



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

Office of Healthcare Inspections

Report No. 13-02053-119

Healthcare Inspection

Questionable Cardiac Interventions and Poor Management of Cardiovascular Care Edward Hines, Jr. VA Hospital Hines, Illinois

April 8, 2014

Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:
Telephone: 1-800-488-8244
E-Mail: vaoighotline@va.gov
Web site: www.va.gov/oig

Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection at the request of Senator Richard Durbin and Congresswoman Tammy Duckworth to assess the merit of allegations concerning cardiovascular care at the Edward Hines, Jr. VA Hospital (facility) in Hines, IL.

We did not substantiate that a patient who died in the operating room received inappropriate care. We also did not substantiate specific allegations that the operation should not have been performed at the facility and that preoperative planning was inadequate. The facility had conducted a review of the care provided for this patient in accordance with policy.

We substantiated that two patients had questionable indications for coronary bypass surgery. Both of the affected patients had diabetes, a condition known to increase the risk associated with surgery. These patients had favorable outcomes but were subjected to open heart surgery and a substantial risk of death or stroke during and after surgery.

We substantiated that preoperative planning was inadequate for a patient who underwent coronary artery bypass surgery. This patient had valvular heart disease, which increases the risk of complications related to bypass surgery and warrants pre-operative consideration of valve repair or replacement. However, even though prior testing revealed the problem, it was not adequately evaluated until the patient was in the operating room. The patient suffered no apparent adverse effects, but the occurrence suggests a process failure that could lead to poor outcomes for other patients.

We found that coronary interventions may have been inappropriate for nine patients who had undergone cardiac catheterizations during 2010–2013. For each of these nine patients, angiogram images and reports were independently evaluated by two interventional cardiologists who agreed that the degree of coronary stenosis had been over-estimated. The patients suffered no apparent immediate harm, but some of them were subjected to an increased risk of bleeding from the medications required after placement of stents. The nine patients who had interventions that may have been inappropriate were receiving VA care 27–154 weeks after the procedures (median, 66 weeks).

We substantiated that there were environmental and equipment deficiencies resulting in delayed and cancelled surgeries. A new operating room, scheduled to open in May 2014, is expected to resolve environmental problems.

We substantiated that hospital beds were often unavailable and that there was poor bed utilization.

We substantiated that the facility did not adequately monitor compliance with two Loyola contracts for cardiology and CT surgery services. Managers failed to ensure that

contract physicians gained access to the electronic health record and were present at the facility for billed services.

We substantiated that facility administrators did not ensure that weekly cardiac catheterization conferences were conducted. However, we identified no requirement for such conferences and noted that facility cardiologists regularly attended conferences at Loyola.

We did not substantiate that staffing or medical support for cardiac surgery was inadequate, that patients experienced excessively long waits to be admitted from the emergency department, that there were delays in or poor quality of echocardiography, that non-board certified physicians were assigned to crucial management positions, that care was inappropriately provided by trainees and non-physician providers, that staff failed to adhere to written policies for the surgical intensive care unit (SICU), that SICU physicians were at Loyola during their VA tours of duty, or that there was a lack of fairness of an Administrative Investigation Board.

We recommended that the Facility Director ensure that:

- Cardiologists performing coronary interventions and surgeons performing cardiac surgery adhere to accepted standards of care.
- Adequate equipment is available in the operating room in accordance with VHA policy.
- Processes are strengthened to improve bed utilization.
- Processes are strengthened to ensure contract oversight in accordance with VA requirements.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 15–18 for the Directors' comments.) We will follow up on the planned actions until they are completed.



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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection at the request of Senator Richard Durbin and Congresswoman Tammy Duckworth to assess the merit of allegations concerning the quality of cardiovascular care and billing practices at the Edward Hines, Jr. VA Hospital (facility) in Hines, IL.

Background

The facility is part of Veterans Integrated Service Network (VISN) 12 and serves over 56,000 veterans, providing inpatient medical, surgical, mental health, geriatric, and rehabilitation services. The facility also provides outpatient primary care at its main campus and at six Community Based Outpatient Clinics. Specialized clinical programs include blind rehabilitation, spinal cord injury, neurosurgery, radiation therapy, and cardiothoracic (CT) surgery.

The facility is affiliated with the adjacent Loyola University Stritch School of Medicine (Loyola), and in certain specialty care areas the facility has procured services from Loyola, including radiation therapy and on-call cardiology and cardiac surgery. These arrangements allow veteran patients to have ready access to Loyola physicians and provide the opportunity for trainees to work in VA's unique healthcare environment. Affiliation agreements promote common standards for patient care, resident and student education, research, and staff appointments.¹

VA Directive 1663² outlines the responsibilities and requirements for procurement of medical services from affiliated institutions. Contracts undergo extensive approval and review processes that are intended to ensure compliance with VA standards for personnel management, medical records access, performance monitoring, and billing.

For patients with chest pain and other symptoms caused by atherosclerosis of the coronary arteries, treatment often includes percutaneous coronary intervention (PCI). During this procedure, a cardiologist threads a catheter from an artery in the groin or arm to the heart. Where there are blockages in the patient's coronary arteries, it is often possible to improve and sustain blood flow by inflation of a balloon and placement of an expandable mesh stent. Although the procedure can be beneficial, it also entails multiple risks. In certain circumstances, coronary artery bypass surgery is appropriate. Detailed recommendations for the use of interventions in specific clinical situations have been published.^{3,4}

¹ VHA Handbook 1400.3, *Affiliation Partnership Councils*, September 24, 2002.

² VA Directive 1663, *Health Care Resources Contracting-Buying*, Title 38 U.S.C. 8153, August 10, 2006.

³ Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI *Guideline for Percutaneous Coronary Intervention*. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *J Am Coll Cardiol*. 2011; 58:e44-122.

⁴ Hillis LD, Smith PK, Anderson JL, et al. 2011 American College of Cardiology Foundation/American Heart Association *Guideline for coronary artery bypass graft surgery: executive summary*. *J Thorac Cardiovasc Surg*. 2012; 143:4-34.

Inappropriate PCI occurs at a lower rate at Veterans Health Administration (VHA) facilities and when funded by Medicare, compared with PCI provided through private insurance.⁵

On February 27, 2013, the OIG received a congressional inquiry regarding the quality of cardiovascular care and allegations of inappropriate billing for procedures. The following allegations were received:

- Unnecessary placement of coronary artery stents and unnecessary open heart surgery
- A 9-month backlog for interpretations and poor image quality of echocardiograms⁶
- Repeated facility failures in the operating room (OR), including leaking roofs, flooding, power outages, and heating and cooling problems causing cancellation of emergency surgeries
- Failure to provide adequate equipment in the OR
- Extreme lack of manpower in cardiac surgery creating a danger for patients
- Misallocation of manpower among services
- Failure to provide adequate medical support to patients on the Surgical Service
- Gross mismanagement and failure to follow written policy in the surgical intensive care unit (SICU)
- Routine lack of beds due to poor utilization by physicians
- Lack of bed availability causing extreme stress to patient care providers and poor patient care
- Excessively long waits for patients waiting to be admitted from the emergency department (ED)
- Last-minute cancellation of procedures
- Inappropriate provision of care by trainees and non-physician providers (nurse practitioners and physician assistants)
- Assignment of non-board certified physicians to crucial management positions
- Failure of administrators to ensure weekly cardiac catheterization conferences
- Failure of administrators to ensure that cardiologists conduct postoperative rounds for cardiac surgery patients
- Billing by cardiologists for procedures they have not performed
- Failure to ensure Loyola physicians performed services paid by VA
- Multiple labor relations and human resource issues
- Failure of senior management to take action in response to identified problems
- Lack of fairness of an Administrative Investigation Board (AIB)

Subsequently, additional allegations were received regarding inappropriate care for a patient who died in the OR, poor perioperative cardiac surgery care,⁷ and that facility SICU physicians were at Loyola during their VA tours of duty.

⁵ Chan PS, Rao SV, Bhatt DL, et al. *Patient and hospital characteristics associated with inappropriate percutaneous coronary interventions*. J Am Coll Cardiol. 2013; doi:10.1016/j.jacc.2013.07.086.

⁶ An echocardiogram is a diagnostic test that uses high-frequency sound waves to create images of the heart.

Scope and Methodology

We evaluated the quality of cardiovascular care provided at the facility from July 1, 2010, through June 30, 2013. We conducted a site visit May 21–23, 2013, to clarify allegations and elicit specific information. We also conducted a site visit July 16–19, 2013. We interviewed senior managers and clinical and administrative staff with direct knowledge of cardiovascular care and supervision of VA and contract staff. We also interviewed faculty members from Loyola.

We reviewed the medical records of cardiology and cardiac surgery patients. We also reviewed relevant VHA and facility policies and facility clinical and administrative reports.

Coronary angiograms provide images of the coronary arteries that guide decisions about the use of PCI. For the evaluation of the quality of interventional cardiology care, coronary angiograms of selected patients were reviewed by 10 VHA interventional cardiologists based outside of VISN 12. Reviewing cardiologists are or were recently members of the Quality Assurance Committee of VHA's Clinical Assessment Reporting and Tracking System for Cardiac Catheterization Laboratories (CART-CL).⁸ Each patient's angiogram and report were independently evaluated by two cardiologists.

Intravascular ultrasonography (IVUS) may be performed at the time of cardiac catheterization using a specialized catheter to obtain images from inside coronary arteries. To assess an allegation that unnecessary surgeries were due to overestimation of coronary artery blockages by IVUS, we identified all patients who had cardiac catheterization with IVUS followed by coronary artery bypass surgery from January 1, 2010, through July 23, 2013.

To evaluate the processing of outpatient echocardiograms, we randomly selected for review 2 percent of the 1,922 echocardiograms performed in 2012 and 5 percent of the 401 studies performed during January–April 2013. We also reviewed the electronic health records (EHRs) of patients for whom the interpretation of echocardiograms was delayed.

To determine patient waiting times for admission from the ED, we reviewed a list of all patients waiting to be admitted to the facility during March 29–June 27, 2013. We identified the 1,190 patients waiting for admission from the ED and evaluated medical record documentation for a 5 percent random sample.

We reviewed physician on-call schedules, time and attendance reports, and the facility's contracts and invoices for interventional cardiology and cardiac surgery on-call services.

⁷ Perioperative care includes evaluation and treatment during the preoperative, intraoperative, and postoperative phases of surgery.

⁸ Byrd JB, Vigen R, Plomondon ME, et al. *Data Quality of an Electronic Health Record Tool to Support VA Cardiac Catheterization Laboratory Quality Improvement: the VA Clinical Assessment, Reporting, and Tracking System for Cath Labs (CART) Program*. Am Heart J. 2013; 165:434-40.

We did not address multiple allegations related to labor relations and human resource issues and allegations that we were unable to clarify and/or for which we were unable to obtain specific information.

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: Quality of Cardiovascular Care

Operative Death

We did not substantiate that a patient who died in the OR received inappropriate care. We also did not substantiate specific allegations that the operation should not have been performed at the facility and that preoperative planning was inadequate. The facility had conducted a review of the care provided for this patient in accordance with VHA policy.⁹

Cardiac Surgery

A. Questionable Cardiac Surgery

We substantiated that two patients had questionable indications for coronary artery bypass surgery. Both of these patients had diabetes, a condition known to increase the risk associated with surgery. The patients had favorable outcomes and were stable 1–2 years after surgery, but both were subjected to open heart surgery and an approximate 5 percent chance of death or stroke during and in the 30 days after surgery.¹⁰

From January 1, 2010, through July 23, 2013, 455 operations involving coronary artery bypass were performed at the facility. During this time, 2,614 cardiac catheterizations were performed; 89 of these procedures involved the use of IVUS. Because of allegations that unnecessary surgeries were due to overestimation of coronary artery blockages by IVUS, we reviewed the care of seven patients who had catheterization with IVUS and subsequently had coronary artery bypass surgery. Bypass operations for these patients were performed during December 2010 through September 2012.

For each of these seven patients, IVUS images and reports were independently evaluated by two interventional cardiologists. In one case, reviewers agreed that the degree of coronary stenosis had been correctly estimated, and this case was not further reviewed. In four cases, reviewers described IVUS and/or angiographic overestimation of stenosis, but these patients had accelerating symptoms and coronary obstructions that nevertheless warranted bypass surgery. The two remaining patients are described below.

- A man in his 60s with a history of diabetes, hypertension, and chronic kidney disease was admitted to the facility with “dizziness and orthostatic hypotension.” While he was hospitalized, a treadmill stress test with radionuclide imaging showed “a predominantly fixed inferior wall perfusion defect with the greatest reversibility in the inferoapical region.” The patient had shortness of breath but

⁹ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010.

¹⁰ Zhang X, Wu Z, Peng X, et al. *Prognosis of diabetic patients undergoing coronary artery bypass surgery compared with nondiabetics: a systemic review and meta-analysis*. J Cardiothorac Vasc Anesth. 2011; 25:288-298.

no chest pain. Cardiac catheterization subsequently revealed “significant” multi-vessel coronary disease with a “mid-LAD” [left anterior descending coronary artery] obstruction described as “severe stenosis on IVUS.” The patient underwent bypass surgery 2 weeks later. His initial postoperative course was unremarkable, but 1 week after discharge he had leg swelling and was treated for an infection at the vein harvest site. Two years after surgery his condition was stable and he was being followed closely by VA Home TeleHealth staff.

Our review found that the degree of coronary stenosis was overestimated and the patient did not have symptoms that warranted bypass surgery.

- A man in his 50s with a history of diabetes, hypertension, and cigarette smoking had a myocardial infarction 15 years earlier and had undergone multiple PCIs, most recently 8 years earlier. Because of “extensive dz [disease] and cont RF [continuing risk factors],” he was referred for treadmill exercise testing. During that test, “The patient exercised for 9 minutes and 26 seconds. The test was stopped by the patient due to fatigue.” An accompanying radionuclide myocardial perfusion study showed “...a small, fixed anteroapical perfusion defect unchanged when compared to...” [a test done 6 years earlier]. Cardiac catheterization done for “abnormal stress test” and “atypical CP” [chest pain] was reported to demonstrate “significant LM [left main coronary artery] disease by IVUS” in addition to disease in other vessels. Bypass surgery was performed 6 weeks later. The patient had an unremarkable postoperative course and was described as “doing very well” 1 year later.

Our review found that the degree of coronary stenosis was overestimated and the patient did not have symptoms that warranted bypass surgery.

B. Unavailable Preoperative Echocardiogram

We substantiated that preoperative planning for a patient who underwent coronary artery bypass surgery was inadequate because results of an echocardiogram were not available. This patient had valvular heart disease, which increases the risk of complications related to bypass surgery and warrants pre-operative consideration of valve repair or replacement. However, even though prior testing had revealed the problem, it was not adequately evaluated until the patient was in the operating room. The patient suffered no apparent adverse effects, but the occurrence suggests a process failure that could lead to poor outcomes for other patients.

A man in his 60s had a 10–year history of coronary artery disease and had undergone PCI. Because of gradually worsening chest pain and decreased exercise tolerance, a treadmill exercise test was performed. That test revealed evidence of coronary ischemia and a subsequent radionuclide perfusion study showed “a medium-sized, partially reversible perfusion abnormality.” Cardiac catheterization 3 weeks later revealed “multi-vessel CAD [coronary artery disease]” and the patient underwent coronary artery bypass surgery after an additional 3 weeks.

The Operation Report describes that “After the appropriate induction of general anesthesia and the placement of appropriate monitoring lines, tubes, and cables.

Anesthesia inserted a TEE [transesophageal echocardiogram] probe for routine intracardiac monitoring.” The report continues:

On inspection of the heart using the TEE, Anesthesia identified the patient also had moderate aortic insufficiency and moderate mitral regurgitation. These were unexpected findings based on the patient's preoperative workup. Cardiology was called in to the Operating Room to perform more complete imaging, which was performed, and consensus was reached that the patient's valvular findings on TEE did not justify valve replacement for either of his valves.

Echocardiography had been performed on the day of cardiac catheterization, 3 weeks before surgery, but was not interpreted until more than 3 months after the surgery. Preoperative physical examinations documented by two internal medicine attending physicians, a cardiology fellow, and a surgical resident indicate that the patient had no cardiac murmurs suggestive of valvular disease. No physical examination is documented by a cardiologist, while the cardiac surgeon documented that the physical examination had been “reviewed and confirmed with resident and patient.”

Notwithstanding the additional time required for assessment of the echocardiographic findings found after the patient was anesthetized, the patient's overall operation time was not substantially prolonged and his postoperative course was uncomplicated. At a clinic visit 2 weeks after surgery, he reported that he “can breathe better and has more energy.” Echocardiography performed 18 months after surgery revealed “moderate MR [mitral regurgitation], AI [aortic insufficiency],” without chamber enlargement. Because the patient had no related symptoms, no additional intervention was advised. Two years after surgery he was under the care of a private physician and reportedly doing well.

Interventional Cardiology

We substantiated that some patients may have had inappropriate cardiology procedures. These patients suffered no apparent immediate harm, but some of them were subjected to a small increased risk of bleeding from the medications required after placement of stents.¹¹

From among the 567 patients who had undergone cardiac catheterizations with coronary artery interventions from January 2011, through February 2013, 16 patients were alleged to have had inappropriate interventions. These patients had a median age of 64 years (range 43–81). For each patient, angiogram images and reports were independently evaluated by two interventional cardiologists. In 10 of 16 cases, reviewers agreed that the degree of coronary stenosis had been over-estimated. In 9 of the 10 cases, patients underwent interventions and 8 of these 9 cases involved placement of coronary stents; in one case, the patient had angioplasty without stent placement. The nine patients who had interventions that may have been inappropriate were receiving VA care 27–154 weeks after the procedure (median, 66 weeks).

¹¹ Brilakis ES, Patel VG, Banerjee S. *Medical management after coronary stent implantation: a review*. JAMA. 2013; 310:189-198.

The CART-CL Quality Assurance Committee reviews all major adverse events that occur in VHA cardiac catheterization laboratories.¹² However, in the absence of major adverse events, a review of practices at individual facilities is prompted by requests from facility or system leaders. Leaders were unaware of problems in the cardiac catheterization laboratory and therefore did not request a review.

Echocardiography

A. Backlog in Processing Echocardiograms

We evaluated the processing of echocardiograms during January 1, 2012, through April 30, 2013, and found no substantial backlog. Facility staff acknowledged that there had been a problem in 2011, at which time there were staffing shortages and technical problems. Delays were reported to be limited to outpatient procedures and mostly due to delays in study interpretation. The patient described above (Issue 1. *Cardiac Surgery, Inadequate Preoperative Planning*) had echocardiography requested prior to 2011.

VHA policy requires that test results be communicated to the ordering practitioner within a timeframe allowing appropriate clinical action to be taken.¹³ Our review of 58 randomly selected echocardiograms performed from January 1, 2012, through April 30, 2013, found no significant delays in the interpretation and reporting of outpatient echocardiograms. The mean time from study to completion for the 38 selected 2012 studies was 8.3 days (median, 3.5; range 0–60). The mean time from study to completion for the 20 studies selected from those completed during January–April 2013 was 6.8 days (median, 5.0; range 0–27).

Echocardiograms were interpreted more than 2 weeks after the studies were performed for 8 of 38 patients from 2012 and for 2 of 20 patients from 2013. Review of the 10 patients' EHRs revealed no negative consequences associated with delayed interpretations.

B. Quality of Echocardiogram Image Acquisition

We did not substantiate the allegation that the quality of echocardiogram image acquisition was poor. In our review of the 58 randomly selected outpatients who had echocardiography testing from January 1, 2012, through April 30, 2013, we found that in 27 of the 58 cases (47 percent) the study was reported to be “technically limited” or had “marginally limited images.” However, acquisition of echocardiographic images may be limited for various reasons and useful information may be obtained despite limitations. We found no published criteria for the acceptable proportion of studies that are considered “technically limited.” Limitations may be attributable to equipment inadequacies, suboptimal technical skills on the part of echocardiography technicians, or patient factors such as obesity and lung disease.

¹² http://www.hsrd.research.va.gov/for_managers/stories/cart-cl.cfm#.UvBM27SGdFw. Accessed February 3, 2014.

¹³ VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009.

Issue 2: Problems in the OR

Environmental Difficulties in the OR

We substantiated that facility deficiencies resulted in unsafe conditions, including conditions leading to cancellation of cardiothoracic (CT) surgeries. We reviewed reports of cancellations for CT Surgery from January 1, 2011, through May 1, 2013. We found that 10 of 48 surgeries had been cancelled because of flooding, heating and cooling problems, or leaking roofs. In one case, an emergency procedure was cancelled after the patient was already anesthetized.

We found ongoing environmental problems in the OR in work orders from January 2011 through September 2013, and in OR reports dated July and September 2012 and January and April 2013. A new operating room is scheduled to open in May 2014.

Adequacy of Equipment in the OR

We substantiated the allegation that the facility did not provide adequate equipment in the OR to ensure safe performance of cardiac surgery. The facility had an expired ventricular assist device (VAD)¹⁴ and did not have duplicate major surgery trays. VHA policy¹⁵ requires facilities that perform complex surgeries to have duplicates of all major surgery instrument sets, including one vascular surgery instrument set available for emergencies. The facility's VAD expiration date was March 2013; on March 27 a request to reorder this device was submitted. As of November 15, 2013, a replacement VAD was not available in the OR.

Issue 3: Cardiology and Cardiac Surgery Programs

Staffing for Cardiac Surgery

We did not substantiate the allegation that insufficient manpower for cardiac surgery caused a danger for patients. We reviewed CT surgery assignments for Quarter 2 of FY 2013 and found adequate staffing levels. We also did not find insufficient house staff (physicians-in-training) assignments for the CT Surgery Service.

Cardiology-Cardiac Surgery Interactions

We did not substantiate the allegation that the facility failed to provide adequate medical support for patients on the Surgical Service. Discussions with facility staff identified a concern that cardiologists were not routinely rounding (examining patients as part of a team effort) on CT surgery patients following cardiac surgery. However, we found no requirement for Cardiology Service physicians to round on postoperative CT surgery patients.

¹⁴ A ventricular assist device is a mechanical pump used to support blood flow in patients with weak hearts.

¹⁵ VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010.

Postoperative Care in the SICU

We did not substantiate the allegation that staff failed to adhere to written policies in the SICU. Facility policy¹⁶ specifies that “Medical care in the SICU will be directed by the SICU Medical Director who will have ultimate authority for the medical care in the SICU.” The policy states that patient care will be provided “...in collaboration with each primary service with the charge of achieving optimal care,” and that “...the primary service may write orders pertaining to routine postoperative surgical care...” Facility staff members described disagreements about clinical care for patients after surgery that had occurred between a surgeon who had performed operations and SICU attending surgeons. However, we noted that episodic failure to achieve consensus about appropriate patient care was associated with interpersonal conflicts, not inadequate policy or the lack of adherence to the policy.

Bed Availability and Bed Utilization by Physicians

We substantiated the allegation that bed availability was a frequent problem. However, we did not substantiate that a lack of beds was due to poor utilization by physicians. VHA policy¹⁷ established utilization management (UM) strategies as a key tool in managing patient flow and required collaboration and communication between UM and patient flow staff. UM reports from March 1, 2013, through June 17, 2013, showed that 34 percent of CT surgery patients did not meet criteria for their bed assignments. Patient flow and bed utilization were managed separately at the facility. We found limited collaboration and communication among UM staff, patient flow staff, and physicians regarding bed utilization.

Waiting Times for Patients Admitted from the ED

We did not substantiate the allegation that patients experienced excessively long waits for admission from the ED. We identified patients waiting to be admitted to the facility during March 29–June 27, 2013, and evaluated progress notes for 60 of the 1,190 patients (5 percent) waiting in the ED. For these patients, the mean time from time of entry of an ED disposition note into the EHR to the time of an admission note from the accepting unit was 2.1 hours (median, 1.8 hours; range, 9 minutes to 9 hours). Facility policy¹⁸ establishes that an acceptable wait time for an assigned inpatient bed is 2 hours.

Cancellation of Procedures

We substantiated the allegation that scheduled CT surgeries were cancelled after patients had been admitted and readied for surgery. According to staff interviews, multiple CT surgeries were cancelled because of environmental issues, other patients requiring emergency surgery, and other patient-related medical issues.

¹⁶ Hines VA Hospital, *Surgical Intensive Care Unit (SICU)*, November 10, 2011.

¹⁷ VHA Directive 2010-021, *Utilization Management Program*, May 14, 2010.

¹⁸ Hines VA Hospital, *Emergency Department Standard Operating Procedures*, May 2013.

Inappropriate Provision of Care by Trainees and Non-physician Providers

We did not substantiate the allegation that care was inappropriately provided by trainees and non-physician providers. We determined that concerns about inappropriate provision of care by trainees and non-physician providers referred to the possibility that surgical trainees did not have proper supervision. However, discussions with facility staff and reviews of EHR documentation revealed no lapses in supervision of trainees.

Board Certification of Physicians in Management Positions

We did not substantiate the allegation that non-board certified physicians were assigned to crucial management positions. VHA policy¹⁹ requires physician service chiefs to be board certified or possess comparable competence. We found that all physician service chiefs were board certified.

Cardiac Catheterization Conferences

We substantiated that facility administrators did not ensure that weekly cardiac catheterization conferences were conducted. However, we identified no requirement for such conferences and noted that facility cardiologists regularly attended conferences at Loyola.

Issue 4: Time and Attendance, Loyola Contracts, and AIBs

Time and Attendance

We did not substantiate the allegation that physicians in the SICU sometimes worked at Loyola during their tours of duty at the facility. Our review of the facility's timekeeping records, including time and attendance audits for VA full-time and part-time employees found no pattern of VA physicians in the SICU not completing their assigned tours of duty.

Loyola Contracts

We substantiated that the facility did not adequately monitor compliance with two Loyola contracts for on-call²⁰ interventional cardiology services and scheduled and on-call CT surgery services.

The interventional cardiology contract delineated services to be rendered from April 1, 2010, through March 31, 2012. The contract allowed for a 6-month extension of services through September 30, 2012. Under the contract, Loyola provided on-call consultation services on nights, weekends, and holidays. When paged, the contractor was required to provide consultation services; if an emergency procedure was needed, the patient was to be transferred to Loyola.

¹⁹ VHA Handbook 1100.19, *Credentialing and Privileging*, November 14, 2008.

²⁰ On-call services are emergency and routine services required after regular business hours or on weekends and holidays to ensure continuous coverage.

The CT surgery contract delineated services to be rendered from December 1, 2009, through November 30, 2011. The contract allowed for a 6-month extension of services through May 31, 2012. Under the contract, Loyola provided on-call services on nights, weekends, and holidays and required CT surgeons to make rounds on weekends and non-Monday holidays. When paged, CT surgeons were required to provide consultation services, or if necessary, be physically present to assess patients and perform or assist in thoracic and cardiac procedures.

We found that contract CT surgeons did not have access to the VA EHR. According to the contract and local requirements, attending physicians must co-sign patient medical records in order to provide evidence of trainee oversight. These surgeons were therefore unable to independently access the EHR or co-sign trainee progress notes.

Loyola submitted monthly bills to the facility for CT surgery services rendered, with supporting documents such as time sheets and on-call schedules. However, the facility did not compare information on time sheets and on-call schedules to verify the accuracy of monthly billings. We found that the April 2012 invoice reflected only 83 hours of on-call time, an amount substantially lower than the monthly average of 400. In October 2012 Loyola submitted a bill that included an additional 149 hours for a physician listed on the April 2012 on-call schedule. Although discrepancies can be explained by facility CT surgeons providing on-call services at no charge, the facility did not investigate variances.

We also found that Loyola's CT surgery and on-call interventional cardiology contracts expired on May 31, 2012, and September 30, 2012, respectively. Purchase orders were used by the facility to ensure continuity of services after the contracts had expired. However, they did not contain terms and conditions required to protect the government's interests, such as statements that providers were independent contractors, that they must carry malpractice insurance, or that they must comply with VA policies. Long term contracts for CT and interventional cardiology services are not projected to be awarded until September 2014.

Although documentation of contract compliance was lacking, none of the contracted physicians were principally involved in the care of the patients described in Issue 1.

Lack of Fairness of an AIB

We did not substantiate the allegation of a lack of fairness of an AIB. We reviewed two AIBs that were conducted at the facility during 2011–2012 and found the AIBs to have been conducted according to VHA policies and procedures.

Conclusions

We did not substantiate that a patient who died in the OR received inappropriate care. We also did not substantiate specific allegations that the operation should not have been performed at the facility and that preoperative planning was inadequate. The facility had conducted a review of the care provided for this patient in accordance with VHA policy.

We substantiated that two patients had questionable indications for coronary bypass surgery. Both of the affected patients had diabetes, a condition known to increase the risk associated with surgery. These patients had favorable outcomes but were subjected to open heart surgery and a substantial risk of death or stroke during and after surgery.

We substantiated that preoperative planning was inadequate for a patient who underwent coronary artery bypass surgery. This patient had valvular heart disease, which increases the risk of complications related to bypass surgery and warrants pre-operative consideration of valve repair or replacement. However, even though prior testing revealed the problem, it was not adequately evaluated until the patient was in the operating room. The patient suffered no apparent adverse effects, but the occurrence suggests a process failure that could lead to poor outcomes for other patients.

We found that coronary interventions may have been inappropriate for nine patients who had undergone cardiac catheterizations during 2010–2013, and eight patients had coronary stents placed. For each of these nine patients, angiogram images and reports were independently evaluated by two interventional cardiologists who agreed that the degree of coronary stenosis had been over-estimated. These patients suffered no apparent immediate harm, but some of them were subjected to a small increased risk of bleeding from the medications required after placement of stents. The nine patients who had interventions that may have been inappropriate were receiving VA care 27–154 weeks after the procedures (median, 66 weeks).

We substantiated that there were environmental and equipment deficiencies resulting in delayed and cancelled surgeries. A new operating room, scheduled to open in May 2014, is expected to resolve environmental problems.

We substantiated that hospital beds were often unavailable and that there was poor bed utilization.

We substantiated that the facility did not adequately monitor compliance with two Loyola contracts for cardiology and CT surgery services. Managers failed to ensure that contract physicians gained access to the electronic health record and were present at the facility for billed services.

We substantiated that facility administrators did not ensure that weekly cardiac catheterization conferences were conducted. However, we identified no requirement for such conferences and noted that facility cardiologists regularly attended conferences at Loyola.

We did not substantiate that there was inadequate staffing or medical support for cardiac surgery, that patients had excessively long waits to be admitted from the ED, that there were delays in or poor quality of echocardiography, that non-board certified physicians were assigned to crucial management positions, that care was inappropriately provided by trainees and non-physician providers, that staff failed to adhere to written policies for the SICU, that SICU physicians sometimes were at Loyola during their VA tours of duty or that there was a lack of fairness of an AIB.

Recommendations

1. We recommended that the Facility Director ensure that cardiologists performing coronary interventions and surgeons performing cardiac surgery adhere to accepted standards of care.
2. We recommended that the Facility Director ensure that adequate equipment is available in the operating room in accordance with VHA policy.
3. We recommended that the Facility Director ensure that processes are strengthened to improve bed utilization.
4. We recommended that the Facility Director ensure that processes are strengthened to ensure contract oversight in accordance with VA requirements.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

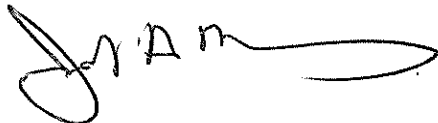
Date: March 19, 2014

From: Director, VA Great Lakes Health Care System (10N12)

Subject: Healthcare Inspection – Questionable Cardiac Interventions and Poor Management of Cardiovascular Care, Edward Hines, Jr. VA Hospital, Hines, IL

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

1. I have reviewed the draft report for Hines VA Hospital and concur with the findings and recommendations.
2. I appreciate the Office of Inspector General's efforts to ensure high quality of care to Veterans at the Hines VAH.



Jeffrey A. Murawsky, MD, FACP

Facility Director Comments

**Department of
Veterans Affairs**

Memorandum

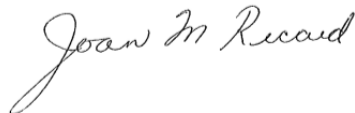
Date: March 19, 2014

From: Director, Edward Hines, Jr. VA Hospital (578/00)

Subject: Healthcare Inspection – Questionable Cardiac Interventions and Poor Management of Cardiovascular Care, Edward Hines, Jr. VA Hospital, Hines, IL

To: Director, VA Great Lakes Health Care System (10N12)

1. I would like to thank the Office of the Inspector General for their thorough inspection of our cardiology and cardiac surgery programs. The OIG staff members conducted themselves with the highest level of professionalism and highlighted opportunities to improve the care we provide to our Veterans.
2. The recommendations made during the visit have already been acted upon and hospital leadership will track each item to assure satisfactory completion.
3. If you have any questions or require additional information, please contact Joan Ricard at (708) 202-5639.



Joan Ricard, FACHE

Facility 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 cardiologists performing coronary interventions and surgeons performing cardiac surgery adhere to accepted standards of care.

Concur

Target date for completion: September 30, 2014

Facility response: After completion of an internal and external review of interventional cardiology we agree that patients with coronary artery lesions of borderline severity might benefit from cross lesion pressure measurements and in some instances the intensification of medical therapy. Of note, none of the patients who had these procedures experienced any adverse effects. In fact, all have reported improvements in their health status. In addition to the already re-instituted cardiac catheterization conferences a random sample of cases will be sent out monthly for protected external review to assure adherence to accepted standards of care to include pressure measurements in borderline lesions and greater use of medical management. Hines VH has requested a VACO cardiology review to identify additional opportunities for improvement. This will be completed by May 2014.

The two surgical cases referenced as having questionable surgery were reviewed on site by a Chief of Cardiology and member of the VACO Clinical Assessment, Reporting, and Tracking (CART) program, and found to have received appropriate care. While it is generally correct that patients with diabetes often have higher risks for procedures, those with diabetes benefit more from cardiac surgery than non-diabetics and the presence of diabetes is thus typically used as an argument in favor of cardiac surgery. The assessment and risk factors in these patients justified the approach taken.

Regarding the unavailable preoperative Echocardiogram; the patient had a full assessment of his cardiac valves during his cardiac catheterization. The valvular lesions were found to be minor, but the report did not document this. In the future, all findings on the cardiac catheterization, however minor, will be present on the report. Completeness of the reports will be part of the external cardiology reviews. The results will be reported quarterly to the Quality Council until compliance of 90% completeness is sustained for two consecutive quarters. The trans-esophageal echo (TEE) was done by anesthesia prior to the surgical procedure and preliminary views indicated moderate valvular lesions. However, after review by a cardiologist within the OR, the valves were found to be less than moderate and did not need surgical intervention. Additional education on TEE will be provided to the Anesthesia staff by May 30, 2014.

Appendix B

Recommendation 2. We recommended that the Facility Director ensure that adequate equipment is available in the operating room in accordance with VHA policy.

Concur

Target date for completion: May 1, 2014

Facility response: The hospital now has backup trays for all major surgical instrument sets and four sets for cardiac surgery. In addition, there is a sufficient supply of Ventricular Assistive Devices and providers have been educated on the procurement process which has ensured no lapse in the conversion to a new device.

Recommendation 3. We recommended that the Facility Director ensure that processes are strengthened to improve bed utilization.

Concur

Target date for completion: July 1, 2014

Facility response: The facility launched a new Bed Management Office that combines the functions of bed movement, admissions, turnover, and discharge into a single office within the bed tower. This model has shown a decreased length of stay (LOS) and increased bed utilization in other VA facilities. Hospital leadership also funded the addition of an observation unit which will move non-acute patients out of acute care beds, freeing up those beds for surgical patients. This data (bed utilization, LOS) is reviewed daily at morning report to the Director and leadership team members.

Recommendation 4. We recommended that the Facility Director ensure that processes are strengthened to ensure contract oversight in accordance with VA requirements.

Concur

Target date for completion: May 1, 2014

Facility response: The contracts for on-call interventional cardiology services and on-call CT surgery services have been reviewed. The local Contracting Officer Representatives will receive additional documented training on contract management and the compliance department will provide a quarterly audit of the contract. The Chief of Staff is currently exploring the feasibility of providing the off-hours coverage through VA employees, thus eliminating the contract.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Jerome E. Herbers, MD Wachita Haywood, RN Debra Boyd-Seale, PhD, RN Sheila Cooley, GNP, MSN Kathy Gudgell, RN, JD Zhana Johnson, CPA, CFE Thomas Seluzicki, CPA, CFE Roberta Thompson, LCSW Judy Brown, Program Support Assistant

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