Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Laboratory Processing Delays and Environmental Safety Concerns
VA North Texas Health Care System
Dallas, Texas

Report No. 13-00636-104

February 5, 2013

VA Office of Inspector General
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 to determine the validity of allegations regarding laboratory processing delays and environmental safety concerns at the VA North Texas Health Care System (HCS), Dallas, TX. A complainant alleged that:

- Specimen containers have unreadable labels that cannot be matched to the paperwork received.
- A patient went to a private provider for a Papanicolaou (Pap) test because of delays receiving results through the VA, and the test was positive for cancer.
- Service leadership took no action when the Pap test delays were reported.
- The ventilation system in the Histology laboratory is not adequate.
- Chemicals and explanted pacemakers are not appropriately stored and disposed.
- Food and drinks are stored in refrigerators meant for laboratory items.

We did not substantiate any of the allegations. We found proper procedures in place for specimen labeling, processing, and documentation of records.

The complainant was not able to identify the patient that was reportedly diagnosed with cancer by a private doctor; however, the Chief of Pathology and Laboratory Medicine Service did know who the patient was and that the patient had normal Pap test results. Service leadership took swift and appropriate actions when it was discovered that Pap tests had not been processed.

Chemicals and explanted pacemakers were all stored appropriately. Although the facility had employee-reported ventilation system problems, the facility took action to evaluate the complaints and verified that there was proper ventilation and safety for all employees in the affected areas. We did not find food or drink in laboratory refrigerators.

The Veterans Integrated Service Network and Facility Directors concurred with the report. No further action is required.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, VA Heart of Texas Health Care Network (10N17)

SUBJECT: Healthcare Inspection – Laboratory Processing Delays and Environmental Safety Concerns, VA North Texas Health Care System, Dallas, Texas

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding laboratory processing delays and environmental concerns at the VA North Texas Health Care System (HCS) (facility) in Dallas, TX.

Background

The facility is part of Veterans Integrated Service Network 17 and provides a broad range of inpatient and outpatient healthcare services to nearly 500,000 veterans in 40 counties in northern Texas and southern Oklahoma. The facility has 613 hospital beds and 240 Community Living Center beds.

Veterans Health Administration (VHA) policy identifies procedures and requirements for VA clinical and anatomic pathology laboratories in facilities' Pathology and Laboratory Medicine Service (P&LMS) and requires that all VA laboratory tests comply with the requirements of Congress' Clinical Laboratory Improvement Amendments, The Joint Commission, College of American Pathologists, and Occupational Safety and Health Administration (OSHA).[1] These requirements include ensuring positive identification of a patient specimen and that all reported laboratory complaints are investigated and corrective actions taken, when indicated.

VHA[2] and OSHA[3] require identification of all operations that involve hazardous chemicals and minimizing staff exposure to chemicals by establishing standard operating

[1] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 6, 2008.
[2] VHA Handbook 1106.01.
[3] OSHA, *Occupational Exposure to Hazardous Chemicals in Laboratories Standard* (29 CFR 1910.1450).

procedures, requirements for personal protective equipment, and procedures for waste disposal.

VHA requires preventative care to be provided to women veterans including cervical cancer screening.[4] One cervical cancer screening method is the Papanicolaou (Pap) test or smear.[5] The Pap test is a way to detect abnormal cervical cells that could develop into cancer if left untreated. Although the College of American Pathologists has no requirement for the turnaround time for Pap tests,[6] it does require active surveillance of laboratory activities and evaluation of results to ensure timely reporting.[7]

In October 2012, a complainant contacted the OIG's Hotline Division with allegations of laboratory processing delays and environmental concerns at the facility. Specifically, the complainant alleged that:

- Specimen containers have unreadable labels that cannot be matched to the paperwork received.
- A patient went to a private provider for a Pap test because of delays receiving results through the VA, and it was positive for cancer.
- Service leadership took no action when the Pap test delays were reported.
- The ventilation system in the Histology laboratory is not adequate.
- Chemicals and explanted pacemakers are not appropriately stored and disposed.
- Food and drinks are stored in refrigerators meant for laboratory items.

Scope and Methodology

We interviewed the complainant on December 4, 2012. We reviewed policies and procedures and evaluated Pap test specimen processing times using facility-provided data from September 2011 through October 2012. We interviewed facility leadership and staff, and observed various areas of P&LMS during an onsite inspection on December 7, 2012.

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.

[4] VHA Handbook 1330.01, *Health Care Services For Women Veterans*, May 21, 2010.
[5] National Cancer Institute at the National Institutes of Health website, http://www.cancer.gov/cancertopics/factsheet/detection/Pap-HPV-testing, accessed November 19, 2012.
[6] College of American Pathologists website, http://www.cap.org/apps/cap.portal, accessed November 19, 2012.
[7] Commission on Laboratory Accreditation, Laboratory Accreditation Program, "Cytopathology Checklist," 2007.

Inspection Results

Issue 1: Specimen Processing Issues

We did not substantiate that specimen labels were unreadable and could not be matched to the paperwork received, that a patient had a diagnosis of cancer by an outside provider because of VA processing delays, or that leadership did not act when a delay was reported.

Specimens are typically received in zipped, plastic biohazard bags with the required paperwork on the outside of the bag in an attached plastic pocket. The complainant stated that specimen labels did not consistently contain the same required elements as on the paperwork that accompanied them. When this occurs, it is standard operating procedure to return the specimen and paperwork to the sender for correction. Furthermore, the complainant did not believe that lab results were ever entered for the wrong patient.

The complainant could not identify the patient that was allegedly diagnosed with cancer by an outside provider because of the delayed processing by the facility. However, the Chief of P&LMS knew the patient, that testing was delayed, and that the patient's Pap test was normal.

The Chief of P&LMS expects Pap test turnaround time to be within 14 days but reported that during the second week of September 2012, Pap specimens were not consistently processed as required. There were 96 Pap tests that were not processed in a timely manner. The Chief of P&LMS contacted the primary care providers of all affected patients, expedited the testing of the specimens, and ensured that the 18 patients with abnormal test results were referred to the Women's Health Physician for follow up. The Chief of P&LMS had previously taken steps to correct issues that resulted in Pap specimen processing delays.

Additionally, we reviewed the average turnaround time (specimen arrival in the laboratory to screening result entry in the electronic health record) for Pap testing at the facility. The average turnaround time from September 2011 through October 2012 was 11.61 days, with a range of 9.63 to 14.89 days.

Issue 2: Environmental Safety Concerns

We did not substantiate that the ventilation system was inadequate, chemicals are stored and disposed improperly, explanted pacemakers are inappropriately stored, or there were food and drinks in refrigerators meant for laboratory items.

We did not find inadequate ventilation within P&LMS. We found that the ventilation issues within P&LMS had been reported from March through June 2011. In August 2011, the facility had an outside contractor assess the indoor air quality in the

two areas of concern reported by staff, Office of Information & Technology and P&LMS. The contractor recommended P&LMS staff exposure monitoring for xylene and formaldehyde to ensure the permissible exposure limit for xylene was not exceeded. The facility complied with the recommendation and performed exposure testing of P&LMS staff for ethyl alcohol, formaldehyde, methanol, and xylene. None of the exposure testing results showed staff overexposure to any of the chemicals tested. The lab continues to log and investigate all employee-reported chemical fumes and conduct exposure testing of employees.

We did not find that flammable and hazardous chemicals, explanted pacemakers, or food and drink were improperly stored; nor were any such instances of non-compliance observed during the College of American Pathologists inspection in March 2012, the OSHA inspection in September 2012, or our onsite inspection of P&LMS.

Conclusions

We did not substantiate any of the allegations.

Leadership took processing delays seriously, and actions were taken to expedite specimen testing for the patients affected, as well as prevent future problems with Pap specimen processing. Appropriate processes are in place for specimen receipt and processing to ensure that specimens are linked to the correct patient.

Complaints by facility staff about chemical fumes were taken seriously, and action was taken to ensure staff safety. The facility continues to maintain an active process to monitor staff for hazardous chemical exposure and investigate reports of chemical fumes when they occur. P&LMS was reviewed within the last few months by the College of American Pathologists and OSHA without findings in these areas. There was no food or drinks in refrigerators meant for laboratory items during our onsite inspection.

We made no recommendations.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the report. No further action is required.

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

Appendix A

Veterans Integrated Service Network Director Comments

Department of Veterans Affairs **Memorandum**

Date: January 22, 2013

From: Director, VA Heart of Texas Health Care Network (10N17)

Subject: **Healthcare Inspection – Laboratory Processing Delays and Environmental Safety Concerns, VA North Texas Health Care System, Dallas, Texas**

To: Director, Dallas Office of Healthcare Inspections (54DA)

Thru: Director, VHA Management Review Service (VHA 10AR MRS OIG Hotlines)

1. Thank you for allowing me to respond to this Healthcare Inspection – Laboratory Processing Delays and Environmental Safety Concerns, VA North Texas Health Care System, Dallas, TX.

2. I concur with the findings of the investigation.

3. If you have further questions regarding this inspection, please call Denise B. Elliott, VISN 17 HSS at (817) 385-3734.

(*original signed by*:)

Lawrence A. Biro
Director, VA Heart of Texas Health Care Network (10N17)

Appendix B

Facility Director Comments

Department of Veterans Affairs **Memorandum**

Date: January 14, 2013

From: Director, VA North Texas Health Care System (549/00)

Subject: **Healthcare Inspection – Laboratory Processing Delays and Environmental Safety Concerns, VA North Texas Health Care System, Dallas, Texas**

To: Director, VA Heart of Texas Health Care Network (10N17)

1. We appreciate the opportunity to review the draft report of the healthcare inspection completed December 4, 2012, at the VA North Texas Health Care System in Dallas, TX.

2. North Texas Health Care System strives to continue to provide exceptional care to our veterans. We welcome the opportunity to continually improve the quality of our service.

3. If you have any questions, please call Tracye Davis, Executive Assistant to the Director at (214) 857-1175.

(*original signed by*:)

Jeffery Milligan
Director, VA North Texas Health Care System (549/00)

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Acknowledgments	Cathleen King, MHA, CRRN, Project Leader Larry Ross, MS Jerome Herbers, MD, Medical Consultant Misti Kincaid, BS, Management and Program Analyst

Appendix D

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