Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 14-01451-276

Healthcare Inspection

Non-VA Colonoscopy Follow-Up Concerns Southeast Louisiana Veterans Health Care System New Orleans, Louisiana

June 26, 2017

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess the merit of allegations regarding the management of follow-up care for patients who had undergone colonoscopies from 2006 through 2012, through Non-VA Care Coordination (NVCC) at the Southeast Louisiana Veterans Health Care System (system), New Orleans, LA.

The specific allegations were:

- System leadership failed to provide appropriate follow-up for approximately 16,000 to 18,000 patients who received colonoscopies through NVCC.
- System leadership failed to notify patients who had been potentially harmed as a result of this failure to provide appropriate follow-up care.
- System clinicians did not timely receive and review the results of colonoscopies completed for seven patients in the community through NVCC referrals.
- The System Director had knowledge of the issue and did nothing about it.

At the time of the initiation of our inspection, system managers had already completed a review of the patients and taken action based on the results of that review. We therefore chose to examine the adequacy of the review conducted by the system.

We could not substantiate that then-system leaders failed to provide appropriate follow-up for approximately 16,000 to 18,000 patients who received colonoscopies through NVCC because we determined that system managers did not reliably identify all potentially affected patients during the course of their review. The exact parameters of the system's query used to identify potentially affected patients are not known because system staff did not save the methodology used to extract the data. We identified patients who had positive stool results who subsequently developed colorectal cancer and were not on the system's review list.

> **OIG UPDATE**: After our review was completed, the system was able to generate a report reflecting evidence of the system's 2014 colonoscopy lookback and confirmed that 12,964 patient's colonoscopy reports were reviewed and clinical reminders were updated to reflect the appropriate return timeframe for those procedures performed between September 1, 2005 and December 30, 2013.

We found that then-system leaders did not take appropriate steps to ensure the validity of case reviews of patients who were identified. Then-system leaders instructed clinicians to review their own patients and assess whether delays in arranging follow-up care after colonoscopy occurred and, if so, resulted in harm. Such a method of review can compromise objectivity and lead to biased conclusions as to the timeliness of care and the quality of care patients received. Under these circumstances, a lookback review conducted by reviewers other than the patients' providers would have been appropriate to ensure objectivity.

We did not substantiate that system managers failed to notify a patient who had suffered harm. Then-system leaders determined an institutional disclosure was warranted, but they were unable to directly contact the family member who was designated as the patient's next of kin in the electronic health record. A certified letter was sent to the family member, and system staff received proof of delivery of the letter.

We substantiated that the system did not timely receive results for two of seven identified patients who underwent NVCC colonoscopy procedures. System managers acknowledged that obtaining documentation of NVCC results had been an ongoing challenge and implemented performance improvement activities to monitor receipt of NVCC consult results prior to our site visit.

We did not substantiate that the then-System Director had knowledge of the issue and did nothing about it. While developing a more flexible clinical reminder for colorectal cancer screening, then-system leaders discovered that because of the large number of NVCC colonoscopy referrals made in the aftermath of Hurricane Katrina, delays in scheduling the procedure, uploading results, and ensuring follow-up may have negatively impacted patients who required follow-up colonoscopies in less than 10 years. When the then-System Director became aware of potential issues with the colonoscopy clinical reminder in 2013, the then-System Director initiated a protected quality review for patients who had undergone NVCC colonoscopies.

We recommended that:

- The System Director ensure that all potentially affected patients, as described in this report, be reviewed by an external (non-system) source to ensure those patients received follow-up care.
- The System Director confer with the Office of Chief Counsel (formerly Regional Counsel) regarding Patients 2 and 3 as described in this report for possible institutional disclosure, and take action as appropriate.

Comments

The Veterans Integrated Service Network and System Directors concurred with the report (see Appendixes A and B, pages 12–17 for the Directors' comments.) Based on information provided to us with the responses, we consider Recommendations 1 and 2 closed. No further action is required.

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

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess the merit of allegations regarding the management of follow-up care for patients who had undergone colonoscopies through Non VA Care Coordination (NVCC)[1] at the Southeast Louisiana Veterans Health Care System (system), New Orleans, LA.

Background

The system, part of Veterans Integrated Service Network (VISN) 16, is an outpatient care facility that provides primary care, specialty care, and mental health services to veterans throughout 23 parishes[2] in southeast Louisiana, including many areas along the Gulf of Mexico. In August 2005, Hurricane Katrina directly impacted system operations when it caused widespread damage along the Gulf Coast with sustained winds of 100-140 miles per hour over more than 400 miles and leaving catastrophic damage from wind and water after a levee broke causing massive flooding of the area.[3]

The system continues to experience flood damage. Construction is underway for a new full-service medical center that is tentatively scheduled for completion in late 2017. The system is providing outpatient and outsourcing services[4] in the community through NVCC program provisions.

NVCC. NVCC refers to care provided in the community at VA's expense that is used when services are not available or cannot be economically provided by a VA facility due to capability, capacity, or accessibility concerns.[5] NVCC should only be considered when the request can be resolved efficiently.[6] Results of NVCC tests and procedures must be scanned into the patient's VA electronic health record (EHR); however, VA policy does not include specific timeliness requirements.[7] The system has utilized NVCC from 2005 to present for a number of healthcare services, including a significant number of referrals to community providers for colonoscopy services.

Colorectal Cancer Screening. Colorectal cancer (CRC) is the third most common cancer (excluding skin cancers) and the third leading cause of cancer deaths in the

[1] VHA Directive 1601, *Non-VA Medical Care Program,* January 23, 2013.
[2] Louisiana is divided into 64 parishes in the same way that 48 other states are divided into counties.
[3] VAOIG. *Audit of VA's Response to Hurricane Katrina*, Report #06-02860-215, September 28, 2007.
[4] The system used the term "outsourced" to signify patients sent to the community for care; in this report, we are using NVCC to signify patients sent to the community for care.
[5] VHA Directive 1601, *Non-VA Medical Care Program,* January 23, 2013.
[6] Ibid.
[7] VHA Handbook 1907.01, *Health Information Management and Health Records*, August 25, 2006. This Handbook was rescinded and replaced by VHA Handbook 1907.01, *Health Information Management and Health Records*, September 9, 2012, which was rescinded and replaced by VHA Handbook 1907.01, *Health Information Management and Health Records*, July 22, 2014, which was rescinded and replaced by VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015. All revisions of the Handbook include scanning requirements for external NVCC documents containing patient results.

United States.[8] Increasing access to and utilization of CRC screening tests has decreased the incidence of CRC and death through prevention and early detection. CRC screening enables the detection of pre-cancerous polyps so they may be removed before they become cancer. Early detection of colon cancer allows for early treatment. One common method of CRC screening includes asking the patient to submit stool samples to test for microscopic or occult blood. Detection of blood is an indication for colonoscopy.

The Veterans Health Administration (VHA) requires that veterans with positive CRC screening tests be followed up with a colonoscopy, unless contraindicated or the primary screening method was a colonoscopy.[9] The most current VHA policy, published in December 2014, does not include a timeframe for a diagnostic colonoscopy. However, the previous VHA policy, which was current at the time of the events discussed in this report, stated that when a diagnostic colonoscopy was indicated, it was to be performed within 60 calendar days of the positive screening test, unless the patient desired a colonoscopy in more than 60 days.[10]

Follow-Up of Abnormal Colonoscopies. If a patient's initial 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 requires more frequent follow-up.

Clinical Reminders. VHA established a national clinical reminder program to assist healthcare systems by directing healthcare providers to perform certain tests or provide treatments for specific populations. Clinical reminders send an electronic message to a provider when a patient is due for routine screening. The National Clinical Reminders Committee develops clinical reminders, such as the CRC screening clinical reminder, for VHA providers.[11] The default timeframe for the VHA follow-up colonoscopy clinical reminder is 10 years. At the system, providers could not modify the default setting when more frequent follow-up intervals were clinically indicated.

After Hurricane Katrina, system staff identified a need for a modifiable CRC screening timeframe reminder and recommended the development of a local clinical reminder with follow-up intervals shorter than the standard 10-year interval. The then-System Director agreed, and a local reminder was implemented.

Protected Quality Reviews. VHA policy outlines quality management activities that may generate confidential documents protected from disclosure under Title 38 of the

[8] American Cancer Society, http//www.cancer.org. Accessed January 5, 2014.
[9] 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. Both Directives require a full colonoscopy for positive CRC screening tests unless contraindicated, or if the primary screening method was a colonoscopy.
[10] Ibid.
[11] VA National Clinical Reminders, http://vista.med.va.gov/reminders/. Accessed February 19, 2015.

United States Code, Section 5705 (38 U.S.C. 5705).[12] The activities must be described in advance and in writing by the Under Secretary for Health, VISN Director, or Facility Director. Under 38 U.S.C. 5705, VHA may not communicate to patients or their personal representatives, information that is obtained from quality management activities.[13]

Disclosure. VHA describes large-scale disclosure as a formal process by which VHA officials inform patients, or their personal representatives, that they have been or may have been affected by an adverse event[14] involving actual or potential harm to multiple patients that is deemed clinically significant. When an adverse event is discovered at or near the time it occurs, clinical or institutional disclosure[15] must proceed as usual if the potential harm to the individual patient is clear. If the adverse event is only recognized after the associated episode of care (for example, through investigation of a sentinel event, a routine quality review, or a lookback[16]), it is appropriate to wait until the required VA Central Office coordination process for large-scale disclosure is completed before making either a large-scale or institutional disclosure to an individual patient, unless the delay will negatively affect patients' health or well-being.

The Principal Deputy Under Secretary for Health (or designee) makes decisions regarding large-scale disclosure of adverse events following a multi-step VA Central Office process that may involve a Subject Matter Expert Review Panel and/or Clinical Review Board.

Allegations. OIG received allegations from an anonymous complainant concerning the management of NVCC colonoscopy procedure results by the system. We initially obtained and reviewed system responses related to these allegations. The system indicated that a review of potentially affected patients from September 1, 2005 through December 1, 2013, had been completed. After reviewing the system responses, OIG determined that system actions taken in response to the following allegations needed to be evaluated:

- System leadership failed to provide appropriate follow-up for approximately 16,000 to 18,000 patients who received colonoscopies through NVCC.
- System leadership failed to notify patients who had been potentially harmed as a result of this failure to provide appropriate follow-up care.

[12] VHA Directive 2008-077, *Quality Management (QM) and Patient Safety Activities That Can Generate Confidential Documents*, November 7, 2008. This VHA Directive expired November 30, 2013 and has not yet been updated.
[13] Ibid.
[14] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. We reviewed two previous versions of this Directive that cover the timeframe of the events discussed in this report (VHA Directives 2005-049 and 2008-002). However, as the system did not begin a review of potentially affected patients until 2013, we used the 2012 version as a reference in this report.
[15] Ibid.
[16] Ibid.

- System clinicians did not receive the results of colonoscopies completed in a timely manner for seven patients in the community through NVCC referrals.
- The System Director had knowledge of the lack of follow-up and did nothing about it.

Scope and Methodology

We conducted site visits on November 5, 2014 and January 5–7, 2015. We interviewed system leadership, including the acting System Director, the acting Chief of Staff, the Chief of Medicine, Nurse Executive, program managers, and staff knowledgeable about the allegations.

We reviewed relevant VA/VHA directives and handbooks, system policies, methodologies employed by the system to conduct a 5705-protected review of NVCC colonoscopy procedures performed between 2006 and 2013, the system's list of patients included in the 5705-protected review, the EHRs of 44 patients, patient complaints, incident reports, peer reviews, and a tort claim. We also reviewed the results from a Healthcare Failure Mode and Effect Analysis concerning cancer process coordination.

VHA Directive 2008-077, *Quality Management (QM) and Patient Safety Activities That Can Generate Confidential Documents*, November 7, 2008, cited in this report expired November 30, 2013. We considered the policy to be in effect as it had not been superseded by more recent policy or guidance. In a June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),[17] the VA Under Secretary for Health (USH) mandated the "…continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."[18] The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "…the timely rescission or recertification of policy documents over which their program offices have primary responsibility."[19]

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.

[17] VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 11, 2017.
[18] VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.
[19] Ibid.

Inspection Results

Issue 1: Appropriate Follow-Up for Approximately 16,000 to 18,000 Patients Who Received Colonoscopies Through NVCC

We could not substantiate that the system failed to provide appropriate follow-up for approximately 16,000 to 18,000 patients who received colonoscopies through NVCC because we determined that system managers (1) did not reliably identify all potentially affected patients during the course of the review and (2) did not take appropriate steps to ensure the validity of case reviews of patients who were identified.

Failure To Reliably Identify All Potentially Affected Patients

In August 2013, then-system leaders identified potential issues with follow-up of a large number of patients who underwent colonoscopies through NVCC.[20]

While developing a more flexible clinical reminder for colorectal cancer screening, then-system leaders discovered that, because of the large number of NVCC colonoscopy referrals made in the aftermath of Hurricane Katrina, delays in scheduling procedures, uploading results, and ensuring follow-up may have negatively impacted patients who required follow-up colonoscopies in less than 10 years.

We attempted to identify the potentially affected patients and compared the list we compiled with the list of patients the system had compiled. The exact parameters of the system's query used to identify potentially affected patients are not known because system staff did not save the methodology they used to extract the data. Using the query that system staff felt most closely represented the parameters used, we identified 11,091 unique patients who received NVCC colonoscopies from January 2, 2006, through November 27, 2013. This number was not consistent with the 10,746 unique patients identified by the system.[21]

In order to further test the system's proper identification of all potentially affected patients, we identified and reviewed NVCC patients who had blood in their stool between January 2005 through December 2013 and were subsequently diagnosed with colon cancer between January 1, 2005 through January 5, 2015.[22] We identified a total of 93 patients. Twenty-six of the 93 patients did not appear on the system's

[20] The large number of patients undergoing NVCC was related to the inability to provide inpatient and many outpatient services after Hurricane Katrina.
[21] The documented number of system-identified, potentially-affected colonoscopy patients varied over time. As of June 6, 2016, the documented number of system-identified patients was 10,695. However, based upon a review of the list of patients provided by the system on June 3, 2016, the total number of unique colonoscopy patients was found to be 10,746.
[22] We selected this timeframe because a patient who had a completely clean colonoscopy would not need another screening for10 years. If polyps were found, the patient would need screening at less than 10 years. Since there are no indications to set follow-up at greater than 10 years, using the 10-year range would theoretically capture all patients subsequently diagnosed with colon cancer.

10,746 unique patients list. We reviewed the 26 patients who did not appear on the system list to determine whether they experienced delays (defined as a longer timeframe than recommended in national clinical guidelines[23] or the providers' recommendations) in receiving initial colonoscopies after being found to have blood in their stool. We did not identify significant delays or adverse outcomes for these patients.

Based on the discrepancies between the numbers system staff retrieved in their 2013 and 2014 database query and our query, as well as the 26 patients we identified in a lookback review who were not on the system's list, we determined that the system had not reliably identified and reviewed all potentially affected patients.

Failure To Take Appropriate Steps To Ensure the Validity of Patient Reviews

We confirmed that then-system leaders initiated a 5705-protected review to evaluate the care of potentially affected patients. However, we identified potential issues with the evaluation process.

Then-system leaders instructed providers to review a list of their assigned patients who underwent colonoscopies to determine the need for follow-up and assess whether delays had occurred resulting in harm.[24] System providers were expected to use their clinical judgment to evaluate for harm and forward the names of patients who may have suffered harm to senior system leaders. If providers were unable to complete reviews of their own patients, other system or contract providers were to complete the reviews.

Then-system leaders identified and reviewed 756 deceased patients and additional patients referred by providers. Patients who required second level reviews were referred to non-system oncologists. VISN 16 reportedly coordinated a review of 125 of the 756 deceased patients to confirm inter-rater reliability. We were not provided documentation to support the reviews.

The protected review was designated as a quality assurance review by the then-System Director despite the fact that these same providers were, in many instances, the individuals initially responsible for following up on the results of the colonoscopies. Such a method of review can compromise objectivity and lead to biased conclusions as to the timeliness of care and the quality of care patients received.

[23] Lieberman et al., Guidelines for colonoscopy surveillance after screening and polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology*. 2012; 143: 844–857.
[24] VHA Directive 2007-004, *Colorectal Cancer Screening*, January, 12, 2007. According to the 2007 Directive that was current at the time of the events discussed in this report, when a diagnostic colonoscopy was indicated, it was to be performed within 60 calendar days of the positive screening test unless the patient desired a colonoscopy in more than 60 days.

Issue 2: Notifying Affected Patients of Harm

We did not substantiate that patients identified by the system as potentially suffering harm related to delays in care were not notified.

The then-System Director designated the review as a quality assurance review, which protected disclosure of the results of the review under 38 USC 5705. System staff informed us that if possible harm is discovered during a 5705 first and/or second level protected review, the case is referred to a Pre-disclosure Committee. Based on the review of this committee, the case is referred to the System Director and regional legal counsel who initiate a disclosure to the patient or family if indicated.

Deceased Patient. We identified a deceased patient who may have suffered harm whose family was notified by the system of the possible harm; we describe our review of this patient's care below.

Patient 1 – A male in his 50s received a routine screening colonoscopy in 2009 (Month 1) through NVCC. The physician who performed the procedure identified five adenomatous polyps, the largest of which measured more than 2 cm. The physician entered a note in the patient's EHR in Month 2 recommending a repeat colonoscopy in 12 months.

The patient subsequently saw his VA primary care provider in Months 15, 16, 18, 24, and 31. In Month 31, the patient was scheduled for a colonoscopy following hospitalization for diverticulosis. The patient ultimately was diagnosed with colon cancer and had surgery to remove part of his colon in Month 35. He died just over a year after his surgery from complications related to his colon cancer.

Then-system leaders, after discussion with legal counsel, determined an institutional disclosure should be conducted. Attempts to meet with the family member who was listed in the patient's EHR as his next of kin were unsuccessful. A certified letter was mailed to the family member and receipt was confirmed.

Non-Deceased Patients. System leaders stated that no harm was found during the protected review of the non-deceased patients. However, they were unable to provide us a tabulated review of the patients indicating the criteria used to determine delay or harm. During our interviews, providers acknowledged that when they reviewed patients, they discovered patients who were overdue for follow-up based on the recommendations from NVCC providers who performed colonoscopies. The patients were reportedly scheduled expeditiously for a colonoscopy.

Issue 3: System Notification of Results From NVCC Colonoscopies for Seven Patients

We substantiated that the system did not receive timely results from NVCC providers for two of the seven patients whose names were provided to us in the original allegation. We describe our review of the care of these two patients below.

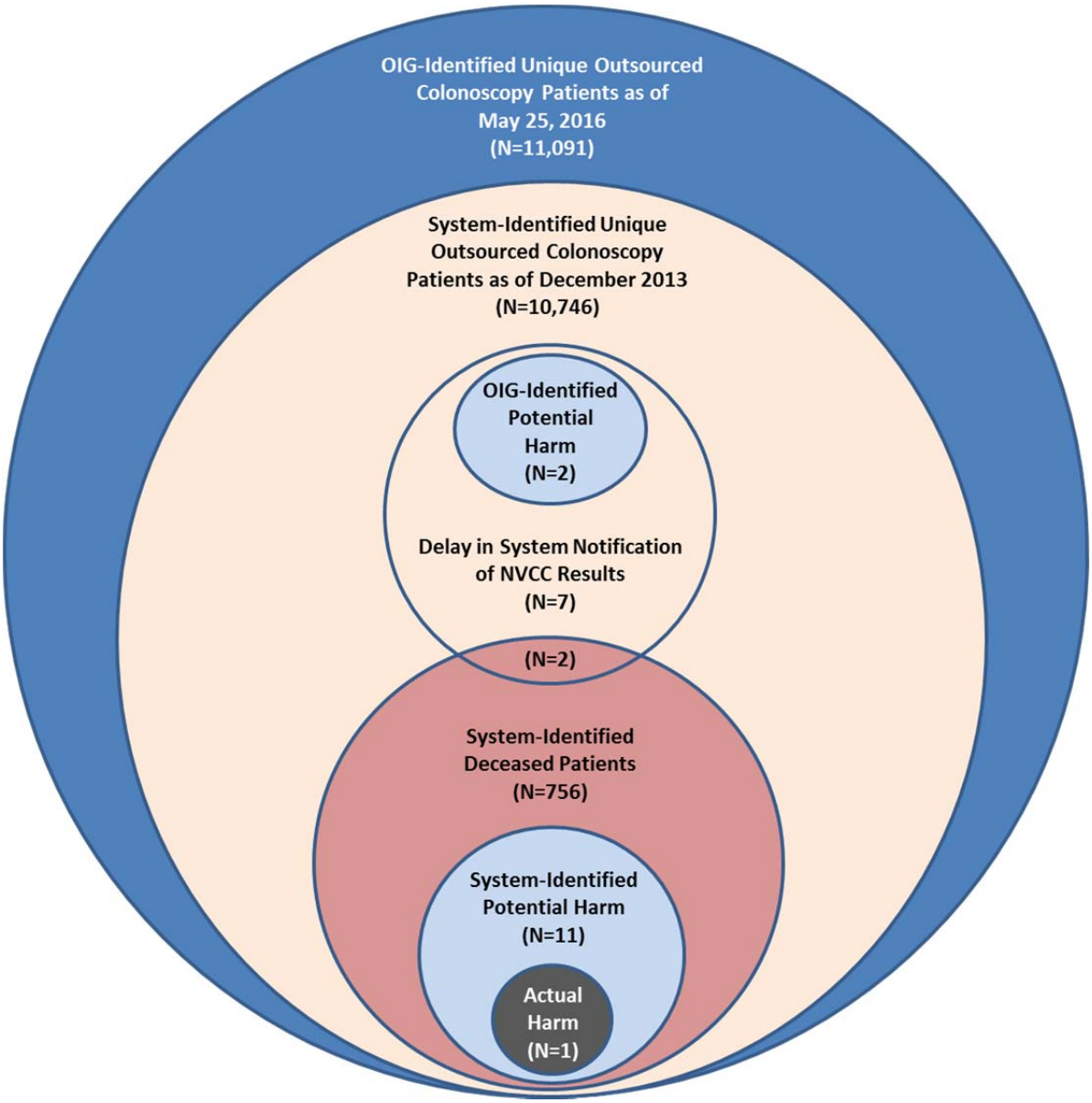
Patient 2 – A male in his 60s received a colonoscopy in 2007 following identification of occult blood in his stool on routine screening for colon cancer. In 2014, system staff discovered that there was no record of the results of that colonoscopy. They requested and received the report, which included a finding that the patient had adenomatous polyps; they mailed a notification letter with the results to the patient. In 2016, the patient's EHR did not contain results of a follow-up colonoscopy. We notified system leadership of this finding.

Patient 3 – A male in his 70s had a routine screening colonoscopy in 2006. The provider requested that it be repeated in 1 year because portions of the colon could not be adequately viewed because of poor preparation. In 2014, system staff determined no report had been received. In 2016, the patient's EHR contained no evidence of a follow-up colonoscopy. We notified system leadership of this finding.

The results of these two patients' NVCC colonoscopies were not available in their EHRs in a timely manner for review by the ordering providers. System managers had identified a problem with receiving results from NVCC providers prior to our site visit and implemented a consult tracking system that alerts system staff when reports are not received by the system after the requested service is provided. Designated staff contact the vendor to obtain reports. When providers order urgent consults, the cancer case management team tracks the consult and contacts the vendor directly.

The figure on the next page summarizes the number of potentially affected patients identified by OIG (N=11,091) and the system (N=10,746) who received NVCC colonoscopies, the number of system-identified deceased patients (N=756), the number of patients with an alleged delay in system notification of NVCC results (N=7), the number of patients identified by OIG (N=2) and the system (N=11) with potential harm, and the number of system-identified patients with actual harm (N=1).

Figure. Potentially Affected Patients Who Received NVCC Colonoscopies



Issue 4: Leadership Knowledge and Action

We did not substantiate that the then-System Director had knowledge of issues with NVCC colonoscopy follow-up and did nothing about it.

The national VHA clinical reminder for routine CRC screening sets the standard follow-up time as 10 years. The timeframe previously could not be adjusted for patients who might require follow-up at shorter intervals. System staff recommended the development of a local clinical reminder with follow-up intervals shorter than the standard 10-year interval. The then-System Director agreed, and a local reminder was implemented. During implementation, system managers identified potential issues with follow-up for NVCC colonoscopies. Soon after being notified of the potential issues, the

then-System Director initiated a 5705-protected review of patients who had undergone NVCC colonoscopy procedures.

The then-system Director and leadership also implemented the following actions to improve quality of care by:

- Enhancing the consult management tracking system with new software that tracks NVCC from initial referral to timely receipt of results of completed appointments to both provider and patient.
- Enhancing the monitoring of abnormal or suspicious findings or diagnosis of malignancy by modifying and hiring more staff for the cancer case management team.
- Researching CRC pre-screening methods and adopting a private sector health care system fecal immunochemical test (FIT)[25] program model.
- Hiring a CRC coordinator and staff to proactively test patients and provide follow-up.
- Enhancing the existing pathology reporting system by adding a backup notification system that notifies the provider through an EHR flag and email of abnormal pathology results when testing occurs within the system and in instances when NVCC providers send specimens to the system's pathology department. If NVCC providers complete pathological testing themselves, the NVCC provider notifies the system through the consult support staff, provider, or cancer case management team nurse.
- Initiating a Healthcare Failure Mode and Effects Analysis in June 2014 to improve the cancer care coordination process.
- Initiating system redesign procedures for NVCC and in-house colonoscopy follow-up and treatment.

Through interviews and onsite observations, we determined that system NVCC staff now use a tracking mechanism to monitor the progress from the initial NVCC referral, NVCC appointment scheduling, completion of the appointment, and uploading of the results into the EHR.

Conclusions

We could not substantiate that the system failed to provide appropriate follow-up for approximately 16,000 to 18,000 patients receiving colonoscopies through NVCC because we determined that system managers did not reliably identify all potentially affected patients during the course of their review. The system was unable to provide the query used to identify potentially affected patients. Using the query that system staff

[25] The fecal immunochemical test (FIT) is a newer screening test for colon cancer that only detects human blood from the lower intestines. The test tends to be more accurate and has fewer false positives than other tests.

felt most closely represented the parameters used, we identified 11,091 unique patients who received NVCC colonoscopies from January 2, 2006 through November 27, 2013. This number was not consistent with the 10,746 unique patients identified by the system. Additionally, we identified patients who had positive stool results who subsequently developed colorectal cancer and were not on the system's review list.

We found that then-system leaders did not take appropriate steps to ensure the validity of case reviews of patients who were identified. Then-system leaders instructed clinicians to review their own patients and assess whether delays in arranging follow-up care after colonoscopy occurred and, if so, resulted in harm. Such a method of review can compromise objectivity and lead to biased conclusions as to the timeliness of care and the quality of care patients received. Under these circumstances, a lookback review conducted by a reviewer other than the patients' providers would have been appropriate to ensure objectivity.

We did not substantiate that system managers failed to notify a patient who had suffered harm. Then-system leaders determined an institutional disclosure was warranted, but were unable to directly contact the family member who was the patient's designated next of kin. A certified letter was sent to the family member, and system staff received proof of delivery of the letter.

We substantiated that the system did not receive timely results for two of seven identified patients who underwent NVCC colonoscopy procedures. System managers acknowledged that obtaining NVCC results documentation had been an ongoing challenge and implemented performance improvement activities to monitor timely receipt of NVCC consult results.

We did not substantiate that the then-System Director had knowledge of the issue and did nothing about it. The then-System Director took action and initiated a 5705-protected quality review for patients who had undergone NVCC colonoscopies.

Recommendations

1. We recommended that the System Director ensure that all potentially affected patients, as described in this report, be reviewed by an external (non-system) source to ensure those patients received follow-up care.

2. We recommended that the System Director confer with the Office of Chief Counsel (formerly Regional Counsel) regarding Patients 2 and 3 described in this report for possible institutional disclosure, and take action as appropriate.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: April 28, 2017

From: Director, South Central VA Health Care Network (10N16)

Subj: Healthcare Inspection—Non-VA Colonoscopy Follow-Up Concerns, Southeast Louisiana Veterans Health Care System, New Orleans, Louisiana

To: Director, Dallas Office of Healthcare Inspections (54DA)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. The South Central VA Health Care Network (VISN 16) has reviewed and concurs with the response submitted by the Southeast Louisiana Veterans Health Care System (system), New Orleans, LA, regarding the Non-VA Colonoscopy Follow-Up Concerns Draft Report.

Skye McDougall, PhD
Director, South Central VA Health Care Network (10N16)

Appendix B

System Director Comments

Department of Veterans Affairs

Memorandum

Date: April 27, 2017

From: Director, Southeast Louisiana Veterans Health Care System (629/00)

Subj: Healthcare Inspection— Non-VA Colonoscopy Follow-Up Concerns, Southeast Louisiana Veterans Health Care System, New Orleans, Louisiana

To: Director, South Central VA Health Care Network (10N16)

Thank you for your thorough and thoughtful investigation of the process we used to audit colonoscopies and set reminders for repeat colonoscopy needs for our Veteran patients. The combined efforts of concerned professionals certainly make for a safer patient care environment.

In working with our Clinical Applications Coordinators, we were able to generate a comprehensive list of records reviewed during our 2014 colonoscopy lookback. Fortunately, we determined a method to pull this data from our health record, but not until after the IG concluded their review. We are now able to provide the IG with evidence that we conducted a thorough review of 12,964 colonoscopy procedures. The action plan for recommendation 1 provides details on findings from the 2014 colonoscopy lookback.

SLVHCS and VISN leadership find that licensed practitioners who were clinically privileged to practice in VHA had appropriate knowledge to conduct reviews of these procedures and the professional integrity to identify potential harm.

Recommendation 1: We recommended that the System Director ensure that all potentially affected patients, as described in this report, be reviewed by an external (non-system) source to ensure those patients received follow-up care.

Concur in principle.

The System Director concurs in principle because in 2014 Southeast Louisiana Veterans Health Care System (SLVHCS) had already conducted a thorough review of all potentially affected patients. Unfortunately, it wasn't until after the IG had completed their review that SLVHCS was able to generate a report reflecting comprehensive detailed evidence of that 2014 colonoscopy lookback.

In 2014, SLVHCS reviewed 12,964 patients who had received colonoscopies between September 1, 2005 and December 30, 2013. Reviewers read the patient's colonoscopy report and entered the appropriate return timeframe into a new electronic reminder. For example, if the Gastroenterologist wanted the patient to return for a colonoscopy in 3 years, the reviewer entered 3 years from the date of the colonoscopy into the electronic reminder. All of the reviewers were clinicians who had sufficient clinical expertise to read colonoscopy results and authority to enter clinical content into the health record.

[Redacted pursuant to 38 U.S.C. §5707.][26] Senior leadership appropriately consulted with legal counsel and determined institutional disclosure should be conducted. Unfortunately, despite multiple attempts to personally contact the patient's next of kin by phone and certified letter- the next of kin did not respond.

OIG's review identified 93 patients with positive fecal occult blood on screening tests who were subsequently diagnosed with colon cancer. Of the 93 patients, only 5 were not included in the 12,964 records. Of these 5, one was not in the date range that was searched; two were done through private insurance, one done as a part of an inpatient admission and one done in another VA as we could not provide the care in-house.

We find that our Colonoscopy Review documents all cases reviewed (Colorectal Cancer Screen Note Review of procedures done between 09.30.2005 and 12.31.2013 including the original list of NVCC and in-house for that time period). The review of all deaths and the OIG review of patients with evidence of occult fecal blood address the patients that may have been affected, and the two high risk groups for significant harm (death and occult blood). Our review is thoroughly documented. We consider our work on this recommendation complete and respectfully request OIG consider closure of this recommendation.

[26] This information has been redacted pursuant to 38 U.S.C §5705 which prohibits the unauthorized disclosure of VA medical quality assurance records.

Recommendation #2. We recommend that the System Director confer with the Office of Chief Counsel (formerly Regional Counsel) regarding Patients 2 and 3 described in the report and will take appropriate action per guidance of Office of Chief Counsel.

Concur

Action Plan: We have conferred with Office of Chief Counsel regarding patients 2 and 3 described in the report following VHA policy on Disclosure of Adverse Events as mentioned above. The Office of Chief Counsel did not recommend disclosure of any kind. Patient 3 died a month before his repeat colonoscopy was due, though not from colon cancer. Patient 2 was notified by certifed letter of the need to contact us to discuss his colonoscopy findings and the need for a repeat colonooscopy. Though he never contacted us, with care and concern for this patient's well-being, we sent another certified letter asking him to contact us to discuss his previous colonsocopy and the need for a repeat colonosocpy. We have received confirmation that he received and accepted the certified letter but he has not responded to us as to date.

We respectfully request closure of this recommendation.

(*original signed by* Ralph M. Schapira, Chief of Staff, *for:)*
Fernando O. Rivera, FACHE
SLVHCS Medical Center Director

Comments to OIG's Report

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

OIG Recommendations

Recommendation 1. The System Director ensure that all potentially affected patients, as described in this report, be reviewed by an external (non-system) source to ensure those patients received follow-up care.

Concur

Action Plan: We find that our Colonoscopy Review documents all cases reviewed (Colorectal Cancer Screen Note Review of procedures done between 09.30.2005 and 12.31.2013 including the original list of NVCC and in-house for that time period). The review of all deaths and the OIG review of patients with evidence of occult fecal blood address the patients that may have been affected, and the two high risk groups for significant harm (death and occult blood). Our review is thoroughly documented. We consider our work on this recommendation complete and respectfully request OIG consider closure of this recommendation.

Target date for completion: We respectively request closure.

OIG Comment: Based on information received from the system, we consider Recommendation 1 closed.

Recommendation 2. We recommended that the System Director confer with the Office of Chief Counsel (formerly Regional Counsel) regarding Patients 2 and 3 described in this report for possible institutional disclosure, and take action as appropriate.

Concur

Action Plan: We have conferred with Office of Chief Counsel regarding patients 2 and 3 described in the report following VHA policy on Disclosure of Adverse Events as mentioned above. The Office of Chief Counsel did not recommend disclosure of any kind. Patient 3 died a month before his repeat colonoscopy was due, though not from colon cancer. Patient 2 was notified by certified letter of the need to contact us to discuss his colonoscopy findings and the need for a repeat colonoscopy. Though he never contacted us, with care and concern for this patient's well-being, we sent another certified letter asking him to contact us to discuss his previous colonoscopy and the need for a repeat colonoscopy. We have received confirmation that he received and accepted the certified letter but he has not responded to us as to date.

Target date for completion: We respectfully request closure.

OIG Comment: Based on information received from the system, we consider Recommendation 2 closed.

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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