



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

Office of Healthcare Inspections

Report No. 14-04361-348

Healthcare Inspection

**Cardiothoracic Surgery Program and
Cardiac Catheterization Laboratory
Concerns**

**Oklahoma City VA Health Care
System**

Oklahoma City, Oklahoma

August 4, 2016

Washington, DC 20420

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Executive Summary

At the request of former Senator Tom Coburn and an anonymous complainant, the VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted reviews to evaluate the alleged closure of the Cardiothoracic (CT) Surgery program and assess Cardiac Catheterization Laboratory (CCL) medication administration and Omnicell[®] medication dispensing system access issues at the Oklahoma City VA Health Care System (facility), Oklahoma City, OK.

Former Senator Coburn requested that OIG evaluate the circumstances behind the alleged closing of the facility's CT surgery program, including media allegations of five patient deaths.

An anonymous complainant submitted allegations that CCL nurses administered narcotic pain medications and sedatives to patients without physicians present and without physicians' orders. The complainant provided two case examples resulting in possible patient harm but did not provide the patients' names. The complainant also alleged that a nurse manager had access to individual staff passwords in the Omnicell[®] medication dispensing system.

We did not substantiate that the facility closed the CT surgery program. Rather, facility leadership paused CT surgeries in June 2014 in order to evaluate the program following patient deaths. CT patients were seen in clinic, CT surgery consults were answered, and CT surgery referrals were made to VA or non-VA facilities as needed during the pause but no CT surgeries were performed. The CT surgery program underwent multiple site visits by both the Veterans Integrated Service Network 16 Chief Surgical Consultant and Chief Medical Officer as well as a consultative assessment by the Veterans Health Administration's National Surgery Office. CT surgeries resumed in October 2014.

We did not substantiate the allegation that CCL nurses administered medications to patients in the CCL without a physician present who ordered the medication. We found documentation of medication administration in the electronic health records for the 27 CCL patients we reviewed, documentation included the times patients were taken into procedure rooms, when the physicians arrived in the rooms, and the times medications were administered.

We identified and reviewed two CCL patients with circumstances similar to the patients described in the allegations who may have suffered harm related to medication administration. We did not substantiate the allegation that these two CCL patients suffered harm.

We could not substantiate that the nurse manager had staff passwords to the Omnicell[®] and could use the passwords to access and remove medications under another nurse's account. We found that access to the Omnicell[®] is processed through Pharmacy Service, and the user creates his or her own unique password, which is secure unless the user shares it with another individual.

Former Senator Coburn also requested OIG “conduct a thorough investigation of the care and management” of multiple areas of the facility; however, specific allegations or concerns were not provided. In response to this request and additional requests from Senator James Inhofe, we are continuing work to evaluate the facility’s quality management program, analyze data from VA’s Strategic Analytics for Improvement and Learning (SAIL) Value Model report, and follow up on the results of an Employee Assessment Review (EAR) survey. Our results from these reviews will be addressed in a future OIG report.

We made no recommendations.

Comments

The Veterans Integrated Service Network and Interim Facility Directors concurred with the report (See Appendixes A and B, pages 7–8 for the Directors’ comments.) No further action is required.



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

Purpose

At the request of former Senator Tom Coburn and an anonymous complainant, the VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted reviews to evaluate the alleged closure of the Cardiothoracic (CT) Surgery program and assess Cardiac Catheterization Laboratory (CCL) medication administration and Omnicell® medication dispensing system access issues at the Oklahoma City VA Health Care System (facility), Oklahoma City, OK.

Background

The facility is part of Veterans Integrated Service Network (VISN) 19, has 192 operating beds, and serves a patient population of over 225,000. The facility was a part of VISN 16 during our review but moved to VISN 19 in October of 2015. The facility operates nine community based outpatient clinics located in Oklahoma and Texas. Health care is provided through primary, tertiary, and long-term care in the areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, geriatrics, and extended care. The facility is a regional referral center for open-heart surgery.

The facility has an academic affiliation with and is physically connected to the Oklahoma University Medical Center and provides clinical experiences for multiple other disciplines through agreements with more than 15 state, community, and private institutions.

In the last 4 years, the facility has had seven different directors (acting or appointed), with Veterans Health Administration (VHA) leaders currently in the process of selecting a new director. Four Associate Directors (acting or appointed) have been at the facility during the last 2 years.

Allegations

On July 21, 2014, former Senator Coburn requested that OIG evaluate the circumstances behind the alleged closing of the facility's CT surgery program, including media allegations of five patient deaths. The Senator also requested that we "conduct a thorough investigation of the care and management" of multiple areas of the facility. The request to evaluate multiple areas of the facility did not include specific allegations of wrongdoing.

In August 2015, we received new allegations from an anonymous complainant that CCL nurses administered narcotic pain medications and sedatives to patients without physicians present and without physicians' orders. The complainant provided two case examples resulting in possible patient harm but did not provide the patients' names.

Further, the complainant alleged that a nurse manager had access to individual staff passwords in the Omnicell[®] medication dispensing system.¹

Scope and Methodology

We conducted an unannounced site visit on June 26, 2014, and a follow-up site visit March 11–12, 2015. We interviewed facility leadership and staff knowledgeable about the CT surgery program. We reviewed the electronic health records (EHRs) of the five CT surgery patients reported about in the media and other relevant documents.

To evaluate the information received from an anonymous complainant in August 2015 regarding two unidentified patients who received care in the CCL, we identified two patients who feasibly represented the patients by querying facility data in VA's Corporate Data Warehouse using identifying details such as facility location, patient gender, encounter dates, and times, and associated clinic stop codes. We reviewed the EHRs and facility data for these two patients.

We also requested and reviewed facility policies and Pharmacy Service processes for issuing Omnicell[®] access and passwords.

Former Senator Coburn's letter also included a request to "conduct a thorough investigation of the care and management" of multiple areas of the facility; however, specific allegations or concerns were not provided. In response to this request and additional requests from Senator James Inhofe, we are continuing work to evaluate the facility's quality management program, analyze data from VA's Strategic Analytics for Improvement and Learning (SAIL) Value Model report, and follow up on Employee Assessment Review (EAR) survey responses. Our results from these reviews will be addressed in a future OIG report.

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations were unfounded. We **can not substantiate** allegations when there is 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.

¹ An Omnicell[®] is a computer-controlled storage machine that is used for dispensing, tracking, and documenting medications used for patients. At the facility, Omnicells[®] are located in different patient care areas; only licensed individuals can retrieve medications from the machines after entering a unique user access name and password. Additionally, the user must associate the medication removed from the Omnicell[®] to a specific patient.

Inspection Results

Issue 1. Cardiothoracic Surgery

We did not substantiate that the facility's CT surgery program was closed in 2014 because of patient deaths. Rather facility leadership paused CT surgeries to evaluate the CT program in response to those deaths.

Facility leadership voluntarily paused CT surgeries for 4 months in 2012 following the departure of the CT Chief until new staff were recruited. On June 9, 2014, the COS paused cardiothoracic surgeries following the deaths of 5 patients, which were subsequently reported in the media.² During both pauses, CT patients were seen in outpatient clinics, CT consults were answered, and the CCL remained open. In addition, patient evaluations for CT surgeries were performed, and referrals for surgery were made to other VA facilities and non-VA facilities, including the Oklahoma University Medical Center (connected to the facility by a hallway) for emergent cases.

At the time of our unannounced June 2014 site visit, the facility's CT Surgery program had three surgeons who held part-time staff positions at the facility and part-time positions at Oklahoma University Medical Center. In 2013, two surgeons were performing about 58 cases annually; the third surgeon joined the staff in 2014 and worked about 30 days before CT surgeries were paused.

During our visit, we learned that the CT surgery program underwent multiple site visits by both the Veterans Integrated Service Network 16 Chief Surgical Consultant and Chief Medical Officer as well as a consultative assessment by the Veterans Health Administration's National Surgery. As National Surgery Office reports are protected from disclosure under 38 U.S.C. 5705, we are unable to discuss the results of the reviews.³ The facility resumed CT surgeries in October 2014.

Issue 2. CCL

Medication Administration. We did not substantiate the allegation that CCL nurses administered narcotic pain medications and sedatives to patients without physicians present or without physicians' orders. We did not find supporting data that two patients were harmed as a result of such medication administration practices.

A cardiac catheterization is an invasive procedure that is performed in a CCL to identify heart disease. The procedure requires arterial access with the patient positioned flat on an x-ray table. The physician uses a special x-ray machine that provides images during the procedure to evaluate the heart. Although intravenous (IV) sedation is an integral

² Healthcare Inspection – *Temporary Closure of the Cardiothoracic Surgery Program*, Oklahoma VA Medical Center, Oklahoma City, OK (Report No. 14-04480-186, March 20, 2015).

³ VHA Handbook. *National Surgery Office*. January 30, 2013.

component of the procedure, respiratory compromise can result from administering these medications.

In VA, cardiac catheterization procedures are documented in patients' EHRs through the Clinical Assessment, Reporting, and Tracking System for Cardiac Catheterization Laboratory⁴ (CART-CL) data repository. The CART-CL system is part of a national quality program that creates a report and automatically times each entry into the EHR.

In accordance with facility policies, RNs may administer medications pursuant to a verbal order under certain circumstances.⁵ In the CCL, when the ordering physician, who is present in the CCL and is unable to immediately enter an order for a medication that is urgently needed, the RN may accept a verbal order to administer the medication. Documentation of the medication administration must subsequently be completed; in CCL, the documentation is completed through CART-CL.⁶

We reviewed a judgement sample of the patient EHRs for 27 (28 percent) of the 95 cases performed in the two cardiac catheterization procedure rooms from February 1, 2015, through March 10, 2015.⁷ Our reviews focused on narcotic pain medications and sedatives administered during CCL procedures and the timelines for administration. We found documentation of the CART-CL reports in the EHRs for all 27 patients, including the times patients were taken into procedure rooms, when the physicians arrived in the rooms, and the times medications were administered.

We compared the medication administration times in the CART-CL EHRs reports with the medication dispensing times recorded in the Omnicell[®] for all 27 patients to compare when the medications were removed for patient administration and when the physician ordered the medication during the procedure. We matched how much medication was removed, how much was given to the patient, when the patient received it, and who ordered and administered the medication to assess the possibility of medication being administered without a physician present to order the medication during the procedure.

We found that all medications were administered to the patients after the physicians arrived in the CCL. The nurse who removed the medications from the Omnicell[®] was also the nurse who was listed on the CART-CL and signed the final document as administering the medications in all 27 patient EHRs. We did not find that nurses administered narcotic pain medications or sedatives without physician orders. Additionally, if any medication was not used for the patient, a record of disposal was noted in the Omnicell[®] by two registered nurses as required.

⁴ The Clinical Assessment, Reporting, and Tracking System for Cardiac Catheterization Laboratories (CART-CL), http://www.hsrdr.research.va.gov/for_managers/stories/cart-cl.cfm. Accessed March 30, 2015.

⁵ Oklahoma VAMC Center Memorandum 11-88, *Physicians' Orders*, August 12, 2010.

⁶ Ibid. See also, Oklahoma VAMC Nursing Service Memorandum 118-14-24. *Administration of Medications by Registered Nurses*. September 9, 2014.

⁷ Because the allegations did not include specific time periods and details or case examples of deficient care in the CCL, we selected the month prior to and up to our onsite visit as our review period.

CCL physicians we interviewed stated that nursing staff only gave medications in the procedure room when ordered by the physician performing the procedure. They were unaware of instances when CCL nurses gave medications to patients without orders. The interviewed nurses who worked in the area also stated that they did not administer medications to patients until ordered by the physicians which was as supported by our review of patient EHRs.

Possible Patient Harm. As part of the above allegations, the complainant cited two examples resulting in possible patient harm. However, the complainant did not provide identifying information for the patients. We reviewed facility medication administration records and identified two patients with circumstances similar to those described by the complainant.

- *Patient A* – The patient was undergoing a procedure in the CCL and developed low blood pressure and low blood oxygenation when a known complication of the procedure occurred. The patient had received IV sedation over a 30-minute period. Due to the patient’s clinical decline, the physician called for the rapid response team. The rapid response team intubated⁸ the patient and administered medications to reverse the anesthesia. The patient was stabilized, sent to the intensive care unit, and eventually discharged home.

The cardiologist documented a pre-procedure assessment for anesthesia. The RN administered the IV sedation during the procedure pursuant to physician orders. The admitting cardiologist in the cardiac care unit documented that respiratory compromise was caused by the sedating medication.

- *Patient B* – The patient was admitted to the hospital for progression of chest pain. The cardiologist performed a cardiac catheterization; during the procedure, the patient received IV sedation. The patient’s percutaneous coronary intervention of two vessels was successful, and the patient was discharged home the next day.

The cardiologist documented a pre-catheterization assessment for anesthesia. The RN administered the IV sedation during the procedure as ordered by the physician. The EHR noted no adverse events from medications administered for the procedure.

Issue 3. Omnicell® Passwords

We could not substantiate the allegation that staff Omnicell® passwords were available to nurse managers. The complainant reported that a nurse manager had staff passwords to the Omnicell® and could remove narcotics using other staff passwords.

⁸ Intubation is a medical procedure in which a tube is placed through the mouth or nose into the lungs to assist with breathing.

We did not find discrepancies between Omnicell® and EHR records during our review of medication administration documentation regarding the nurses who removed, administered, and signed verifying that the medication administration record was correct.

Pharmacy Service staff grant new nurses access to the Omnicell® system after notification of the need for access by a nurse educator. When the new nurse accesses the Omnicell® for the first time, he/she uses a temporary password provided by the pharmacy manager. The user is immediately prompted to change the temporary password to one selected by the user before the system can be used further. The password is secure unless the user shares it with another individual.

Conclusions

We did not substantiate that the facility closed the CT surgery program. Rather, facility leadership paused CT surgeries in order to evaluate the program following patient deaths. CT patients were seen in clinic, CT surgery consults were answered, and CT surgery referrals were made to VA or non-VA facilities as needed during the pause but no CT surgeries were performed. The CT surgery program underwent multiple site visits by both the Veterans Integrated Service Network 16 Chief Surgical Consultant and Chief Medical Officer as well as a consultative assessment by the Veterans Health Administration's National Surgery Office. As National Surgery Office reports are protected from disclosure under 38 U.S.C. 5705, we are unable to discuss the results of the reviews.⁹ CT surgeries resumed in October 2014.

We did not substantiate the allegation that CCL nurses administered medications to patients in the CCL without a physician present who ordered the medication. We found documentation of medication administration in the CART-CL reports in the EHRs for the 27 CCL patients we reviewed, documentation included the times patients were taken into procedure rooms, when the physicians arrived in the rooms, and the times medications were administered.

We did not find that the two patients with circumstances similar to the patients described in the allegations we reviewed suffered harm related to medication administration. We found all medications documented in the EHRs as ordered by the physician who was present in the CCL room at the time the medications were administered.

We could not substantiate that the nurse manager had staff passwords to the Omnicell® and could use the passwords to access and remove medications under another nurse's account. We found that access to the Omnicell® is processed through Pharmacy Service and that the user creates his or her own unique password that is secure unless the user shares it with another individual.

We made no recommendations.

⁹ VHA Handbook. *National Surgery Office*. January 30, 2013.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

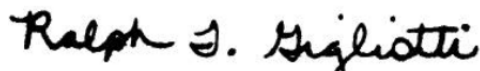
Date: May 4, 2016

From: Director, Rocky Mountain Network (10N19)

Subj: Healthcare Inspection—Cardiothoracic Surgery Program and Cardiac Catheterization Laboratory Concerns, Oklahoma City VA Health Care System, Oklahoma City, Oklahoma

To: Director, Dallas Office of Healthcare Inspections (54DA)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank you for the thorough review of the Cardiothoracic Surgical Program and the Cardiac Catheterization Laboratory at the Oklahoma City VA Health Care System.
2. I have reviewed the report and response from Oklahoma City and concur with the report and the response.
3. If you have any questions or concerns, please contact Ruth Hammond, VISN 19, Quality Management Specialist, (303) 202-8169.



Ralph T. Gigliotti, FACHE
Director, South Central VA Health Care Network (10N19)

Interim Facility Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: May 4, 2016

From: Interim Director, Oklahoma City VA Health Care System (635/00)

Subj: Healthcare Inspection—Cardiothoracic Surgery Program and Cardiac Catheterization Laboratory Concerns, Oklahoma City VA Health Care System, Oklahoma City, Oklahoma

To: Director, Rocky Mountain Network (10N19)

1. We appreciate the opportunity to work with the Office of Inspector General as we continuously strive to improve the quality of healthcare for America's veterans.
2. I concur with the findings of the Healthcare Inspection. The importance of this review is acknowledged as we continually strive to provide the best possible care.
3. If you have any questions, please contact Adrienne Risenbeck, Director, Office of Quality, Safety, and Value, Oklahoma City VA Health Care System, at (405) 456-3146.



Gerald K. Darnell, Psy. D.
Interim Director, Oklahoma City VA Health Care System (635/00)

OIG Contact and Staff Acknowledgments

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