Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Clinical Laboratory Issues
Cheyenne VA Medical Center
Cheyenne, Wyoming

Report No. 05-02085-13 **November 1, 2005**

VA Office of Inspector General
Washington, DC 20420

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

TO: VISN 19 Director

SUBJECT: Healthcare Inspection - Clinical Laboratory Issues, Cheyenne VA Medical Center, Cheyenne, Wyoming

Purpose

The Department of Veterans Affairs Office of Inspector General's (OIG) Office of Healthcare Inspections (OHI) reviewed the allegations of unreliable laboratory test values and inadequate management response at the Cheyenne VA Medical Center (facility), Cheyenne, Wyoming. The purpose of the inspection was to determine the validity of the allegation.

Background

The facility is a primary and secondary treatment facility and provides a broad range of inpatient and outpatient health care services. Outpatient care is provided at three community based outpatient clinics (CBOCs) located in Fort Collins and Greeley, Colorado; and Sidney, Nebraska. The facility is part of Veterans Integrated Service Network (VISN) 19 and serves a veteran population of about 49,500 in a primary service area that includes 17 counties in Wyoming, Colorado, and Nebraska.

The complainant, a CBOC physician, alleged unreliable laboratory tests associated with falsely elevated potassium levels, inconsistent white blood cell counts (WBC), and erroneous high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol values. In addition, the complainant alleged that facility managers did not adequately address these concerns when they were brought to their attention.

To evaluate the reliability of these laboratory values, it was essential to determine if appropriate controls were in place to ensure the accuracy of these test results. The VA has designated the College of American Pathologists (CAP) to inspect and accredit Veterans Health Administration laboratories for all phases of testing. CAP accreditation

generally signifies compliance with laboratory quality standards. Accredited laboratories are required to participate in external proficiency testing (PT) and to perform internal quality control (QC) evaluations to ensure accuracy and comparability of test results between laboratories. We confirmed that the facility laboratory received CAP re-accreditation in June 2005.

In addition, it was necessary to determine if actions should have been taken by facility managers to minimize variability, which may have been responsible for the alleged erroneous laboratory results. To do so, we examined the three analytical phases of testing: (1) correct specimen collection and processing (pre-analytic), (2) prompt and accurate analysis and recording of results (analytic), and (3) appropriate interpretation and reporting of results (post-analytic). Studies have shown that variability is inherent to any laboratory testing and that most variation occurs in the pre-analytic phase.[1,2,3]

The pre-analytic phase of testing at CBOCs is outside the control of the main laboratory. The CBOC technicians collect and process all specimens. A private courier transports the specimens from the Fort Collins and Greeley CBOCs to the main laboratory in Cheyenne for analysis. Because courier delivery occurs late in the afternoon, the majority of these samples are stored in the main laboratory and not analyzed until the next business day.

Scope and Methodology

We visited the facility from June 7-9, 2005, and interviewed the complainant, facility managers, a pathologist, the quality manager, and laboratory staff. We consulted VHA Regional Laboratory Commissioners and a chemist outside VISN 19 to discuss laboratory practices. We reviewed relevant documents, including policies and procedures; product instructions; and QC, PT, and calibration records.

We conducted the inspection in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

[1] Gordon Schectman, et al., "Variability in cholesterol measurements: comparison of calculated and direct LDL cholesterol determinations," *Clinical Chemistry*, 42:5 (1996): 732-737.
[2] Becton-Dickinson, "Troubleshooting Erroneous Potassiums in a Clinical Laboratory Setting," *Lab Notes*, Vol. 13, No. 3, (Summer 2003).
[3] Becton-Dickinson, "Managing Preanalytical Variability in Hematology," *Lab Notes*, Vol. 14, No. 1, (2004).

Inspection Results

Issue 1: Unreliable Laboratory Values

We substantiated the complainant's allegation of unreliable laboratory values associated with falsely elevated potassium levels and inconsistent WBC counts caused by inappropriate practices in the pre-analytic phase of testing. However, we did not find evidence that the HDL and LDL cholesterol values were erroneous. Therefore, we did not substantiate this portion of the allegation.

a. Potassium

In February 2004, the complainant ordered two blood samples to be obtained from a CBOC patient and processed at different laboratories in order to compare results. The first sample, collected and processed by a CBOC technician and analyzed at the main laboratory, had an abnormal potassium value of 6.5 milliequivalents/liter (meq/l).[4] The second sample, collected and analyzed 27 minutes later at a private laboratory within the proximity of the CBOC, had a normal potassium level of 4.6 meq/l. The complainant suspected that the facility result was erroneous.

Secondary (confirmatory) testing[5] at a private laboratory verified the accuracy of the facility results, indicating that the inconsistent values may be attributable to the pre-analytic phase of testing. During the next 5 months, the laboratory manager and CBOC staff implemented several actions in an effort to minimize inconsistencies, including use of proper blood collection techniques and the adjustment of the centrifuge speed to ensure optimal sample separation.

Concurrently, the complainant analyzed the potassium results from samples obtained at the CBOCs and the facility.[6] He observed that about 8-9 percent of the samples obtained at the CBOCs had higher potassium levels. He hypothesized that the time required to transport specimens to the facility caused the elevated values.

The laboratory manager consulted with a product representative from Becton-Dickinson (BD).[7] The representative stated that the blood collection tubes used by CBOC staff were intended for samples that would be analyzed within 2 hours of collection.[8] These tubes were not appropriate for use at the CBOC because the additional time required to

[4] Facility reference (normal) range for potassium is 3.5-5.1 meq/l.
[5] Confirmatory test result was 6.2 meq/l.
[6] Based on samples collected before 12:00 p.m. from March to August 2004.
[7] Becton-Dickinson is the manufacturer of the blood collection system.
[8] BD product information.

transport specimens to the main laboratory prevented timely processing. The laboratory manager immediately replaced the existing tubes with the correct product.

We concluded that improper use of blood collection tubes is the most likely explanation for one known erroneous potassium level and may have contributed to other elevated results. However, the laboratory manager needs to continue to monitor patient results until specimen integrity from the CBOCs is assured.

b. White Blood Cell Count

In December 2004, the complainant reported concerns regarding inconsistent WBC values involving one of his patients. The patient had been diagnosed with Chronic Lymphocytic Leukemia (CLL)[9] and was receiving care at both the Cheyenne and the Eastern Colorado Healthcare System (Denver) facilities. The complainant noted that the test results in 2004 varied between facilities by as much as 50 percent.[10] According to the complainant, this patient had not undergone any treatment that might have explained the discrepancies.

The laboratory manager determined that blood samples at the Cheyenne CBOC were being mechanically mixed, using a tube rocker, beyond the manufacturer's recommendations. While this practice may not affect patients with normal cells, CLL patients have fragile cell membranes, and excessive mixing may cause cell fragmentation and reduce WBC values. The laboratory manager immediately instructed staff to discontinue rocking blood samples. Instead, he recommended that the staff manually invert the tubes several times to thoroughly mix the blood. We subsequently reviewed the medical records of the above patient and determined that the corrective action taken by the laboratory and CBOC staff had resolved the inconsistent WBC values for this patient.[11]

We concluded that an inappropriate laboratory practice related to specimen handling (over mixing) resulted in erroneous WBC values. We substantiated the complainant's allegation; however, because facility managers had already taken appropriate corrective actions, we did not make any recommendations.

[9] CLL is a type of cancer in which the bone marrow makes too many lymphocytes (a type of white blood cell). It is a blood and bone marrow disease and it is the second most common type of leukemia in adults.
[10] Denver VAMC: 44 (February), 50.2 (June), and 50.5 K/cmm (September); Cheyenne VAMC 12.6 (March), 20.4 (August) and 28.3 K/cmm (December).
[11] Progress notes recorded on July 13, 2005, reported WBC counts of 41.2 K/cmm from both facilities.

c. HDL and LDL Cholesterol

In November 2004, the complainant notified facility managers of a shift in HDL and LDL values. He had been monitoring these values for some time and observed a significant change. He detected a decrease in HDL values with a corresponding increase in calculated LDL results. Because clinicians refer to these values to establish a patient's risk for developing cardiovascular disease, the complainant was concerned that treatment decisions were being based on erroneous HDL and LDL results.

The laboratory manager acknowledged that the laboratory started using a new reagent to test HDL in July. In October, he consulted Dade-Behring (DB), reagent manufacturer, when he noticed a significant change in QC values. The DB representative acknowledged that the new reagent would produce lower, but more accurate results.

While we recognize the complainant's concerns about the change in HDL and LDL values, we did not find evidence of laboratory errors that caused this shift. Therefore, we did not substantiate this allegation. We determined that the laboratory employed acceptable testing methods[12] and performed appropriate quality measures.[13] However, we concluded that better communication between laboratory staff and clinicians regarding the expected shift in HDL and LDL values might have mitigated concerns regarding the accuracy of results. In addition, had laboratory staff incorporated actual patient specimens in their initial QC/calibration process, earlier recognition of the shift in values might have been identified.

Issue 2: Management Response

We did not substantiate the allegation that facility managers insufficiently addressed the complainant's concerns.

During our interview with the complainant, he acknowledged that the corrective actions taken to address the erroneous potassium and WBC results were adequate. However, the complainant continues to have concerns about the shift in HDL and calculated LDL values resulting from the new reagent introduced by the manufacturer. While he believes that systematic errors still occur, we found no evidence contrary to what CAP and the facility had already established. Our review of electronic mail correspondence and minutes from Laboratory Quality Assurance and Medical Staff meetings indicated that managers were responsive and timely in addressing the complainant's concerns.

[12] DB new product announcement packet dated March 17, 2004, and subsequent technical bulletin dated March 10, 2005. This new method was certified by the Cholesterol Reference Method Laboratory Network.
[13] CAP Proficiency Survey Results and QC data were within acceptable limits for HDL.

Conclusions

We concluded that improper practices in the pre-analytic phase of testing resulted in erroneous potassium and WBC values. We determined that facility managers took appropriate corrective actions to address the WBC concerns. However, until the integrity of CBOC specimens is assured, the laboratory manager needs to monitor patient potassium values to ensure accurate results.

We concluded that HDL and LDL values were accurate but may have been misleading because the laboratory manager had not immediately notified clinicians of the expected shift in values when a new reagent was introduced. Complete and timely communication might have alleviated clinical concerns.

Overall, managers were responsive to the issues reported by the complainant. Appropriate interventions were implemented to address all concerns, and no negative patient outcomes were identified.

Recommendations

The VISN Director should ensure that the facility Director instructs the laboratory manager to:

a. Monitor patient laboratory results and take appropriate actions to ensure the integrity of specimens from CBOCs.
b. Notify clinicians of changes in test methodologies that could affect patient results.

VISN 19 Director Comments

The VISN Director concurred with the recommendations. The medical center Risk Manager will provide administrative oversight of the monitoring process, there will be a periodic evaluation of specimen integrity over a 3-month period, and the Laboratory Manager has already begun notifying clinicians of changes.

Inspector General Comments

The VISN Director agreed with the recommendations and provided acceptable implementation plans. We will monitor the implementation of these recommendations.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: September 14, 2005

From: VISN 19 Network Director

Subject: Healthcare Inspection – Clinical Laboratory Issues, Cheyenne VA Medical Center, Cheyenne, Wyoming – Project Number: 2005-02085-HI-0227

To: Assistant Inspector General For Healthcare Inspections

Thru: Director, Management Review Service (10B5)
VA Central Office, Washington, D.C.

1. Thank you for the opportunity to review the Draft Report of this Healthcare Inspection. I concur with the Office of Inspector General's inspection findings. The recommended improvement actions are attached.

2. Should you have any questions regarding the action plans, please contact the Quality Manager at the Cheyenne VAMC, Laurel Williams, at (307) 778-7525.

Lawrence A. Biro

LAWRENCE BIRO
Network Director
VISN 19 Rocky Mountain Network

cc: David M. Kilpatrick, MD
Cheyenne VAMC
Medical Center Director

OIG RECOMMENDATIONS FOR CLINICAL LABORATORY ISSUES
CHEYENNE VAMC, CHEYENNE, WYOMING
Project Number-2005-02085-HI-0227

September 14, 2005

Recommendation: Monitor patient results and take appropriate actions to ensure the integrity of specimens from CBOC's

Concur **Target Completion Date**: December 19, 2005

a. The Director, Patient Care Service Line and the Medical Center Director will temporarily assign the medical center risk manager (also a Medical Technologist) to the administrative oversight of the monitoring process.

b. There will be periodic evaluation of specimen integrity over a 3-month period, October 1, 2005, through December 31, 2005. This will be accomplished by periodically comparing patient lab results at the CBOC's with the hospital results. Worksheets will be developed to track progress.

Recommendation: Notify clinicians of changes in test methodologies that could affect patient results.

Concur **Target Completion Date**: September 5, 2005

a. The Laboratory Manager has already notified clinicians of changes. He recently notified them of changes in INR results (September 5, 2005) and the differences that may be seen in patient lab results.

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	Julie Watrous, Director, Los Angeles Office of Healthcare Inspections (310) 268-3005
Acknowledgements	George Wesley, MD Daisy Arugay

Appendix C

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