additional patients identified in further review who may have been adversely affected, to determine the appropriate action to take, if any.

Concur

Target date for completion: Completed

Facility response: The facility consulted with internal Risk Management and the Office of Chief Counsel/Office General Counsel to determine appropriate action to take regarding the care of the four patients described in the report as well as any additional patients who experienced a delay in follow-up and whose clinical outcome may have been adversely affected.

Recommendation 3. We recommended that the Facility Director ensure that providers communicate positive colorectal cancer screening results to patients and document notifications in electronic health records according to Veterans Health Administration test notification policy.

Concur

Target date for completion: December 31, 2016

Facility response: The facility will ensure that provider communication of all positive fecal immunochemical tests (FIT) is done using the standard patient notification letter

that is captured in the electronic medical record and will track its use in all applicable clinical settings.

Recommendation 4. We recommended that the Facility Director ensure that processes are in place to monitor providers' compliance with Veterans Health Administration colorectal cancer screening policy.

Concur

Target date for completion: December 31, 2016

Facility response: The facility has an established process to track patients who meet VHA criteria for colorectal cancer screening with a positive FIT to determine if appropriate follow-up care (when desired by the patient) is provided. The process will be improved to include monitoring of individual providers for compliance with the colorectal cancer screening policy with feedback of non-compliance given to the provider.

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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Appendix D

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