



**Department of Veterans Affairs
Office of Inspector General**

Office of Healthcare Inspections

Report No. 13-00940-193

Healthcare Inspection

Alleged Delays in Notifying Patients of Biopsy Results W. G. (Bill) Hefner VA Medical Center Salisbury, North Carolina

May 13, 2013

Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to a complaint concerning delays in reporting biopsy test results to patients and possible delays in treatment at the W.G. (Bill) Hefner VA Medical Center (facility), Salisbury, NC. The complainant alleged that patients are not notified of their “gastro region” biopsy results within an acceptable time and that some delays were as long as 18 months.

We substantiated the allegation that the facility was not timely in notifying patients of gastrointestinal biopsy results. However, we did not find that extensive notification delays, beyond several months, occurred frequently or that resulting treatments were delayed.

We found that 35 percent of the patient electronic health records we reviewed either contained no documentation that biopsy test results were communicated to patients or contained documentation indicating that patients were notified beyond the timeframe required by VHA policy. In addition, we found that facility managers had not implemented a process to periodically monitor the communication of outpatient biopsy test results to patients.

During our review, we also found that the facility’s written policy for reporting critical test results to ordering practitioners does not fully address all critical test results, specifically the communication of biopsy results for procedures performed on an outpatient basis.

We recommended that procedures be implemented to ensure timely patient notification of test results, notifications be documented in patients’ electronic health records, performance improvement processes be strengthened to include periodic monitoring of test result communication to patients, and the facility’s written policy regarding the communication of critical results be revised to address biopsy test results discovered during outpatient procedures.

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 5–8 for the Directors’ comments.) We will follow up on the planned actions until they are completed.



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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review to determine the merit of an allegation regarding delays in notifying patients of biopsy results at the W.G. (Bill) Hefner VA Medical Center in Salisbury, NC (the facility).

Background

The facility is part of the Veterans Integrated Service Network (VISN) 6, also known as the Mid-Atlantic Health Care Network. It is a 484-bed facility with inpatient services that include acute medicine, cardiology, psychiatric services, and extended care. The facility also provides primary and specialized outpatient services, including dermatology, ophthalmology, and psychiatry.

On December 5, 2012, an anonymous complainant contacted the OIG hotline and alleged that patients are not notified of their “gastro region” biopsy results within an acceptable time and that some delays were as long as 18 months.

Gastro-intestinal biopsies are live tissue samples taken during diagnostic procedures called endoscopies. An endoscopy is a procedure that moves a long thin tube with a camera on the tip through a body passageway or opening to see inside an organ.¹ The most common gastro-intestinal endoscopy is a colonoscopy, which is performed to explore and test tissue from the large bowel or colon. Most endoscopies, including colonoscopies, are done as outpatient procedures.²

After a biopsy is performed, the laboratory tests the tissue for abnormalities, such as cancer cells, and a diagnostic practitioner or pathologist confirms the test result. The pathologist then notifies the practitioner who ordered the test. After receiving the test results, the ordering practitioner is responsible for notifying the patient of the results.³

Scope and Methodology

We interviewed facility managers and staff and reviewed relevant facility policies, procedures, and committee minutes. We reviewed a sample of 105 electronic health records (EHRs) of patients who had biopsies performed during outpatient colonoscopies. Our sample included a random selection of 35 patients from each of the first three quarters of fiscal year 2012.

¹ National Institute of Health, “Endoscopy,” <http://www.nlm.nih.gov/medlineplus/endoscopy>, accessed on February 20, 2013.

² National Institute of Health, “Colonoscopy,” <http://www.nlm.nih.gov/medlineplus/endoscopy>, accessed on February 20, 2013.

³ VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009.

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: Delays in Notifying Patients of Biopsy Results

We substantiated the allegation that the facility was not timely in notifying patients of gastrointestinal biopsy results. However, we did not find that excessive notification delays, beyond several months, occurred on a frequent basis or that resulting treatments were delayed.

Veterans Health Administration (VHA) Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009, requires that test results be “communicated to patients no later than 14 calendar days from the date on which the results are available to the ordering practitioner.” In cases where significant abnormalities are found, such as new malignancies, patients should be notified sooner; although, VHA policy does not include a specific time requirement. The ordering practitioner does not need to notify patients personally but may delegate an appropriate licensed or certified staff member when clinically appropriate.

VHA’s policy does not stipulate the manner of patient notification that an ordering practitioner or delegate must use to communicate test results. However, VHA does require that patient notification or attempts to notify a patient are documented in the patient’s EHR. If it is important for the patient to take action quickly, such as returning for additional evaluation, the documentation must include information that the patient received and understood the test result.

The facility chief of staff is responsible for monitoring test result communication, resolving deficiencies with service chiefs, and ensuring that test results are communicated to patients in accordance with VHA policy.

Our review of 105 EHRs found:

- Seventeen (16 percent) records showed documentation that biopsy test results were communicated to patients within a median of 18 days (range 15–127 days) after the results were available.
- Twenty (19 percent) records had no documentation that biopsy test results were communicated to patients or that notification attempts were made. Therefore, we were unable to determine when (or if) these patients were notified of their biopsy test results.
- Sixty-eight (65 percent) records showed documentation that biopsy test results were communicated to patients within a median of 3 days (range 0–14 days) after the results were available, which met VHA requirements.

The majority of test results were normal, but for 2 of the 20 records that had no documentation of patient notifications, the patients had critical test results or new malignancies. However, both patients were seen in the surgical clinic within 27 days after the test results were available to the ordering practitioner, indicating that the patients had been notified at some point of their results.

According to senior medical staff, when the diagnostic practitioner enters the test result in the patient's EHR, an electronic message is automatically sent to inform the ordering practitioner that the test result is available. Although the ordering practitioner may read and acknowledge receipt of the message, the practitioner may choose not to perform any other tasks, such as generating a test result notification letter to a patient. Supervisors have encouraged practitioners to use the notification letter to convey test results to patients, but the facility has no standard procedures to communicate results or document that results have been communicated. Furthermore, the facility has no process to periodically monitor the communication of test results to patients.

Though we found that the majority of test results were normal and that the two patients with critical test results were not harmed, the facility did not meet VHA requirements for timely notification of test results to patients. Furthermore, the lack of accountability and monitoring may subject patients to a higher risk of anxiety and, if test results are critical, possible harm.

Issue 2: Inadequate Policy for Reporting Critical Test Results to Practitioners

During our review, we also found that the facility's written policy for reporting critical test results to ordering practitioners does not fully address all critical test results, specifically the communication of biopsy results for procedures performed on an outpatient basis.

VHA requires medical centers to have a written policy in place regarding communication of critical test results from a diagnostic practitioner to an ordering practitioner. Critical test results, such as a new malignancy, are "...values and interpretations that if left untreated could be life threatening or place a patient at serious risk." The policy should describe the communication process, including timeframes, between the diagnostic and ordering practitioners. The policy should also outline a system of surrogate practitioners in the event that the ordering practitioner is not available. Additionally, defined timeframes and processes must be monitored for compliance.⁴

According to senior medical and laboratory staff, new malignancies, discovered during any procedure or evaluation, are critical test results. However, the facility policy does not address critical biopsy test results discovered during outpatient procedures such as colonoscopies.⁵ Thus, the facility policy does not fully meet VHA policy requirements to describe and monitor communication processes between the diagnostic practitioner and ordering practitioner and to outline a system of surrogate practitioners. We were unable

⁴ VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009.

⁵ Medical Center Memorandum 659-11-41, *Critical Diagnostic Tests and Test Results*, January 25, 2012.

to ascertain whether the lack of policy requirements contributed to the delays in notifying patients of test results described under Issue 1.

Conclusions

We substantiated the allegation that the facility was not timely in notifying patients of gastrointestinal biopsy results. However, we did not find that extensive notification delays, beyond several months, occurred on a frequent basis or resulting treatments were delayed.

We found that 35 percent of the EHRs in the review had either documentation indicating that patients were notified beyond the timeframe required by VHA policy or no documentation that biopsy test results were communicated to the patients. In addition, facility managers had not implemented a process to periodically monitor the communication of outpatient biopsy test results to patients.

We also identified a weakness in the facility's critical test result policy. Specifically, the policy does not address communication of critical biopsy test results, such as new malignancies, discovered during outpatient procedures.

We made three recommendations.

Recommendations

1. We recommended that the Facility Director implement procedures to ensure that patient notifications are timely and documented in patients' electronic health records.
2. We recommended that the Facility Director ensure that performance improvement processes be strengthened to include periodic monitoring of test result communication to patients.
3. We recommended that the Facility Director ensure that the facility's written policy on critical test results addresses critical biopsy test results from outpatient procedures.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 9, 2013

From: Director, Mid-Atlantic Healthcare Network (10N6)

Subject: **Healthcare Inspection – Alleged Delays in Notifying Patients of Biopsy Results, W. G. Hefner VA Medical Center, Salisbury, NC**

To: Director, Bedford Regional Office of Healthcare Inspections (54BN)
Director, VHA Management Review Service (VHA 10AR MRS OIG Hotlines)

1. The attached subject report is forwarded for your review and further action. I have reviewed the responses and concur with the facility's recommendations.
2. Please contact Kaye Green, Director, Salisbury VA Medical Center, at (704) 638-3344, if you have any further questions.

(original signed by:)

DANIEL F. HOFFMANN, FACHE

Facility Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 10, 2013

From: Director, W. G. (Bill) Hefner VA Medical Center, Salisbury,
NC (659/00)

Subject: **Healthcare Inspection – Alleged Delays in Notifying Patients of
Biopsy Results, W. G. Hefner VA Medical Center, Salisbury, NC**

To: Director, Mid-Atlantic Healthcare Network (10N6)

1. I have reviewed the draft report of the Office of Inspector General and I concur with the recommendations.
2. I have included my response in the attached Director's Comments.
3. Please contact me if you have any questions or comments.

(original signed by:)

Kaye Green FACHE

Director, W. G. (Bill) Hefner VA Medical Center (659/00)

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 implement procedures to ensure that patient notifications are timely and documented in patients' electronic health records.

Concur

Target date for completion: May 15, 2013

Facility response:

The Medical Center Director will ensure the Chief of Staff develops policy and procedures to notify patients of test results according to Veterans Health Administration (VHA) Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009. The Chief of Staff Office is developing a Medical Center Memorandum that outlines expectations and procedures for notifying patients of diagnostic tests. Education will be provided to all appropriate clinical staff. Upon implementation of the new Medical Center Memorandum, the Office of Performance and Quality will perform monthly monitoring of electronic health records to ensure compliance.

Recommendation 2. We recommended that the Facility Director ensure that performance improvement processes be strengthened to include periodic monitoring of test result communication to patients.

Concur

Target date for completion: July 15, 2013

Facility response:

The Medical Center Director will require that at least fifty charts each month be assessed for compliance with documentation of communicating test results. The evaluation method will be conducted by the Office of Performance & Quality. Effectiveness of compliance with the new policy will be assessed by reviewing electronic health records. A sample of at least 50 electronic health records will be reviewed for presence of documentation of patient notification related to diagnostic tests and that the notification occurred within the required 14-day timeframe. At least 50 electronic health records, from 50 unique patients, will be selected at random each month from various categories. The electronic health records will be reviewed to determine the number of compliant cases for documentation of patient notification of test results within the 14-day timeframe. The sampling will occur indefinitely to ensure compliance with the Medical Center Memorandum. Results of the audit will be reported

to the Clinical Executive Board and to the Executive Committee of the Governing Body for ongoing oversight.

Recommendation 3. We recommended that the Facility Director ensure that the facility's written policy on critical test results addresses critical biopsy test results from outpatient procedures.

Concur

Target date for completion: June 15, 2013

Facility response:

The Medical Center Director will ensure that Medical Center Memorandum 659-11-41 (*Critical Diagnostic Test and Test Results*) is revised to include critical biopsy test results as a critical test result. The pathologist will be required to report the critical biopsy test result to the ordering provider, or designee within one working day of confirmation of the result. If the evaluation of any anatomic pathology specimen concludes that there is malignancy, and that there has been no prior definitive diagnosis of that malignancy (excluding skin squamous and basal cell carcinomas), the patient's provider must be personally notified by verbal communication within 1-working day of the time the diagnosis is made. To ensure compliance, the pathology service will monitor all critical biopsy test results to ensure that the ordering provider or designee is notified within one working day of confirmation of the result. Results of the monitor will be reported monthly until >90% for three months then will move to quarterly reporting to the Clinical Executive Board and the Executive Committee of the Governing Body for ongoing oversight.

OIG Contact and Staff Acknowledgments

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