

Office of Healthcare Inspections

Report No. 13-04212-346

Healthcare Inspection

Administrative and Quality of Care Concerns Martinsburg VA Medical Center Martinsburg, West Virginia

May 21, 2015

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding physician leaders' mismanagement and abuse of power at the Martinsburg VA Medical Center (facility), Martinsburg, WV. It was alleged that physician leaders:

- Overlooked the medical neglect of a patient who died from metastatic lung cancer.
- Denied transfer of critically ill patients to facilities that provide a higher level of care.
- Disregarded specialists' opinions by modifying consultations.
- Gave a specialty clinic nurse authority to delay procedures without informing responsible specialists.

We did not substantiate the four allegations. However, during the course of our review of a patient's case, we identified quality of care and administrative issues not identified in the original allegations. The facility failed to provide notification and follow-up on a patient's abnormal imaging test result leading to a delay in diagnosis and treatment of lung cancer. In addition, the facility did not pursue all required administrative procedures in this case, including initiation of a root cause analysis and the institutional disclosure process. The facility also did not complete actions recommended by the Peer Review Committee.

We recommended that the Facility Director ensure that the facility:

- Comply with Veterans Health Administration and facility test results notification requirements.
- Strengthen the root cause analysis process.
- Evaluate the care of the subject patient with Regional Counsel for possible disclosure(s) to the surviving family member(s) of the patient.
- Strengthen and monitor the peer review process.

Comments

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

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

John Vaidly M.

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) conducted an inspection to determine the validity of allegations made by a complainant regarding administrative mismanagement, specifically physician leaders' mismanagement and abuse of power, leading to quality of care issues at the Martinsburg VA Medical Center (facility), Martinsburg, WV.

Background

Facility Profile. The facility offers a broad range of inpatient, outpatient, emergency, medical, surgical, geriatric, long-term care, and mental health services. The facility has a total of 465 beds comprised of 71 hospital, 121 community living center, 265 domiciliary, and 8 Compensated Work Therapy Transitional Residence beds. The facility also has seven community based outpatient clinics located in Western Maryland, Northwest Virginia, and West Virginia and is part of the Veterans Integrated Service Network (VISN) 5. In fiscal year 2013, the facility served 34,347 unique patients.

Within the last 4 years, OHI conducted two other hotline inspections at the facility. A 2010 inspection¹ did not substantiate senior leadership's mismanagement of fee basis care.² The inspection determined that leadership did not educate the staff about the fee basis decision process and that this communication gap contributed to misperceptions. Two years later, an OHI inspection did not substantiate compromised perioperative patient safety but found clinical and administrative mismanagement of Rapid Response Team³ and Cardiac Arrest Team activity.⁴

Allegations. In July 2013, a complainant contacted the OIG Hotline Division and alleged mismanagement and abuse of power by physician leaders who:

- Overlooked the medical neglect of a patient who died from metastatic lung cancer.
- 2) Denied transfer of a patient to a facility that provides a higher level of care.
- 3) Disregarded specialists' opinions by modifying consultations.

¹ Alleged Issues in Fee Basis Care, OIG Report No.10-02006-29, November 16, 2010.

² Non-VA care coordination refers to medical care provided outside of the VA to eligible veterans when care at VA medical facilities is not feasibly available. It was formerly known as fee basis, purchased care, or non-VA care. http://www.boise.va.gov/docs/FeeGUIDEBOOK.pdf. Accessed February 12, 2014.

³ A rapid response team is a group of health care providers who respond quickly to assess and treat patients who are unstable or show signs of clinical distress, deterioration, or change. http://journals.lww.com/anesthesia-analgesia/pages/articleviewer.aspx?year=2010&issue=09000&article=00015&type=abstract. Accessed March 31, 2014.

⁴ Quality of Care and Patient Safety Issues, Report No. 11-02756-201, June 13, 2012.

4) Gave a specialty clinic nurse authority to delay procedures without informing responsible specialists.

The allegation also described concerns of retaliation that were outside of the scope of this report.

In addition to the original allegations, during the course of our review we identified issues related to the facility's quality of care and quality management program.

Scope and Methodology

We conducted a site visit November 6–7, 2013. We interviewed the complainant, the former facility Director, current facility leadership, and current and former employees with knowledge of the pertinent issues.

We reviewed applicable Veterans Health Administration (VHA) and facility policies, memoranda, and procedures. Additionally, we reviewed electronic health records (EHRs), meeting minutes, peer reviews, tort claim summaries, and other relevant documents. We requested and the facility denied having any issue briefs, root cause analyses (RCAs), patient incidents, and patient advocate reports applicable to the allegations for fiscal years 2010, 2012, and 2013.

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.

Case Summary

A male patient in his mid-seventies had a medical history that included chronic obstructive pulmonary disease, obesity, hypertension, diabetes mellitus, and prior cigarette smoking. A chronology of significant clinical events for the patient included (times after initial complaint are approximate):

- Day of initial complaint, summer 2009 The patient presented to a Primary Care Provider (PCP) complaining of shoulder pain. The PCP ordered a chest x-ray.
- One week after initial complaint A radiologist interpreted the chest x-ray as showing "increased interstitial lung markings" that were "more pronounced" than in a 2006 x-ray. The radiologist also recommended further evaluation with computed tomography (CT) imaging.
- Twenty-nine weeks after initial complaint During the patient's next follow-up appointment, the PCP ordered chest CT imaging.
- Thirty-three weeks after initial complaint The radiologist interpreted the chest CT to reveal "a lung mass measuring 3.2 x 2.5 cm, suspicious for malignancy."
 The report was not formally acknowledged by the ordering practitioner (the PCP),

either by co-signature of the report or by documented communication in a clinical chart entry regarding the new lung mass.

- One year and 7 weeks after initial complaint During a routine visit, the PCP documented the patient's complaint of a "persistent, dry cough" but did not include mention of the chest CT results showing the new lung mass. The PCP advised the patient to return to clinic for follow-up in 8 months.
- One year and 18 weeks after initial complaint The patient presented to the PCP's clinic, unscheduled, complaining of cough and "being out of breath when walking" as well as generalized weakness and weight loss. The PCP ordered a chest x-ray, diagnosed pneumonia, prescribed a course of outpatient antibiotics, and advised the patient to return to clinic in 8 months.
- One year and 19 weeks after initial complaint The patient presented to the facility's emergency department with continued shortness of breath and persistent cough after completing the antibiotic course. A physician's assistant noted the abnormal CT scan and ordered a repeat CT that revealed the 3.2 x 2.5 cm lung mass had progressed and was "encompassing the right lower lobe of the lung (and now) with liver metastases." The patient was admitted to the facility and diagnosed with advanced lung cancer (Stage IV) complicated by metastatic involvement of the liver.⁵ The next day, the Chief of Primary Care notified the Chief of Staff (COS) of the patient's case.
- One year and 20 weeks after initial complaint The Chief of Primary Care advised the PCP that the patient "requires an apology and a disclosure..." and to contact Risk Management. Additionally, a hospitalist informed the patient and family that there had been a "delay in the diagnosis of the lung mass" which had been identified on a chest CT. No formal institutional disclosure was made. The next day, the PCP informed the patient that "[T]he reason for not discussing the case with him during that time [when the CT was done and results were available] was not negligence, but was because of me being uninformed." A few days later, due to the patient's poor prognosis and rapid deterioration, the family transferred the patient to a private inpatient hospice facility located closer to their home.
- One year and 21 weeks after initial complaint The patient died in the hospice facility.

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⁵ Staging describes the severity of a person's cancer and whether or not cancer has spread in the body. Stages range from I to IV with IV indicating cancer has spread to distant tissue or organs. http://www.cancer.gov/cancertopics/factsheet/detection/staging. Accessed on February 12, 2014.

Inspection Results

Issue 1: Physician Leaders' Mismanagement and Abuse of Power

Allegation 1. We did not substantiate the allegation that physician leaders overlooked medical neglect related to a patient who died from metastatic lung cancer. The Chief of Primary Care notified the COS of the patient's case on the day following the patient's hospital admission with advanced lung cancer. Physician leaders reviewed the case, identified concerns with medical care and, 2 days later, advised the PCP that the patient "requires an apology and a disclosure" and to contact Risk Management."

Although we did not substantiate this allegation, while reviewing this patient's care, we identified several quality of care and administrative concerns.

Communication of Test Results

VHA policy requires that test results be communicated to the ordering practitioner within a timeframe allowing appropriate clinical action to be taken. We determined that the absence of timely follow-up of imaging results contributed to the delay in diagnosis and treatment of lung cancer. We did not find evidence that the radiologist notified the PCP directly regarding the suspicious malignancy noted in the CT scan report (see above chronology), as would be expected by the local policy. We did not find evidence that the PCP acknowledged this report, either by co-signature or by an EHR entry, or that the PCP discussed the imaging results with the patient before the clinical disclosure.

Adverse Events and RCA

The facility's internal reviews of the incidents did not fully adhere to VA National Center for Patient Safety (NCPS) guidelines for completion of RCAs. RCAs are VHA's method to evaluate system and process weaknesses that may have contributed to adverse events or close calls. Handbook 1050.1, VHA National Patient Safety Improvement Handbook, dated May 23, 2008, specifies the identification, evaluation, and reporting requirements for potential and actual adverse events. An RCA team gets to a root cause by asking "why" until it either runs out of questions to ask or decides that there are no new answers to consider. The goal of an RCA is to learn more about system weaknesses so that corrective actions may be taken and future adverse events may be prevented. Responsible facility staff informed us that an RCA or other internal systemic review was not initiated following this adverse event.

⁶ "Disclosure of adverse events" refers to the forthright and empathetic discussion of clinically-significant facts between providers or other VHA personnel and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future. VHA Directive 2008-002, *Disclosure of Adverse Events to Patients*, January 18, 2008.

⁷ VHA Directive 2009-019, Ordering and Reporting Test Results, March 24, 2009.

Disclosure

VHA first implemented national requirements in 1995⁸ to ensure consistent processes among VHA facilities in disclosing the occurrence of adverse events related to patients' clinical care.⁹ VHA recognizes three types of disclosure: clinical,¹⁰ institutional,¹¹ and large-scale.¹² Appropriate disclosure may include any or all types.

In 2008, VHA directed that clinical disclosure was warranted for "Adverse events ... sustained in the course of their care, including cases where the adverse event may not be obvious or severe, or where the harm may only be evident in the future." Under the guidance of the Chief of Primary Care, the PCP provided the patient with a clinical disclosure. However, we found no documented evidence that facility made an institutional disclosure.

Peer Review

Protected peer review is a non-punitive, confidential process used to evaluate care provided to patients by individual providers. According to VHA policy, the formal process of peer review involves evaluation of specific episodes of care, determination of necessary specific actions based on evaluations, confidential communication with providers, and identification of systems and process issues that may require special actions.¹⁴

The facility initiated the peer review process in this case but did not complete all actions recommended by the Peer Review Committee.

Allegation 2. We did not substantiate the allegation that physician leaders denied transfer of a patient to a facility that provides a higher level of care.

VHA policy states that if a facility cannot provide a service, but the service is offered by another VHA facility within the facility's VISN, the facility would enter a consultation request for transfer. If the service is not available in a timely manner within the VISN due to capability, capacity, or accessibility, the service may, with approval, be provided

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https://vaww.portal.oig.va.gov/directorates/54/Hotlines/2013-04212-HI-0482/Administrative/VHA Directive Disclosure of Adverse Events Jan 18 2008.pdf, accessed February 27, 2015.

⁹ VHA Directive 2008-002, *Disclosure of Adverse Events to Patients*, January 18, 2008.

¹⁰ A clinical disclosure is an informal process for informing patients or their personal representative of harmful adverse events related to the patient's care. VHA Directive 2008-002.

¹¹ An institutional disclosure is a formal process by which facility leaders together with clinicians and others, when appropriate, inform the patient or patient's representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury. The patient is also provided specific information about patients' rights and recourses. VHA Directive 2008-002.

¹² A large-scale disclosure is a formal process by which VHA officials assist with coordinating the notification to multiple patients, or their personal representatives, that they may have been affected by an adverse event resulting from a systems issue. This process usually includes public notification and direct communication to key stakeholders. VHA Directive 2008-002.

¹³ VHA Directive 2008-002.

¹⁴ VHA Directive 2010-025, Peer Review for Quality Management, June 03, 2010.

outside of the VA through non-VA care (formally known as fee basis).¹⁵ Facility policy requires that the COS or designee document in the EHR the authorization for patient transfers from the facility to private facilities for non-VA care.¹⁶

We reviewed the EHR of the patient identified in the original allegation. In this case, one specialty provider requested urgent transfer of the patient to another VHA facility that provided cardiothoracic surgery. However, since no beds were immediately available at the receiving VHA facility, the COS considered transfer to a community hospital (non-VA care) by the next morning. The COS consulted with other specialists involved in this patient's treatment who agreed that transfer was indicated and that the patient was stable enough to wait for VHA bed availability. The patient was transferred to the receiving VHA facility when a bed became available later that day.

While on site, OHI inspectors learned of an additional patient with alleged denial of transfer. In this case, there was no EHR or other documented evidence to support that the specialty provider requested transfer of the patient for a higher level of care that included dialysis.¹⁷ The patient opted to utilize his alternative health benefit and go to a community hospital.

We found that in these two cases, patients received the recommended higher level of care without adverse outcomes and the COS did not deny transfer.

Allegation 3. We did not substantiate the allegation that physician leaders disregarded specialists' opinions by modifying consultations.

According to facility management officials, the facility's process for consultations included:

- A provider entered a consultation to a specialty service.
- The specialty provider reviewed the consultation within 24 hours to determine if:
 - A specialty care appointment was clinically indicated; if so, the service contacted the patient within 7 days and a specialty clinic appointment was scheduled for within 14 days.
 - A specialty care appointment was not clinically indicated; if so, the specialty service canceled or discontinued the consult.
 - Additional information and/or testing was needed, the specialty provider documented this information in the patient's EHR.

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¹⁵ VHA Directive 2008-056, VHA Consult Policy, September 16, 2008.

¹⁶ Martinsburg VAMC MCM 11-78, *Inter-Facility Transfer and Referral*, extended to April 30, 2009.

¹⁷ Dialysis is used to filter toxins from the blood when a person's kidneys are damaged. http://diabetes.about.com/od/glossaryofterms/g/dialysis.htm. Accessed on March 31, 2014.

 Specialty service staff discontinued or cancelled consultations received for a patient already undergoing treatment in that specialty clinic.

Management authorized modification of some specialty providers' clinic schedules to ensure that patients were getting first available consult appointments. This sometimes involved scheduling the patient with a provider other than the one initially assigned. Management stated that these changes enhanced patient access and clinic efficiency by more evenly distributing workload. Although these schedule changes may have contributed to a staff member's perception of being disregarded, the patient advocate reported that no patients registered complaints regarding specialty services appointment scheduling.

Allegation 4. We could not substantiate the allegation that physician leaders gave a specialty clinic nurse authority to delay procedures without informing responsible specialists.

We requested details related to this allegation. However, because the complainant did not provide patient names or other information to support this allegation, we could not review cases and make a determination as to its merit.

Conclusions

We did not substantiate the four allegations related to physician leaders' mismanagement and abuse of power. After learning about the delayed diagnosis case, physician leaders identified concerns and took prompt actions to provide the patient with disclosure and to contact Risk Management. We determined that the COS did not deny transfer of patients to facilities that provide a higher level of care. We found that a staff member's perception of being disregarded may have developed because of leadership policies to change clinic schedules in an effort to improve patient access, clinic efficiency, and workload distribution. Finally, in the absence of specific examples, we could not determine whether the facility gave authority to a specialty clinic nurse to delay procedures without notifying specialists.

During the course of our review, we identified quality of care and administrative issues not identified in the original allegation. The facility failed to notify and follow up on a patient's abnormal imaging test result, leading to a delay in diagnosis and treatment of lung cancer. In addition, the facility did not pursue all required administrative procedures, including initiation of an RCA regarding this adverse event. Although the PCP provided a clinical disclosure, the facility lacked written evidence of consultation with Regional Counsel to determine if the event warranted an institutional disclosure. We also found that the facility initiated the peer review process but did not complete all actions recommended by the Peer Review Committee.

Recommendations

Recommendation 1. We recommended that the Facility Director ensure that the facility comply with Veterans Health Administration's and facility test results notification requirements.

Recommendation 2. We recommended that the Facility Director ensure that the facility strengthen the root cause analysis process.

Recommendation 3. We recommended that the Facility Director ensure that the facility evaluate the care of the subject patient with Regional Counsel for possible disclosure(s) to the surviving family member(s) of the patient.

Recommendation 4. We recommended that the Facility Director ensure that the facility strengthen and monitor the peer review process.

VISN Director Comments

Department of **Veterans Affairs**

Memorandum

Date: SEP 04 2014

From: Director, VISN 5 (10N5)

Subject: **Draft Report—Healthcare Inspection—Quality of Care and**

Administrative Concerns, Martinsburg VA Medical Center,

Martinsburg, West Virginia

To: Director, Baltimore Office of Healthcare Inspections (54BA)

Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. I have reviewed the draft OIG report and concur with the Martinsburg VAMC's response to the recommendations.

2. If you have any questions please contact Jeffrey Lee, VISN 5 Quality Management Officer at 410-691-7816.

Director, VISN 5 (10N5)

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: September 3, 2014

From: Acting Director, Martinsburg VA Medical Center (613/00)

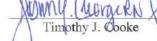
Subject: Draft Report—Healthcare Inspection—Quality of Care and

Administrative Concerns, Martinsburg VA Medical Center,

Martinsburg, West Virginia

To: Director, VA Capitol Health Care Network (10N5)

- 1. I have reviewed the draft report and concur with the OIG recommendations.
- 2. Thank you for the opportunity to review the draft report. Our corrective actions have been established with planned completion dates as detailed in the attached report.
- 3. If you have any questions please contact V. Denise O'Dell, RN, Chief of Quality Management at 304-263-0811, extension 4035.



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 facility comply with Veterans Health Administration's and facility test results notification requirements.

Concur

Target date for completion: October 31, 2014.

Facility response: Currently the facility is monitoring and tracking patient notification of test results as follows: Patient notification of test results is monitored via the Clinical Service's monthly clinical pertinence reviews on Providers. Beginning July, 2014, it will be required by all Clinical Services who are responsible for notifying patients of their test results, that this line item is added to their Service's clinical pertinence reports. Secondly, as a standing report of the facility's Patient Record Committee, they monitor compliance of patient notification on abnormal results. This is a random review of twenty (20) laboratory and twenty (20) diagnostic reports. Currently, the Patient Record Committee is reporting 100% compliance from this review; however, to give a broader review to ensure compliance, beginning July, 2014 the number of random reviews will be increased from twenty (20) to fifty (50) reports monthly. From the dates mentioned in this report, around or about 2010, the facility has since purchased voice dictation software that requires the Radiologist to use the primary diagnostic code for all test results. By utilizing this software, it is certain that all critical/urgent results are communicated to the ordering provider by a view alert.

Recommendation 2. We recommended that the Facility Director ensure that the facility strengthen the root cause analysis process.

Concur

Target date for completion: October 31, 2014.

Facility response: The VAMC has formal channels to initiate root cause analyses, however, a few additional processes to ensure thorough capture of adverse events that have potential for a root cause analysis will be implemented.

When Clinical or Institutional Disclosure is being considered or when a disclosure has been complete, the Risk Manager will discuss the incident with the Patient Safety Manager to determine if the event should have a root cause analysis completed.

The Patient Safety Manager will provide "Stop the Line" training sessions specifically for providers. This training will include the opportunity and process providers can initiate to

have an adverse event considered for a root cause analysis. This will raise awareness of opportunity to report events and strengthen the root cause analysis process.

Recommendation 3. We recommended that the Facility Director ensure that the facility evaluate the care of the subject patient with Regional Counsel for possible disclosure(s) to the surviving family member(s) of the patient.

Concur

Target date for completion: NA

Facility response: The case was sent for review by the Regional Counsel/Office of General Counsel and the National Center for Ethics in Health Care. Based on that review, the decision was made to not provide a formal disclosure to the family. The conclusion was that the patient was the ethically appropriate decision maker and he was properly informed.

Recommendation 4. We recommended that the Facility Director ensure that the facility strengthen and monitor the peer review process.

Concur

Target date for completion: October 31, 2014

Facility response: The Risk Manager will review and confirm all FY 14 recommendations by the Peer Review Committee were communicated and acted upon.

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Jennifer Christensen, DPM, Team Leader Donald Braman, RN Thomas Jamieson, MD Terri Julian, PhD Melanie Oppat, LDN, MEd

Appendix D

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Director, Martinsburg VA Medical Center (613/00)

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U.S. Senate: Shelley Moore Capito, Joe Manchin III,

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