Administrative Closure

Alleged [redacted] Surgeon Competency and Quality of Care Concerns,
Oklahoma City VA Medical Center, Oklahoma City, OK
MCI# 2013-01759-HI-0402

On February 14, 2013, the Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) received allegations regarding the quality of patient care provided by two [redacted] surgeons (Physicians A and B) at the Oklahoma City VA Medical Center (facility), Oklahoma City, OK. Neither physician was employed by VHA at the time of the complaint. A senior [redacted] surgeon, who also no longer worked at the facility or for VHA, alleged:

- Facility leadership ignored his request to place Physician A on a formal plan of supervision after he expressed concerns regarding Physician A's surgical skills and that Physician A subsequently performed surgeries that harmed patients (Patients 1 and 2).
- Facility leadership hired Physician B despite his expressed concerns regarding the physician's lack of recent experience. Physician B subsequently performed a surgery (Patient 3) which would have harmed the patient had the complainant not intervened when called to assist.
- The facility did not disclose intraoperative errors to the families of Patients 1 and 3 or to Patient 2.

The complainant initially anonymously contacted the OIG Hotline Division on April 20, 2012, regarding Physician A and Patient 1 (MCI 2012-02655-HI-0395). We administratively closed the complaint after reviewing pertinent documentation and interviewing facility leadership. We determined the facility acted promptly in initiating a thorough case review of Patient 1.

In this complaint, the complainant identified himself and made allegations similar to his April 2012 complaint concerning the facility leadership's failure to heed his warnings regarding Physician A's lack of skills. Additionally, he alleged Patient 1's [redacted] would have [redacted] had the autopsy report been available at the time of the review. He also presented additional patient care concerns related to Physician A (Patient 2) and another physician (Physician B) and patient care concerns (Patient 3).

We conducted telephone interviews with the complainant, facility leadership, quality management staff, staff physicians, a physician's assistant, registered nurses, perfusionists, and other key staff knowledgeable of the physicians and identified patients. We reviewed Patients 1, 2, and 3's electronic health records and operative reports, and Patient 1's autopsy report. We reviewed the surgical peer reviews for Patients 1, 2, and 3. We also reviewed relevant VHA and local policies, directives, memoranda, and standard operating procedures; administrative investigation board reports; credentialing and privileging profiles and documentation; Focus Professional Practice Evaluations (FPPE) for Physicians A and B; and Executive Committee of the Medical Staff minutes.

Case Summaries

Patient 1: Patient 1 was a man [redacted]. On [redacted] Physician A performed a [redacted]. Physician A did not document complications in the post-operative report. The patient did well until about 8:30 p.m. when he became hypotensive and pulseless. ICU staff called a code and Physician A responded emergently. Physician A opened his chest and found the heart was not beating and there was no significant blood in the sac surrounding the heart. Resuscitation efforts continued for about 25 minutes. Physician A pronounced the patient dead at 9:12 p.m.

On March 21, an Oklahoma University Medical Center pathologist performed an autopsy. The report stated, "The native coronary arteries all demonstrate severe atherosclerosis with 70 percent to 90 percent stenosis in the bypassed segments. The right coronary artery and left anterior descending artery distal respective grafts are patent with mild atherosclerotic stenosis. The left obtuse marginal artery distal to the bypassed segment distal to the graft site appears grossly obstructed; microscopic sections demonstrate probable before death blood clot formation blocking over 95 percent of the artery. No definitive signs of acute ischemia or infarction are seen grossly or microscopically within the heart muscle. The final diagnosis was sudden death."

Patient 2: Patient 2 is a man [redacted]. The patient's pre-operative diagnoses were [redacted] Physician A performed a [redacted]. The patient recovered uneventfully from surgery and was discharged home [redacted]. Physician A documented "no apparent complications" in the operative report. The complainant dictated a separate addendum to the operative report.

Patient 3: Patient 3 was a man [redacted], Physician B performed [redacted] replacement and coronary artery bypass graft (left anterior descending artery and first diagonal branch left anterior descending). The complainant was the first assistant. There were no complications listed in the Thoracic Surgery Brief Operative Report. The patient left the operating room in satisfactory hemodynamic condition and was taken to the Surgical Intensive Care Unit.

On October 5, the patient had no obvious signs of bleeding and no signs of respiratory distress. He was extubated on October 6. However, on October 9, due to arterial blood gas "panic" values, he received four units of packed red blood cells, two units of platelets, and four units of fresh frozen plasma. On October 11, he was intuhated due to respiratory distress and on October 12, he was noted to be in septic shock, hypoxic respiratory failure, thrombocytopenia, hypernatremia, elevated transaminase, and acute renal failure. He died on October 29. The

cause of death was listed as "multi-organ system failure." Other significant conditions contributing to his death were cardiogenic shock and liver failure. There was no autopsy.

Issue 1: Responsiveness To Physician Competence Concerns

We determined the facility leadership responded appropriately to the complainant's concerns related to Physician A.

Prior to his facility employment, Physician A completed a fellowship, but was not board certified; he completed 12-15 cases during his fellowship. At the time of Patient 1's surgery, Physician A had been at the facility for 9 months, had completed his FPPE successfully, and had conducted over 40 cardiac surgeries. Prior to Patient 1's death, there were no known deaths associated with a surgery performed by Physician A at the facility.

The complainant told us he had participated in 43 cases with Physician A and had performed over half the technical aspects required at Physician A's request. He told us that, prior to taking leave in March 2012, he expressed concerns to facility leadership about Physician A's ability to perform cardiothoracic surgery without supervision and asked that Physician A's cases be cancelled until his return. However, Physician A's scheduled surgeries were not cancelled and he performed surgery on Patient 1. The complainant believed the patient died due to Physician A's lack of skills. Physician A performed a second surgery 1 week later (Patient 2) during which the complainant was re-called into the operating room and found that Physician A had ligated a major branch coronary artery as well as the distal portion of the main coronary artery. The complainant asserted that had he not taken over a major portion of the operation, the patient would likely have sustained major complication.

We interviewed facility staff familiar with Physician A and learned that although many staff (operating room nurses, perfusionists, physician assistant) had concerns related to Physician A's skills, we found no evidence any had reported patient safety concerns to the Chief of Staff (COS) or Chief of Surgery prior to Patient 1's surgery. Staff also commented that the complainant was often critical of others.

The COS recalled the complainant expressed concerns about Physician A's competence in the winter of 2012; however, the COS noted Physician A had no bad outcomes, passed his FPPE, and had been granted full privileges. Although the COS recalled staff voicing concerns that Physician A was slow, it did not surprise him because Physician A had recently completed the fellowship program. The COS admitted in retrospect that it was unusual that Physician A needed assistance that frequently.

The Chief of Surgery told us the complainant told him Physician A was "green" in the fall of 2011, however, he said it was common for a cardiothoracic surgeon to have assistance with complex cases and that a new surgeon will have assistance for 6-12 cases until they are comfortable with complex cases. He noted that, prior to coming to the VA, Physician A was operating with only a physician's assistant.

The Chief of Surgery told us that, at Christmas time, Physician A complained about the way the complainant was treating him. And, in January and February 2012, the complainant started to express concerns about Physician A. The Chief of Surgery said there seemed to be "bad blood"

between the two of them and that the complainant appeared to be the only one concerned with Physician A's competence. Nursing staff and perfusionists told him Physician A was green but "okay." Additionally, the Chief of Cardiothoracic Surgery, where Physician A trained, told the Chief of Surgery he would not have finished the program if they did not think he was competent. During our interview, the Chief of Surgery expressed the sentiment that no matter what Physician A's level of technique, the complainant would not have been satisfied.

Patient 1's death was immediately reported to Quality Management and Physician A did not perform surgeries for 5 days while a surgical peer review was conducted and presented to the Peer Review Committee. [redacted] (b)(3):38 U.S.C. 5705 [redacted] Because the peer review did not indicate with certainty Patient 1's death was due to surgical error, Physician A's suspension was removed. However, due to staff reports of concerns related to intraoperative events during Patient 2's surgery (there was no negative outcome to the patient, but the case was identified as a "close call"), the Professional Standards Board determined Physician A would be placed on an FPPE and a cardiac surgeon from another VA medical center would monitor him. Physician A resigned soon after.

During the course of this review, we learned of circumstances that may have complicated and potentially delayed the COS and Chief of Surgery's response to the complainant's concerns related to Physician A. In October 2012, an Administrative Investigation Board was convened to investigate an alleged hostile work environment within the facility's Cardiothoracic Program. The Board submitted its fact findings and conclusions in January 2013. Of note, the Board concluded the complainant had a longstanding history of unacceptable behavior; it was impossible to maintain a successful cardiothoracic program with the complainant's behavior and lack of interpersonal skills; the complainant's behavior/comments were conductive of a hostile work environment; the complainant did not consistently help educate team members to maintain his high level of expectation regarding quality patient care; and it was impossible to maintain a successful cardiothoracic program with the complainant's behavior, and lack of interpersonal skills and level of awareness.

We determined that, although the complainant communicated his concerns regarding Physician A prior to March 2012, the complainant had a pattern of criticizing facility staff and the University surgical staff. We found there were no documented negative outcomes related to any surgeries performed by Physician A in the 9 months prior to Patient 1's surgery and concerns regarding Physician A's skills from other staff to leadership came after Patient 1 and 2's surgeries. We determined facility leadership responded appropriately by suspending Physician A until the results of Patient 1's peer review were known and that the Level 2 peer review was not conclusive evidence that Physician A was not able to safely perform surgery. We also found facility leadership responded timely after Patient 2's surgery when it again suspended Physician A's surgical privileges and moved to place Physician A on an FPPE with supervision from a surgeon from another facility. The surgeon tendered resignation from the facility to be effective June 5, 2012.

Issue 2: Credentialing and Privileging

We did not substantiate the allegation that Physician B was not properly credentialed and privileged and found Physician B's Credentialing and Privileging documents were compliant with VHA policy.

Credentialing is the systematic process of screening and evaluating qualifications and other credentials, including licensure, required education, relevant training and experience, and current competence and health status. VHA Handbook 1100.19[1] requires each facility to verify, through the appropriate primary sources, a number of items, including professional education, training, and licensure. The Handbook also requires that privileges are delineated. Delineated clinical privileges are an accurate, detailed, and specific description of the scope and content of patient care services for which a practitioner is qualified. They are based on credentials and performance and are authorized by the facility. The delineation of privileges must be facility and provider specific. Privileges can only be granted within the scope of the medical facility's mission and are based on the provider's experience and training. An FPPE is a process whereby the facility evaluates the privilege-specific competence of the practitioner who does not have documented evidence of competently performing the requested privileges of the facility. The Handbook 1100.19 requires that consideration for the FPPE is to occur at the time of initial appointment to the medical staff, or the granting of new, additional privileges.

The complainant reported having known Physician B for years and prior to hiring, expressed concerns about Physician B's recent experience to the Chief of Surgery. Specifically, the complainant reported that Physician B had been out of the practice of cardiac surgery for some time as a result of an injury and other factors. Additionally, the complainant alleged that perfusionists were asked by the Chief of Surgery to check on Physician B and they reported to the Chief of Surgery that Physician B had been asked to not return to a locum tenens assignment in Texarkana, TX for issues regarding competence. They also related to the Chief of Surgery that Physician B had performed one open-heart operation in at least a year and that the surgeon at Texarkana expressed concerns about his skills.

Physician B was an experienced thoracic surgeon for many years and had been doing locum tenens work since 2010. We learned the COS and the facility's risk management department reviewed Physician B's qualifications prior to his appointment in September 2012. We found the NPDB-HIPD had no negative reports, and Physician B's current competency was determined by peer/professional references, evaluation of his ability to perform the privileges requested, and verification of training. We reviewed the credentialing committee minutes, which indicated no further action was required. In Vet Pro, the Chief of Surgery contemporaneously wrote, "[sic Physician B] is very experienced and has good references. He has been active as a cardiothoracic surgeon on a locum tenens basis in Texas recently." On interview, the COS iterated that the facility had called other facilities prior to appointment to verify Physician B's surgical competence. After Physician B's appointment was approved in September 2012, a 3-month FPPE was instituted as required.

[1] VHA Handbook 1100.19, *Credentialing and Privileging*, November 14, 2008.

3: Disclosure

We did not substantiate the allegation that the three patient cases described by the complainant required disclosure.

VHA Handbook 1004.08[2] defines the phrase "disclosure of adverse events" as a discussion of clinically-significant facts between facility staff and patients or their personal representatives about the occurrence of a harmful adverse event. The Handbook defines adverse events as untoward incidents, diagnostic or therapeutic misadventures, iatrogenic injuries or other occurrences of harm or potential harm directly associated with care or services provided. The Handbook requires institutional disclosure of adverse events that occur during a patient's care that results in or is reasonably expected to result in death or serious injury and provided specific information about patient rights and recourse.

Patient 1: The complainant reported that the peer review for Patient 1 was conducted before the autopsy results were available to the reviewer. (b)(5), 38 U.S.C. 5705 The complainant asserted that, given the description of the graft to the artery, it is likely that the tension on the graft resulted in some degree of kinking in the native coronary artery at the anastomosis producing the thrombus and the death and was the result of technical error or misadventure.

Patient 1's operative care was peer reviewed. The peer reviewer from the Michael E. DeBakey VAMC in Houston assigned a Level 2 (most experienced, competent practitioners, might have managed the case differently in one or more of the aspects listed) and documented that disclosure was not warranted.

The autopsy showed "the native coronary arteries all demonstrate severe atherosclerosis with 70 percent to 90 percent stenosis in the bypassed segments. The right coronary artery (RCA) and left anterior descending artery (LAD) distal respective grafts are patent with mild atherosclerotic stenosis. The left obtuse marginal artery distal to the bypassed segment distal to the graft site appears grossly obstructed; microscopic sections demonstrate probable before death blood clot formation blocking over 95 percent of the artery. No definitive signs of acute ischemia or infarction are seen grossly or microscopically within the heart muscle. The final diagnosis was sudden death."

The pathologist who performed the autopsy told us the patient had a fairly sick heart prior to surgery with fibrosis, severe atherosclerosis, and significant cardiac hypertrophy. The bypass grafts were patent, intact and did not indicate problems with the grafts. There was an early thrombus in the native left obtuse marginal artery occluding a significant portion of the lumen. He reported that it is not possible to specifically age when the thrombus formed (pre, intra, or post-surgery) but it likely occurred sometime after surgery and before death. The final diagnosis was sudden death. The pathologist also indicated that if the patient had a myocardial infarction within 4–6 hours of death, it would not necessarily have time to show up in the histology. The pathology findings did not definitively support or disprove the complainant's theory. We could not substantiate the allegation that disclosure was required in this case.

[2] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 12, 2012 (corrected copy).

Patient 2: Patient 2 recovered post-operatively as expected and was discharged home. The surgery did not result in or was not expected to result in serious injury or death. The complainant maintained that the patient's family was not told of the events of the operation and specifically that Dr. (b)(6) had ligated two of the patient's coronary arteries and that this could have an impact on future percutaneous interventions on his coronary arteries as well as having an impact on the value of the grafts that eventually were successfully sewn to the patient's coronary arteries.

(b)(3):38 U.S.C. 5705

Patient 3: At our request, a peer review was performed.

(b)(3):38 U.S.C. 5705

We have no recommendations and, therefore, are administratively closing this case.

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Healthcare Inspections

8/12/13