Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 14-02576-40

Healthcare Inspection

Point of Care Testing Program Concerns
Louis Stokes Cleveland VA Medical Center
Cleveland, Ohio

December 1, 2015

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to complaints about lapses in policy compliance and quality oversight for the point of care testing program by Pathology and Laboratory Management Service at the Louis Stokes Cleveland VA Medical Center (facility), Cleveland, OH.

A complainant alleged that some facility staff members improperly shared point of care operator identification barcodes with those who had not been issued identification barcodes or whose identification barcodes had lapsed due to lack of training. The complainant alleged that some patient point of care laboratory values could not be linked to the correct patient's electronic health record because operators entered incorrect patient identifiers. The complainant also alleged that management failed to track misuse of operator identifications and incorrect patient identifiers, including unresolved errors, and that testing operators were not trained in accordance with facility policy.

We substantiated the allegations that some staff shared test operator identifications and improperly entered patient identifiers. We did not substantiate the allegation that management failed to track misuse of operator identifiers and incorrect patient identifiers including unresolved errors. The facility had a process established to track missing or incorrect patient identifiers; however, we found that managers did not consistently track errors to resolution. We substantiated that staff not trained in accordance with facility policy and procedure were performing tests, and we found weaknesses in the training and competency assessment process, which may have been a contributing factor.

We recommended that the Facility Director ensure that point of care testing policies related to proper identification of patients and test operators comply with all Veterans Health Administration requirements and that point of care testing policies are enforced to include the management process to track issues of error and system misuse and follow them to resolution. We recommended that the Facility Director ensure that all users have completed orientation, training, and competency assessment in accordance with facility and Veterans Health Administration policy. Further, we recommended that the Facility Director evaluate circumstances when sharing or misuse of barcode identifiers became an ongoing practice, in violation of policy, and confer with the Office of Human Resources and the Office of General Counsel to determine appropriate administrative action, if any.

Comments. The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and initiated a comprehensive corrective action plan to address all recommendations. (See Appendixes A and B, pages 12–15 for the Directors' comments.) Since managers have completed all elements of the corrective action plan, we consider the recommendations closed.

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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations regarding lapses in policy compliance and quality oversight for the point of care testing (POCT) program at the Louis Stokes Cleveland VA Medical Center (facility), Cleveland, OH.

Background

The facility is a 660-bed tertiary care facility in Veterans Integrated Service Network 10. In addition to its main campus in Cleveland, the facility provides care throughout northern Ohio at 13 community based outpatient clinics, 3 Vet Centers, 2 Comprehensive Resource Referral Centers, a Psychosocial Resource Rehabilitation Center, a chronic dialysis center, and an ambulatory surgery center.

Requirements for Point of Care Testing

Veterans Health Administration (VHA) laboratories must meet the requirements of the Clinical Laboratory Improvements Amendments (CLIA)[1] for all laboratory testing, including POCT and testing at all other ancillary locations. POCT refers to laboratory services performed within the health system but outside the physical limits of the main clinical laboratory.[2] Facility policy refers to POCT as ancillary testing, and the out-of-laboratory locations as ancillary test sites.[3] Non-laboratory staff, for example physicians and nurses, perform POCT at the patient's bedside. The complexity of the tests determines the qualifications and training requirements of the test operator.[4]

Some tests are classified by CLIA as waived tests because they are simple, have a low risk for incorrect results, and can be performed without routine regulatory oversight. These simple tests can be performed at the point of care and include those cleared for home use. However, CLIA advises that waived tests are not completely error-proof, and they need to be performed correctly by trained personnel in an environment where good testing

[1] The Clinical Laboratory Improvement Amendments (CLIA) are federal regulatory standards that establish a program to regulate laboratories that perform testing on patient specimens to ensure accurate and reliable test results. The CLIA regulations (42 CFR 493) apply to laboratory testing in all settings including commercial, hospital, and physician office laboratories. *CLIA Fact Sheet ICN 006270*, July 2014, US Department of Health and Human Services, Centers For Medicare & Medicaid Services, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1243307.html. Accessed on November 13, 2014.
[2] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 6, 2008. This Handbook was scheduled for recertification by the end of October 2013 but has not yet been recertified.
[3] Louis Stokes Cleveland VA Medical Center, Medical Center Policy 113-004, *Ancillary Testing/Point of Care Testing Programs*, December 4, 2012.
[4] FDA, Medical Devices, CLIA Categorizations, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm393229.htm (and) CDC, CLIA, Test Complexities, http://wwwn.cdc.gov/clia/Resources/TestComplexities.aspx. Accessed on November 13, 2014.

practices are followed.[5] VHA and facility policy requires training and ongoing competency assessments for individuals performing all patient testing, including POCT.[6,7] CLIA non-waived tests are of moderate or high complexity with more stringent standards for quality control, personnel qualifications, and responsibilities.

An example of a CLIA waived test is the glucometer blood glucose test. Facility laboratory managers reported that this test accounted for up to 90 percent of POCT. A glucometer is a device intended to measure glucose quantitatively in the blood.[8] Providers use blood glucose measurements mainly in the treatment of patients with diabetes.[9]

The kaolin activated clotting time (ACT) is an example of a CLIA non-waived test, classified as moderately complex.[10] To perform this test, the facility uses an i-STAT® portable clinical analyzer, a device that accommodates multiple cartridges, each designed to perform different laboratory tests. One of its more frequent applications is in the operating room to monitor high dose heparin[11] during cardiovascular surgery.

Facility POCT Program

Facility policy cites 12 POCT procedures performed outside of the main hospital laboratory at ancillary testing sites within the hospital, at community based outpatient clinics, and in the home based primary care setting.[12] The facility provided additional information indicating these 12 procedures involved 24 different testing options utilizing different test equipment.

[5] US Centers for Disease Control and Prevention, CLIA, Waived Tests, http://wwwn.cdc.gov/clia/Resources/WaivedTests/. Accessed on November 13, 2014.
[6] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 6, 2008.
[7] Louis Stokes Cleveland VA Medical Center, Medical Center Policy 113-004, *Ancillary Testing/Point of Care Testing Programs*, December 4, 2012.
[8] Blood sugar, or glucose, is the main sugar that the body makes from food eaten. Glucose is carried through the blood to provide energy to the body cells. US National Library of Medicine. http://www.nlm.nih.gov/medlineplus/bloodsugar.html. Accessed on November 13, 2014.
[9] US Food and Drug Administration; Regulatory Information, Guidance Document, Review Criteria for Assessment of Portable Blood Glucose Monitoring, http://www.fda.gov/RegulatoryInformation/Guidances/ucm094134.htm. Accessed on November 13, 2014.
[10] Code of Federal Regulations Title 21 Sec. 864.7140 - activated whole blood clotting time tests.
[11] Heparin is used to prevent blood clots from forming in people who have certain medical conditions or who are undergoing certain medical procedures that increase the chance that clots will form. Heparin is in a class of medications called anticoagulants ('blood thinners') that works by decreasing the clotting ability of the blood. US National Library of Medicine. http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682826.html. Accessed on November 13, 2014.
[12] Louis Stokes Cleveland VA Medical Center, Medical Center Policy 113-004, *Ancillary Testing/Point of Care Testing Programs*, December 4, 2012.

A supervisory medical technologist[13] manages the POCT program with four staff members including a senior medical technologist, two medical technologists, and a medical technician. The supervisory medical technologist works under the direction of the Chief of Pathology and Laboratory Management Service.

Patient and Operator Identification Procedures for POCT

VHA requires facilities to establish standards, procedures, and policies for reporting timely, accurate, reliable, and clear test results. Staff must enter all laboratory results, regardless of where testing is performed, into the patient's electronic health record (EHR).[14] One of VHA's pathology and laboratory medicine accrediting organizations, The College of American Pathologists[15] Commission on Laboratory Accreditation, requires a documented procedure describing methods for patient identification.[16]

Many devices used for POCT, including the glucometer and the i-Stat® clinical analyzer used by the facility, are designed to accept information that identifies the patient as well as staff operating the test device. An optical scanner built into most devices reads barcodes to uniquely identify both the patient and the operator. Staff identify patients for POCT by scanning unique barcodes embedded on identification wristbands or on preprinted labels that accompany patient charts to the point of care location. Devices also have a key pad for manual entry of patient identification in the event that a patient arrives without a wristband barcode.

POCT device operators scan their assigned operator identification barcodes, usually affixed to a VA identification badge, establishing them as the unique device operator for each POCT procedure.[17] Some devices, such as the i-STAT® analyzer, also allow for manual keypad entry of operator identification. Glucometers at the facility, however, require scanning of an operator barcode. Operator identification barcodes are issued following completion of competency training for each specific device that the operator is authorized to use. If operators fail to complete refresher training, their competency expires, and the POCT software prevents their access to devices.

Test results are electronically transferred from the POCT device to the patient EHR. To ensure that POCT operators enter accurate information, the facility uses Precision Web®

[13] Medical technologists and medical technicians collect samples and perform tests to analyze body fluids, tissue, and other substances. Supervisory positions in a laboratory are typically held by medical technologists who have a higher level of education (for example, a bachelor's degree). Medical technicians usually need an associate's degree or a postsecondary certificate. US Department of Labor, Bureau of Labor Statistics. http://www.bls.gov/ooh/healthcare/medical-and-clinical-laboratory-technologists-and-technicians.htm. Accessed on November 12, 2014.
[14] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures,* October 6, 2008.
[15] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures* mandates that all laboratory testing within VA used for the diagnosis, treatment, and prevention of disease in patients must meet the requirements of certain accrediting organizations including, The College of American Pathologists.
[16] *Point of Care Checklist* POC.04300, College of American Pathologists Commission on Laboratory Accreditation July 2011.
[17] *Point of Care Checklist* POC.04700, College of American Pathologists Commission on Laboratory Accreditation July 2011.

(P-Web) software to verify patient and operator identifiers and to block transmission of inaccurate data to the patient EHR if there are errors in either of the identifiers.

Allegations

A complainant alleged lapses in policy compliance and quality oversight of the facility's POCT program. Specifically the complainant alleged that:

- POCT operators improperly shared operator barcode identifications with those who had not been issued barcode identifications or whose identifications had expired due to lapses in training.
- Laboratory personnel were unable to link POCT values to the correct patient EHRs because operators entered incorrect patient identifiers.
- Management failed to track misuse of operator identifications and incorrect patient identifiers including unresolved errors.
- Staff did not receive adequate training in POCT.

Scope and Methodology

The period of our review was August 2014–April 2015. We conducted a site visit September 10–11 2014. We interviewed laboratory personnel; physicians; and other clinical, supervisory, and administrative staff. We reviewed relevant facility policies and procedures, training materials, manufacturer's descriptions of equipment, and results of a POCT audit conducted by the facility.

We **substantiated** allegations when the facts and findings supported that the alleged events or actions took place. We **did not substantiate** allegations when the facts showed the allegations were unfounded. We **could not substantiate** allegations when there was 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.

Inspection Results

Issue 1: POCT Identification Errors

We substantiated the allegation that staff improperly shared operator barcode identifications and entered incorrect patient identifiers.

Operator Identifier Errors

Current facility policy, which was established in September 2014, prohibits sharing operator identifier barcodes and considers doing so a reportable security violation.[18] Facility managers noted that prior to the issuance of the current POCT Barcode Label policy, all facility staff had completed annual security training related to VA data systems, which includes the National Rules of Behavior. The National Rules of Behavior include the following statement, "I will not share my password or verify codes. I will protect my verify codes and passwords from unauthorized use and disclosure. I will not divulge a personal username, password, access code, verify code, or other access requirement to anyone." The facility considers the National Rules of Behavior as applicable to the security of POCT operator identifiers including the barcodes.[19]

We learned that staff used the barcode identifiers of co-workers to access devices when their access was blocked due to an expired competency. Nursing staff told us that they had some knowledge of "borrowing or loaning" on infrequent occasions, but only one admitted to "loaning" a barcode identifier. However, the Chief of Anesthesiology and some anesthesiology staff reported sharing barcode identifiers as an acceptable practice in the operating room and a necessity to ensure uninterrupted care when staff failed to complete required POCT training and had their operator identification barcodes revoked. They felt the requirement to repeat POCT competency assessment every 6 months was burdensome given their lack of administrative time and felt that borrowing another staff member's operator barcode prevented disruptions in patient care. They acknowledged that facility policy prohibits sharing operator barcodes but felt it was a reasonable practice when both staff members involved were in the same room with the patient.

The Chief of Anesthesia also felt that because anesthesia staff are highly skilled and perform these tests regularly, competency testing could be less frequent than every 6 months and that designated anesthesia personnel could conduct the testing. Laboratory staff clarified that 6-month competency testing occurs during the first year following new operator training on devices but, thereafter, testing occurs annually.

A lack of communication between operating room staff, primarily anesthesia staff, and laboratory staff led to additional misunderstandings related to the POCT program and

[18] Louis Stokes Cleveland VA Medical Center, *Point of Care Testing, Operator (DUZ) Barcode Label Policy*, September 9, 2014.
[19] VA Handbook 6500, *Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program*, September 20, 2012, Appendix D - Department of Veterans Affairs National Rules of Behavior.

sharing barcode identifiers. Laboratory personnel believed that anesthesia residents and Certified Registered Nurse Anesthetist (CRNA) students did not perform POCT procedures and, therefore, did not require barcodes. However, anesthesia staff and the Chief Perfusionist[20] reported that anesthesia residents are operators and access the POCT system by borrowing barcodes. The Chief Perfusionist told us that CRNA students are also operators and borrow barcodes to perform POCT procedures.

Other factors that may have contributed to barcode sharing included inconsistencies in the laboratory training process, the lack of a standardized system to facilitate training and supervisory oversight, and insufficient administrative time to complete training and competency assessments.

Nurse educators conduct glucometer training for nursing employees as part of the orientation process, and laboratory staff conduct the subsequent 6-month competency training for new employees and the annual competency training required thereafter. However, laboratory staff informed us of inconsistencies between nursing[21] and laboratory[22] versions of the training material. Nursing training materials covered POCT procedures but did not include policy requirements or barcode security. Thus, nursing staff did not receive training regarding sharing barcodes when performing POCT.

In addition, the Chief of Anesthesia felt that some competency test questions were not appropriate for non-laboratory staff, thereby frustrating non-laboratory staff and enforcing their hesitancy to complete training and competency testing. Laboratory staff also noted that although there is a detailed checklist for training on the i-Stat® system, no such checklist exists for glucometer training. Therefore, trainers rely on memory to complete each step and may miss a step during glucometer training, including barcode security.

A standardized system known as the Talent Management System (TMS) is used throughout VA to facilitate and track competency and other mandated training. However, the facility does not utilize this system for POCT competency. Although the POCT system locks out test operators when their competency expires, their supervisors are not officially aware of this issue until informed by email or phone calls from the laboratory. Laboratory staff suggested that incorporating POCT training into TMS would make supervisory oversight more efficient and improve employee access to testing.

Patient Identifier Errors

Of the 93,214 POCT procedures performed from October 1, 2013, through April 1, 2014, the facility audit found 149 patient identifier errors. Of those errors, 85 (56 percent) were corrected within 1 week, and 52 (34 percent) were identified as illicit

[20] A perfusionist operates equipment to support or temporarily replace the patient's circulatory or respiratory function during medical procedures, such as cardiac surgery. Commission on Accreditation of Allied Health Professions. http://www.caahep.org/Content.aspx?ID=46 Accessed on March 23, 2015.
[21] *Precision Xceed Pro*®, Power Point Presentation, Louis Stokes Nursing Education Department 2013.
[22] *Point of Care Testing is as simple as 1,2,3!* Power Point Presentation, Louis Stokes Department of Pathology and Laboratory Medicine.

self or friend testing by employees. Managers were unable to resolve 12 errors accounting for 8 percent of errors or 0.13 percent of tests performed. As part of the same audit, the facility reported that staff reviewed the 85 EHRs of the patients who experienced a delay in posting of laboratory results and found no delay in care or adverse medical outcome.

Staff provided additional insight into how patient identifier errors may have unintentionally occurred. A staff member recalled an incident whereby he affixed a patient identifier barcode to a piece of medical equipment to facilitate repeated POCT scans during a surgical procedure. However, he inadvertently scanned the original patient's barcode for subsequent surgical patients in the same area. The correct information was manually entered into each patient's EHR as part of the anesthesia record. The scanned POCT results were identified as errors by the P-Web system.

On another occasion, staff printed incorrect patient identifier barcodes, confusing two patients with the same last name and last four digits of their social security numbers. In both of the above instances, P-Web identified the errors and prevented the incorrect information from being transferred to the EHRs.

Although patient misidentification due to typographical errors during manual keypad entry can occur, on occasion staff must intentionally enter alternative patient identifiers such as when an unresponsive patient presents to the Emergency Department. Under these circumstances, when a patient's identifying information is unavailable, or the patient is unresponsive and unaccompanied by next of kin or a significant other, test operators must manually enter an alternative patient identifier, typically all zeros, to facilitate emergent POCT. When identifying information becomes available, test operators then contact the laboratory to provide proper identification for the test results so they may transfer the results to the correct EHR. Although established procedure allows staff to use an alternative identifier for unidentified patients in an emergency, several staff members told us that some staff enter alternative identifiers, such as all zeros, to perform glucose testing on themselves or a co-worker.

The POCT audit of 93,214 procedures performed during FY 2014 quarters 1 and 2 revealed an operator and patient barcode identifier error rate of 0.41 percent. An audit of 102,214 POCT procedures performed during FY 2014 quarters 3 and 4 indicated a decline in the overall error rate of 0.19 percent. However, facility managers expanded the second audit to include blood chemistry (i-STAT®) and blood gas analysis (GEM), in addition to blood glucose.

Issue 2: Tracking Errors

We did not substantiate the allegation that management failed to track misuse of operator identifiers and incorrect patient identifiers including unresolved errors. The facility had a process established to track missing or incorrect patient identifiers; however, we found that managers did not consistently track errors to resolution.

Facility managers collected data on blood glucose and hemoglobin A1c (HbA1c)[23] POCT conducted during the first 2 quarters of FY 2014. Of the 93,214 POCT episodes conducted at 37 sites within the facility, staff made 128 (0.2 percent) operator errors. Managers reported that 28 operators of the approximately 1,250 operators who conducted POCT during the data collection period were responsible for all of the reported errors.

VHA requires a system to ensure that all pathology and laboratory medicine problems and complaints are documented followed by an investigation and corrective action when indicated.[24] The P-Web software verifies POCT patient and operator identifiers and blocks data transfer to the EHR if there are inaccuracies. Laboratory personnel check the P-Web software daily for errors and send a "please correct" e-mail to the operator who caused the error. The e-mail also notes that operators must respond within 72 hours, or laboratory personnel will terminate their access to the POCT system. Laboratory staff spoke of frequent delays in receiving corrective actions despite repeated notifications to operators and their supervisors.

Since the initial OIG communication with the facility, facility staff has made progress in resolving identifier errors by revising procedures to track errors to resolution. Laboratory staff resolve errors using a newly instituted *Point of Care Data Error Resolution* form. If there is no response to error resolution requests within 48 hours, the operator and supervisor receive a second communication. If there is still no response, reports of the error move up the management chain and eventually elevate to the Chief of Staff and Associate Director for Patient Care Services. POCT staff felt that this change in procedure has reduced the time between identification of errors and corrective actions, and the POCT audits indicated some improvement. In quarters 1 and 2, FY 2014, 56 percent of errors were resolved within a week, whereas 67 percent were resolved within a week during quarters 3 and 4. However, the most notable improvement involved self-testing. In the first audit, 34 percent of patient identification errors were attributed to employee self-testing; this declined to 1.9 percent in the second audit.

In addition to the procedural changes in data error resolution, the facility mandated in-service training for those test operators with high barcode errors. Laboratory staff presented multiple training sessions during different shifts on the nursing units. However, the trainers did not know who the problem users were and if any of them attended the session. Included in our interviews were five nursing staff who were identified as being among the 28 having barcode error issues. At the time of our site visit, none of them had attended the in-service and could not recall any retraining regarding barcode policy and security offered since the beginning of 2014.

[23] The HbA1c test is an indicator of how the blood glucose level has been controlled over a period, whereas results from routine testing with a glucometer are influenced by daily fluctuations in the blood glucose concentration. "Hb" refers to hemoglobin, the oxygen-carrying pigment that gives blood its red color. "A1c" is a designation for the chemical component within hemoglobin to which glucose is bound. *Hemoglobin A1c (HbA1c)*, Emedicinehealth®, http://www.emedicinehealth.com/hemoglobin_a1c_hba1c/article_em.htm Accessed April 2, 2015.
[24] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 6, 2008.

Issue 3: Staff Training

We substantiated the allegation that some staff were not trained in accordance with facility policy.

VHA requires laboratory services and ancillary testing sites to provide training and ongoing competency assessments of the individuals performing patient testing, including POCT.[25] The Clinical Laboratory Assessment Tool used by VA's Pathology and Laboratory Medicine Services National Enforcement Program specifies that facilities must assess new employee competency prior to patient testing and semi-annually for the first year.[26] The College of American Pathologists Commission on Laboratory Accreditation requires semiannual competency testing during the first year of duty, annually thereafter, and whenever problems are identified with employee performance.[27]

Facility policy reflects VHA and industry standards and requires that staff demonstrate competency through an initial and an annual competency assessment while new employee reassessments occur after 6 months.[28,29] The nursing education department conducts initial glucometer blood glucose POCT training while laboratory staff conducts 6-month reassessments. Laboratory staff provide training and reassessments for all other POCT device operators including 6-month reassessments for new employees and annual reassessments. A laboratory computer application maintains competency records, and when the period for a test operator's competency has expired, the operator cannot access the POCT system to perform a test procedure.

An operating room contract perfusionist stated that his POCT training was conducted "on-the-job" by other operating room employees. These co-workers never expressed (to him) a concern about policy violations. He was trained to use the i-STAT® brand portable clinical analyzer to perform the ACT test, which is classified as non-waived or moderately complex by CLIA regulations The POCT laboratory staff was not aware that the employee was performing this test from October 2013 through February 2014. Furthermore, since he had not completed training and competency assessment with laboratory staff, he had no barcode identifier. As a result, he used the barcodes of other staff, which was in violation of facility policy.

During his interview, the employee's supervisor, who was also a contract perfusionist, acknowledged awareness of the policy requiring laboratory staff to conduct training and issue barcode identifiers. He explained that he and his staff provided the new employee

[25] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 6, 2008.
[26] *VA Clinical Laboratory Assessment Tool*, CL.255.05. VA Pathology and Laboratory Medicine Services National Enforcement Program. April 12, 2010.
[27] *Point of Care Checklist* POC.06900, College of American Pathologists Commission on Laboratory Accreditation July 2011.
[28] Louis Stokes Cleveland VA Medical Center. *Pathology & Laboratory Medicine Manual of Laboratory Policies*, 4th Edition, June 2013.
[29] Louis Stokes Cleveland VA Medical Center, Medical Center Policy 113-004, *Ancillary Testing/Point of Care Testing Programs*, December 4, 2012.

with step-by-step instructions on the i-Stat® unit and loaned him their barcode operator identifiers. As a justification for circumventing the policy, he stated that the employee was experienced and had performed the test many times at other facilities, although with a different brand of equipment.

A further reason for not following the POCT policy was attributed to the difficulties that contract employees have "getting into the system" for basic matters like background and fingerprinting and issuance of personal identity verification badges, pagers, or lockers. We were told that access to VA equipment, computers, training, and other processes cannot be accomplished until a contract employee is fully integrated into the VA system. According to the Chief Perfusionist, the facility provides virtually no guidance, support, or oversight for managing contract employees and has no officially designated contact person to speak with regarding administrative matters.

The Chief of Pathology and Laboratory Management Services stated that he investigated the circumstances surrounding the unauthorized training and operator barcode usage by the one contract employee. He did not determine who provided training, but he felt that he obtained sufficient facts to be satisfied that there have been no other employees trained by means contrary to policy. Other laboratory staff who were interviewed also said that, to their knowledge, all other POCT operators in the operating room were trained and completed competency assessments with POCT laboratory staff. They confirmed that there were no authorized trainers in the OR and that all new staff must be trained by laboratory staff.

Despite the situation laboratory staff described during interviews, we received conflicting information during interviews of the Chief of Anesthesia and Chief Perfusionist. They reported that anesthesia residents, who were not trained by laboratory staff, performed POCT in the operating room. Since laboratory staff did not train them, they were not issued barcode operator identifiers and borrowed from other anesthesia staff.

The Chief of Anesthesia noted that residents are highly experienced by the time they arrive at the facility to participate in major cases. He further explained that the POCT devices are the same or similar to POCT devices they have used in the past, and the residents have performed POCT many times. He reasoned that they have so little time at the facility, it does not make sense for the residents to spend a half day in the laboratory learning a procedure they are already familiar with, so he allows them to use his barcode.

Conclusions

We substantiated the allegations that staff improperly shared operator barcode identifications and entered incorrect patient identifiers. We did not substantiate the allegation that management failed to track misuse of operator identifiers and incorrect patient identifiers, including unresolved errors. The facility had a process established to track missing or incorrect patient identifiers; however, we found that managers did not consistently track errors to resolution. By the time of our site visit in September 2014, the facility had made improvements in the process to consistently track and correct these errors.

We also substantiated the allegation that staff not trained in accordance with facility policy and procedure were performing tests. We also identified weaknesses in the competency assessment process that may have contributed to training problems, which could have led to expiration of competency or sharing of barcodes.

Recommendations

1. We recommended that the Facility Director ensure that point of care testing policies related to proper identification of patients and test operators comply with Veterans Health Administration requirements including all accreditation and regulatory standards incorporated in these requirements.

2. We recommended that the Facility Director enforce point of care testing policies to include the management process to track issues of error and system misuse and follow them to resolution.

3. We recommended that the Facility Director ensure that all users of point of care testing equipment complete orientation and ongoing training and competency assessments in accordance with facility and Veterans Health Administration policy, to include contract employees and students.

4. We recommended that the Facility Director evaluate circumstances when sharing or misuse of barcode identifiers became an ongoing practice, in violation of policy, and confer with the Office of Human Resources and the Office of General Counsel to determine appropriate administrative action, if any.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: August 24, 2015

From: Director, VA Healthcare System of Ohio (10N10)

Subj: Healthcare Inspection – Point of Care Testing Program Concerns, Louis Stokes VA Medical Center, Cleveland, Ohio

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

1. The findings from the Office of Inspector General Healthcare Inspection of Inadequate Compliance with Point of Care Testing Policies at the Louis Stokes Cleveland VA Medical Center were reviewed.

2. Attached is the facility response addressing each recommendation.

(original signed by:)
Jack G. Hetrick, FACHE
Network Director, VISN 10

Appendix B

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: August 13, 2015

From: Director, Louis Stokes VA Medical Center (541/00)

Subj: Healthcare Inspection – Point of Care Testing Program Concerns, Louis Stokes VA Medical Center, Cleveland, Ohio

To: Director, VA Healthcare System of Ohio (10N10)

1. The findings from the Office of Inspector General Healthcare Inspection of Inadequate Compliance with Point of Care Testing Policies at the Louis Stokes Cleveland VA Medical Center were reviewed.

2. Attached is the facility response addressing each recommendation.

Susan M. Fuehrer
Medical Center Director

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 point of care testing policies related to proper identification of patients and test operators comply with Veterans Health Administration requirements including all accreditation and regulatory standards incorporated in these requirements.

Concur

Target date for completion: August 31, 2015

Facility response: The Point of Care Testing (POCT) section within Pathology & Laboratory Medicine Service (P&LMS) has reviewed and updated all policies pertaining to identification of patients and operators. Per policy, each POCT operator is required to have a unique identifier when performing POCT testing. POCT staff is solely responsible for issuing barcode identifiers. Operators must present valid identification and sign for all barcodes. Medical center policy prohibits the sharing of barcodes. POCT operators are aware of the policies as part of semi-annual/annual competency assessments. Medical Center Policy 113-004 Ancillary Testing/Point of Care Testing Programs includes newly updated POCT policies.

Recommendation 2. We recommended that the Facility Director enforce point of care testing policies to include the management process to track issues of error and system misuse and follow them to resolution.

Concur

Target date for completion: October 31, 2014

Facility response: Pathology & Laboratory Medicine Service implemented a new process to flag Point of Care Testing (POCT) errors to resolution. POCT staff review and track data on a daily basis to identify errors. POCT staff sends error messages to the POCT operator and Nurse Manager to obtain the correct information. Upon receipt of the correct information, there is closure of the recorded action. POCT staff sends a second message, if no response within 24 hours. If there is no response within 48 hours, the issue is elevated to the POCT Supervisor who reaches out to the Nurse Manager by phone and follow-up email. If the POCT Supervisor is unable to get resolution within one working day, the issue is elevated to the Assistant Chief of Pathology & Laboratory Medicine Service (P&LMS) who pursues resolution through a Chief Nurse. If the issue remains unresolved after speaking with a Chief Nurse, the Chief of P&LMS notifies the Chief of Staff (COS) and the Director of Patient Care Services.

Recommendation 3. We recommended that the Facility Director ensure that all users of point of care testing equipment complete orientation and ongoing training and competency assessments in accordance with facility and Veterans Health Administration policy, to include contract employees and students.

Concur

Target date for completion: June 30, 2015

Facility response: Memorandums of Understanding detailing the process for coordination of new employee and non-employee training, certification and competency for Point of Care Testing were collaboratively developed between POCT staff with Primary Care staff and Anesthesia staff. The agreed upon Memorandums of Understanding for each service were reviewed and signed by the Chief and Assistant Chief of Pathology, Laboratory Medicine Service, the Associate Chief of Staff for Ambulatory Care and the Chief of Anesthesiology. Memorandums of Understanding will continue to be developed and implemented for service specific issues.

Recommendation 4. We recommended that the Facility Director evaluate circumstances when sharing or misuse of barcode identifiers became an ongoing practice, in violation of policy, and confer with the Office of Human Resources and the Office of General Counsel to determine appropriate administrative action, if any.

Concur

Target date for completion: October 31, 2014

Facility response: Executive Leadership ensures robust processes to deter and identify misuse of barcode identifiers. No further instances of misuse and sharing of barcode identifiers have resulted since strengthened oversight. The Chief of Staff reviews compliance during a weekly meeting with Pathology & Laboratory Medicine Service. The Executive Leadership Board receives Point of Care Testing compliance reports on a quarterly basis.

Appendix C

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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