



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Quality of Care Concerns
Regarding a Patient Who
Had Cardiac Surgery at the
VA Ann Arbor Healthcare
System
Michigan



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to allegations concerning the care of a patient who underwent cardiac surgery in 2015 at the VA Ann Arbor Medical Center (Facility) that, along with three community based outpatient clinics, comprises the VA Ann Arbor Healthcare System in Michigan. The complainant alleged that

- The patient received inappropriate care during cardiac surgery that ultimately led to death,
- The bypass pump catheter had been “misplaced” [improperly placed] by an anesthesiologist at the beginning of surgery, leading to body and brain anoxia during surgery,¹ and
- The patient was abandoned by an anesthesiologist during surgery.

The OIG was unable to substantiate that the patient received inappropriate care during cardiac surgery that ultimately led to death. The patient underwent an elective, scheduled open-heart surgery to repair a mitral valve prolapse, which required diversion of blood flow through the heart (cardiopulmonary bypass (CPB)).² The patient did not receive adequate blood flow to the brain during the surgery that was most likely related to the position of a catheter inserted into the aorta to establish CPB; the patient died six days after surgery. Due to a lack of evidence as to how or when the CPB catheter became misplaced, the OIG was unable to determine whether the patient received inappropriate care that resulted in the patient’s death. According to interviews, and a review of still shots of the imaging study done to determine catheter position at the start of surgery, it appeared that the CPB catheter was not improperly placed at that time. The OIG reviewed the operative team’s interventions during surgery, which seemed to reflect reasonable responses to the patient’s intraoperative clinical presentation and did not support suspicions of a CPB catheter misplacement until the patient was taken off CPB.

The care provided to a patient undergoing cardiothoracic surgery is guided by standards defined by specialty organizations such as the American Society of Anesthesiologists, American Association for Thoracic Surgery, American Society of Extracorporeal Technology, and the

¹ Anoxia is a condition characterized by an absence of oxygen supply to an organ or tissue.

² Diversion of blood flow is accomplished by insertion of catheters into large blood vessels in the patient’s chest that are connected to the CPB machine. The CPB machine temporarily takes over the normal function of the heart and lungs during surgery.

Association of Operating Room Nurses.³ The OIG used guidelines developed by professional organizations, Veterans Health Administration (VHA) directives, medical bylaws, and surgical experience to evaluate the care provided to the patient. The OIG focused on three phases of the patient's perioperative experience: (1) preoperative, (2) intraoperative, and (3) postoperative,⁴ and determined that care provided during the three phases of surgery was consistent with guidelines, directives, and Facility policy related to the care of a surgical patient.

The OIG did not substantiate that the CPB catheter was misplaced [improperly placed] at the beginning of surgery.⁵ The OIG found documentation in the electronic health record (EHR), and confirmed during staff interviews, that the CPB catheter was placed by a surgical fellow under the supervision of the attending cardiothoracic surgeon (surgeon). Review of the EHR and interviews determined the cannulation (placement of the CPB catheter into the aorta) and initiation of CPB appeared unremarkable and no issues were reported to the surgeon regarding the function or position of the CPB catheter during initiation and maintenance of CPB.

The surgeon told the OIG it was first discovered that the CPB catheter was not in the correct position towards the end of the procedure, when the cross-clamp on the aorta (large blood vessel in the chest) was removed. The CPB catheter is intended to maintain a position within the aorta and any migration out of the aorta (such as into the subclavian artery, a blood vessel branching from the aorta), would represent malpositioning. Evidence is not available to determine how long the catheter was malpositioned during the surgery, other than the patient's subsequent death which indicated a significant period elapsed while the patient's brain was receiving insufficient blood flow. The position of the CPB catheter resulted in poor perfusion of the brain (brain anoxia) and the patient's death.

The anesthesiologist conducted a transesophageal echocardiogram (TEE) at the start of surgery and interpreted the images as showing the CPB catheter in proper position. According to the TEE and other information available at the start of the procedure, it did not appear that the catheter was improperly placed at that time. Anesthesiology and surgical team members also reported in

³ American Society of Anesthesiologists (ASA) *Standards for Basic Anesthesia Monitoring*. October 21, 1986, Amended October 20, 2010, last affirmed October 28, 2015; Nishimura, RA., Otto, C. et al., *AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease*; AmSect. *Standards and Guidelines for Mechanical Circulatory Support*. December 2015; Baker, RA, Bronso, S. et al. *Report from Amsect International Consortium for Evidence Based Perfusion: American Society of Extracorporeal Technology, Standards, and Guidelines for Perfusion Practice*. The Journal of Extracorporeal Technology. 2013 (3)45; AORN, 2015 *Guidelines for Perioperative Practice*.

⁴ The preoperative phase begins when the patient is informed of the need for surgery, the intraoperative phase includes the surgical procedure, and the postoperative phase includes the immediate recovery period and continues until the patient resumes usual activities.

⁵ Within the context of this report, when discussed in relation to the patient at issue, the CPB catheter refers to the cardiopulmonary bypass catheter that was placed in the aorta.

interviews that the TEE showed the CPB catheter was in the aorta at the beginning of surgery and not in the left subclavian artery.

Providers were monitoring indicators of perfusion: (a) blood pressure, (b) oxygen saturation levels, and (c) urine output. The patient's blood pressure, which was being monitored in part through an intra-arterial catheter in the left arm, appeared normal as the CPB catheter was most likely very close to, if not in, the left subclavian artery, and perfusing the left arm, even though it was failing to adequately perfuse the rest of the body and the brain. Oxygen levels as documented in anesthesia and perfusion intraoperative records were within normal levels. The OIG noted the perfusionist administered a diuretic (a medication used to increase the flow of urine) and there was a response approximately 20 minutes later.⁶ The anesthesiologist told the OIG that the patient's urine output was not discussed with the surgeon and that lower urine output is common when patients go on CPB. The OIG determined that, when considered with other factors indicating perfusion (blood pressure and oxygen levels within normal limits), the providers' assessment of the patient's urine output during CPB was reasonable.⁷

The OIG did not substantiate that the patient was abandoned by the anesthesiologist during surgery. During interviews, operating room staff and the anesthesiologist told the OIG that the anesthesiologist was present for the critical points of the procedure. Critical points include induction,⁸ placement of the CPB catheter (also known as cannulation),⁹ application of the cross-clamp to the aorta prior to CPB,¹⁰ removal of the cross-clamp, and removal of the CPB catheter.

The OIG reviewed the Facility's quality management processes and records. VHA's safety program goals are to prevent harm to patients and build a culture of safety. Accomplishing these goals requires "reviewing adverse events to identify underlying causes and implementing changes needed to reduce the likelihood of recurrence."¹¹ The required processes include root cause analysis (RCA), peer review, and disclosures.

⁶ A perfusionist is "a certified medical technician responsible for extracorporeal oxygenation of the blood during open-heart surgery and for the operation and maintenance of equipment." [Merriam Webster.com](https://www.merriam-webster.com/dictionary/perfusionist). (The website was accessed on December 14, 2017.)

⁷ "There is no consensus on the optimal amount of urine during CPB." See Young Song and Dong Wook Kim et al. *Urine Output During Cardiopulmonary Bypass Predicts Acute Kidney Injury After Cardiac Surgery*, *Medicine – Observational Study*. Wolters Kluwer Health, Inc. 95, no. 22, (June 2016):1.

⁸ "The induction of anesthesia refers to the transition from an awake to an anaesthetized state." *British Journal of Hospital Medicine*, May 2013, Vol 74, No 5.

⁹ A cannula is a tube for insertion into a vessel, duct, or cavity.

¹⁰ Cardiopulmonary bypass (CPB) is a form of external "circulation whose function is circulatory and respiratory support along with temperature management to facilitate surgery on the heart and vessels."

¹¹ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

The OIG determined the Facility did not complete an RCA as required for this sentinel event. An “RCA is a specific type of focused review that is used for all adverse events,” and is required to be completed within 45 days.¹² Sentinel events are specific types of adverse events defined “as unexpected occurrences involving death, serious physical or psychological injury, or risk thereof” that require “immediate investigation and response.”¹³ Although the Chief of Staff told the OIG that an investigation was completed by Patient Safety staff, other Facility leaders indicated an RCA had not been completed. The Patient Safety Manager did not provide the OIG evidence that a structured review or report was done.

OIG Update: *Upon receipt of the draft report in September 2018, the Facility provided the OIG documentation of a fact-finding review that was conducted by a Facility team. The Facility team determined there were no systemic issues and therefore, decided to not conduct an RCA.*

A peer review is a confidential, non-punitive process for evaluating health care provided by an individual provider. The OIG determined the Facility conducted internal and external peer reviews on the cardiac surgeon. The University of Michigan, who contracted with the Facility to provide the anesthesiologist’s services for this patient, conducted a review on the anesthesiologist but declined to provide the results of the review to the Facility.¹⁴ The University did not consider the review to be a peer review.

OIG Update: *Upon receipt of the draft report in September 2018, the Facility provided the OIG documentation of a fact-finding review that was conducted by a Facility team. The Facility team focused on the surgeon during the review.*

The OIG found the Facility completed a clinical disclosure to the patient’s family but did not complete an institutional disclosure to assist the family in determining actions and recourse as needed. VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012, states that disclosure is warranted for sentinel events. Facility policy also requires institutional disclosures in cases resulting in serious injury or death. The policy requires specific documentation for institutional disclosures in the EHR by the Patient Safety Manager, Risk Manager, Quality Manager, or the Chief of Staff.

The OIG determined that the surgeon and/or anesthesiologists implemented individual modifications in their surgical/anesthesia practices after the patient’s surgery. While these modifications might be successful or improve patient care, they were not determined or endorsed through a systematic quality review. A peer review and a systematic quality review by the

¹² VHA Handbook 1050.01.

¹³ VHA Handbook 1050.01.

¹⁴ VHA Directive 2010-025, *Peer Review for Quality Management*, June 30, 2010, requires a peer review for a “death during or within 30 days of a surgical procedure.” A peer is “a health care professional who has similar or more advanced education, training, experience, licensure, or clinical privileges or scope of practice to the provider being reviewed.”

Facility, particularly an RCA, would have allowed for more accurate and rapid communication of actual causes of harm to this patient, and improved care for other patients at the Facility.

The OIG made one recommendation to the Veterans Integrated Service Network (VISN) Director related to the Facility's compliance with RCA, peer review, and disclosure requirements.

The OIG made one recommendation to the Facility Director regarding a review of the stated modifications made by the anesthesiologist and surgeon for their cardiothoracic surgeries.

Comments

The Veterans Integrated Service Network Director and Facility Director concurred with the recommendations and provided acceptable action plans. (See Appendixes A and B, pages 21–24 for the Directors' comments.) The OIG will follow up on the planned actions until they are completed.



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Abbreviations

AmSect	American Society of Extracorporeal Technology
AORN	Association of Operating Room Nurses
ASA	American Society of Anesthesiologists
CPB	cardiopulmonary bypass
CT	computed tomography
EHR	electronic health record
ICU	intensive care unit
MV	mitral valve
OIG	Office of Inspector General
PCP	primary care provider
RCA	root cause analysis
SvO2	venous oxygenation saturation
TEE	transesophageal echocardiogram
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
WNL	within normal limits



Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to allegations concerning the care of a patient who underwent cardiac surgery in 2015 at the VA Ann Arbor Medical Center (Facility). This Facility and three community based outpatient clinics (CBOCs) comprise the VA Ann Arbor Healthcare System in Michigan. The allegations focused on whether a patient received inappropriate care during cardiac surgery that ultimately led to death; whether a cardiopulmonary bypass (CPB) catheter was improperly placed leading to body and brain anoxia;¹⁵ and whether the patient was abandoned by an anesthesiologist during the surgery.

Background

Facility Profile

The Facility, part of Veterans Integrated Service Network (VISN) 10, provides healthcare services to veterans residing in Michigan and Northwest Ohio. The Facility is a major tertiary care referral center with CBOCs in Toledo, Ohio, and in Jackson and Flint, Michigan. The Facility is affiliated with 112 colleges and universities including the University of Michigan's Schools of Medicine, Dentistry, Social Work, Nursing, Public Health, Ross Business School, and Engineering, as well as the University of Toledo College of Medicine. The Facility operated 102 inpatient and 40 Community Living Center beds and served over 68,000 veterans in fiscal year 2017.

Cardiovascular Disease and Surgery

Heart Circulation

The heart serves as a pumping system that takes blood in from the body and sends it to the lungs for oxygen and returns oxygenated blood to the body. Valves control the continuous flow of blood through the four chambers of the heart (right atrium and ventricle, then left atrium and ventricle). Venous blood returns to the right atrium by the inferior and superior vena cava. After the blood flows into the left atrium, it passes through the mitral valve (MV) into the left ventricle. The left ventricle contracts and blood is circulated throughout the body via the aorta.

¹⁵ Anoxia is a condition characterized by an absence of oxygen supply to an organ or tissue.

Mitral Valve Disease

MV regurgitation is a condition in which the MV does not close tightly, allowing blood to flow backward in the heart. As a result, blood cannot move through the heart and body efficiently and may cause the person to feel tired or out of breath. If it is severe, and left untreated, it can cause heart failure or heart rhythm problems. A valve problem that can cause MV regurgitation is MV prolapse, an abnormal movement of the MV during certain phases of the heartbeat. MV prolapse is the most common valve abnormality, affecting “approximately 2 to 3 percent of the population in the United States.”¹⁶

Intraoperative Diagnostic Test

A transesophageal echocardiogram (TEE) is an ultrasound of the heart that may demonstrate the location and severity of the MV disease. TEE is used during the MV repair or replacement operation.¹⁷

Mitral Valve Surgery

During MV surgery, a midline chest incision is performed, the heart is inspected, the left atrium is accessed, and the MV is repaired or replaced.¹⁸ MV surgery can be performed on the arrested heart with the assistance of cardiopulmonary bypass (CPB). CPB is a form of external “circulation whose function is circulatory and respiratory support along with temperature management to facilitate surgery on the heart and vessels.”¹⁹ During most open-heart surgeries, the heart is temporarily stopped by an infusion of high potassium solution (cardioplegia). The cardioplegia solution may be cold or warmed. If the solution is cold and infused directly into the arteries through the CPB, it may result in hypothermia. This process reduces the heart’s oxygen consumption, which helps to preserve the heart during surgery and allows the surgeon to work on it when it is not full of blood or beating.²⁰

¹⁶ Mitral valve prolapse is a heart valve that abnormally moves out of position. <https://www.mayoclinic.org/diseases-conditions/mitral-valve-prolapse/symptoms-causes/syc-20355446>. (The website was accessed on May 13, 2018.); Ahmed S, Bernath GA. Valvular Heart Diseases. In: Elmoselhi A. eds. *Cardiology: An Integrated Approach* New York, NY: McGraw-Hill.

¹⁷ Duque M, Machado HS (2016) *Intraoperative Transesophageal Echocardiography: Review and Evolution*. *J Anesth Clin Res* 7:634.

¹⁸ Kaneko T, Yammine M, Loberman D, Aranki S. Mitral Valve Replacement. In: Cohn LH, Adams DH. eds. *Cardiac Surgery in the Adult, 5e* New York, NY: McGraw-Hill; Okada, S, et al. Acquired Heart Disease. In: Brunicardi, F et al. eds. *Schwartz's Principles of Surgery*, 10e New York, NY: McGraw-Hill; 2015.

¹⁹ Sarkar M, Prabhu V. Basics of cardiopulmonary bypass. *Indian Journal of Anaesthesia*. 2017;61(9):760-767.

²⁰ Sarkar and Prabhu, 2017.

The CPB pump is operated by perfusionists.²¹ In order to place the patient on CPB, the surgeon inserts venous and aortic catheters into the heart.²² In addition, catheters for infusing the cold cardioplegia solution are inserted into the right atrium and into the ascending aorta. The surgeon initiates the CPB and venous circulation is directed towards the bypass machine. The CPB circuit “includes pumps, cannulae [sic-tubes also called catheters], tubing, reservoir, oxygenator, heat exchanger, and arterial line filter.” The CPB has “systems for monitoring pressures, temperature, oxygen saturation, hemoglobin, blood gases, [and] electrolytes” as well as safety features.²³ Oxygenation of the blood is provided by the CPB machine. During CPB, an aortic cross-clamp is applied to isolate the coronary arteries from the aortic blood flow. After the repair is completed, the cross-clamp is removed, CPB support is gradually withdrawn (weaned), and the patient’s heart takes over the circulation. The weaning process includes a period of gradual rewarming. The final step is removal of the CPB catheters (venous and aortic).²⁴

Potential CPB complications

Clinical complications of CPB can be bleeding from arterial cannulation, cannula malposition causing selective cerebral perfusion, plaque dislodgement, and dissection. The effects of CPB can cause inflammatory responses, kidney injury, and acute respiratory distress syndrome.²⁵

Allegations

In July 2017, the OIG Hotline Division referred allegations made by a confidential complainant to the OIG Office of Healthcare Inspections regarding a patient who died in 2015. The complainant alleged

- The patient received inappropriate care during cardiac surgery that ultimately led to death,
- The bypass pump catheter had been “misplaced” by an anesthesiologist at the beginning of surgery, leading to body and brain anoxia during surgery, and
- The patient was abandoned by an anesthesiologist during surgery.

²¹ A perfusionist is “a certified medical technician responsible for extracorporeal oxygenation of the blood during open-heart surgery and for the operation and maintenance of equipment” (such as a CPB pump) “controlling it.” [Merriam Webster.com](https://www.merriam-webster.com/dictionary/perfusionist). (The website was accessed on December 14, 2017.)

²² Within the context of this report, when discussing the CPB catheter in relation to the patient at issue, the OIG is referring to the CBP catheter that was inserted into the aorta.

²³ Sarkar and Prabhu, 2017.

²⁴ Sarkar and Prabhu, 2017; Wasnick JD, Hillel, Z. et al. Cardiac Anesthesia and Transesophageal Echocardiography: *Routine Cardiac Surgery and Anesthesia*. New York, NY: McGraw-Hill. 2011.

²⁵ Sarkar and Prabhu, 2017.

Scope and Methodology

The OIG conducted a site visit October 10–12, 2017. OIG staff interviewed the complainant, Chief of Staff, Patient Safety Manager, attending physicians, and medical residents for surgery and anesthesiology. In addition, the staff interviewed members of the surgical team who performed the surgery including the perfusionist, circulating nurse, and surgical technician. OIG medical consultants reviewed images of the TEE done on the day of surgery with subject matter experts to determine where the CPB catheter was placed.

Also reviewed were relevant Veterans Health Administration (VHA) and Facility policies and procedures; credentialing, competency, and quality reviews; training records; the University of Michigan–VA contract for anesthesiology services; pertinent medical literature; and the patient’s electronic health record (EHR).

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to substantiate an allegation when the available evidence is insufficient to determine whether or not an alleged event or action took place.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Patient Case Summary

The patient was in his/her 50s and had a history of MV prolapse, MV regurgitation, hypertension, and obstructive sleep apnea. Other medical history included a fracture to the right radius in the late 1990s and a congenital malformation of the left hand with multiple corrective surgeries as a child.²⁶

In late 2014, the patient established care with a Facility primary care provider (PCP) after an approximately seven-year absence. The patient reported to the PCP about being diagnosed with MV prolapse through an echocardiogram. The patient also reported palpitations daily but remained physically active. The patient's only medication was daily aspirin. The PCP performed a physical exam noting vital signs and weight within normal limits. The PCP heard a heart murmur; the rest of the physical exam was unremarkable. The PCP ordered a transthoracic echocardiogram, a type of heart ultrasound, to evaluate the murmur.

In early 2015, the transthoracic echocardiogram results indicated moderate to severe MV regurgitation with posterior leaflet prolapse.²⁷ Based on these results, the PCP recommended to the patient an evaluation with a cardiologist and entered the consult that day.

Approximately 10 weeks later, the patient contacted the PCP for approval to continue working. The patient reported failing to pass an employment examination due to the murmur. The PCP agreed to draft a letter to the employer.

In summer 2015, the cardiologist evaluated the patient and recommended a referral for a TEE, a cardiac catheterization, and a consultation with a cardiac surgeon.²⁸ The cardiac catheterization showed pressures were normal within the right ventricle, but mildly elevated in the left ventricle. Comparison to the same evaluation in 2007 showed an interval progression of mild pulmonary hypertension, low cardiac output, and nonobstructive coronary artery disease.²⁹ The surgeon evaluated the patient for MV repair or replacement and discussed the surgical risks. The patient elected to proceed with the surgery. Cardiothoracic surgery staff completed the preoperative history and physical, ordered bloodwork, a chest x-ray, and pulmonary function testing in

²⁶ The radius is “the bone on the thumb side of the human forearm.” [Merriam Webster.com](#). (The website was accessed on December 14, 2017.) The term congenital refers to “an acquired characteristic during development in the uterus and not through heredity.” [Merriam Webster.com](#). (The website was accessed on December 14, 2017.)

²⁷ In this context, a leaflet refers to “a flap in a cardiac valve.” [Merriam Webster.com](#). (The website was accessed on December 14, 2017.)

²⁸ A cardiac catheterization is “a medical procedure in which a thin, flexible catheter is inserted through an artery or vein (as of the arm or leg) and passed into the heart for the diagnosis and treatment of heart conditions.” [Merriam Webster.com](#). (The website was accessed on December 14, 2017.)

²⁹ Nonobstructive coronary artery disease is “plaque that would not be expected to obstruct blood flow or result in anginal symptoms.” T. Maddox, M. Stanislawski, G. Grunwald et.al. *Nonobstructive Coronary Artery Disease and Risk of Myocardial Infarction*, JAMA, 1754-1763:(17).

preparation for the surgery. The preoperative assessment, bloodwork, and studies were unremarkable.

Approximately four weeks later, the patient arrived at the Facility for surgery. Surgical staff reviewed the patient's history and noted no changes from the preoperative assessment. The anesthesiologist noted that another physician, in preparation for surgery, inserted a catheter into the left radial artery to monitor blood pressure.³⁰ The physician also threaded a catheter from the right internal jugular into the pulmonary artery to measure the pressure in the heart and lung prior to endotracheal anesthesia.³¹ A nurse inserted a urinary catheter in the patient's bladder to monitor urine output. The surgeon performed a sternotomy and inserted the heart catheters in preparation for connection to the CPB.³² The patient was successfully placed on CPB. The surgeon performed the valve repair and did not recognize any complications. Operating room documentation entered and scanned into the EHR did not indicate issues or difficulties in the operative period prior to connection to the CPB pump, during the MV repair procedure, or during the CPB disconnection. The total CPB time was 2 hours and 32 minutes. The total clamp time was 1 hour and 52 minutes.

After the surgery, the surgeon documented an addendum to a postoperative note:

Cannulation and institution of cardiopulmonary bypass appeared unremarkable. There were no reported issues during initiation and maintenance of CPB. I was notified about midway through the mitral valve repair that urine output had decreased. I confirmed that CPB circuit pressures were unremarkable, venous saturation was normal, and flow rates and venous return was appropriate for [the size of the patient]. After removal of the cross-clamp, it was apparent that central aortic pressure was much lower than the arterial line pressure measured in the left radial artery. We measured the central aortic pressure using the antegrade cardioplegia line and confirmed central hypotension. I immediately withdrew the aortic cannula back approximately 1 cm, from its insertion position of 3.5–4 cm. The radial artery pressure fell from about 70 mm Hg to approximately 30 mm Hg. Hypotension was treated with vasoconstrictors. The patient easily weaned from

³⁰ A radial artery is “the smaller of the two branches into which the brachial artery divides just below the bend of the elbow and which passes along the radial side of the forearm to the wrist then winds backward around the outer side of the carpus and enters the palm between the first and second metacarpal bones to form the deep palmar arch.” [Merriam Webster.com](https://www.merriam-webster.com/dictionary/radial%20artery). (The website was accessed on December 14, 2017.)

³¹ The term endotracheal means “applied or effected through the trachea.” [Merriam Webster.com](https://www.merriam-webster.com/dictionary/endotracheal). (The website was accessed on December 14, 2017.)

³² A sternotomy is a “surgical incision through the sternum.” [Merriam Webster.com](https://www.merriam-webster.com/dictionary/sternotomy). (The website was accessed on December 14, 2017.)

cardiopulmonary bypass with stable hemodynamics, normal mixed venous saturation, and urine output increased.³³

After surgery, the patient did not wake up from anesthesia. A computed tomography scan was completed the night of surgery and showed findings consistent with diffuse anoxic brain injury. Neurology staff evaluated and followed the patient in the intensive care unit (ICU); an electroencephalogram and a magnetic resonance image were completed.³⁴ The patient's condition and studies remained consistent with diffuse anoxic brain injury. After a short stay in the ICU without improvement, the patient was transferred to the University of Michigan Health System. The patient's condition did not change. Three days after transfer, the family decided to transition the patient to palliative care; the patient died the following day.

³³ "The term hemodynamic means "relating to or functioning in the mechanics of blood circulation." [Merriam Webster.com](#). (The website was accessed on December 14, 2017.)

³⁴ An electroencephalogram is "the tracing of brain waves." A magnetic resonance image is "a noninvasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves." [Merriam Webster.com](#). (The website was accessed on December 14, 2017.)

Inspection Results

Issue 1: Alleged Inappropriate Care during Cardiac Surgery

The OIG was unable to substantiate that the patient received inappropriate care during cardiac surgery that ultimately led to death. The patient underwent an elective, scheduled open-heart surgery to repair a mitral valve prolapse that required diversion of blood flow through the heart (CPB).³⁵ The patient did not receive adequate blood flow to the brain during the surgery that was most likely related to the position of a catheter inserted into the aorta to establish CPB; the patient died six days after surgery. Due to a lack of evidence as to how or when the CPB catheter became misplaced, the OIG was unable to determine whether the patient received inappropriate care resulting in death. According to interviews, and a review of the still shots of the imaging study done to determine catheter position at the start of surgery, it appeared that the CPB catheter was not misplaced at that time. The OIG reviewed the operative team's interventions during surgery, which seemed to reflect reasonable responses to the patient's intraoperative clinical presentation and did not support suspicions of a CPB catheter misplacement until the patient was taken off CPB.

Multiple criteria, standards, and elements of performance are utilized and reviewed to ensure quality, safety, and efficient anesthesiology and surgical care during a surgical procedure.³⁶ The care provided to a patient undergoing cardiothoracic surgery is guided by standards defined by specialty organizations such as the American Society of Anesthesiologists (ASA), American Association for Thoracic Surgery, American Society of Extracorporeal Technology (AmSect), and the Association of Operating Room Nurses (AORN).³⁷ The OIG used clinical guidelines developed by professional organizations, VHA directives, local policies, medical bylaws, and surgical experience to evaluate the care provided to the patient.^{38,39} OIG staff reviewed information documented in the patient's EHR and provided in interviews.

³⁵ Diversion of blood flow is accomplished by insertion of catheters into large blood vessels in the patient's chest that are connected to the CPB machine. The CPB machine temporarily takes over the normal function of the heart and lungs during surgery.

³⁶ Facility Policy Memorandum 112-07 *Preanesthesia Care Unit Policy and Procedure*, August 29, 2012.

³⁷ VHA Handbook 1123, *Anesthesia Services*, March 7, 2007. This VHA Handbook was scheduled for recertification on or before the last working day of March 2012 and has not been recertified.

³⁸ ASA. Standards for Basic Anesthesia Monitoring. October 21, 1986, Amended October 20, 2010, last affirmed October 28, 2015; Nishimura, RA., Otto, C. et al., AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease; AmSect. Standards and Guidelines for Mechanical Circulatory Support. December 2015.

³⁹ Baker, RA, Bronso, S. et al. Report from Amsect International Consortium for Evidence Based Perfusion: American Society of Extracorporeal Technology, "Standards, and Guidelines for Perfusion Practice." *The Journal of Extracorporeal Technology*. 2013 (3)45; AORN, 2015 *Guidelines for Perioperative Practice*; Wasnick et al., 2011.

The inspection focused on three phases of the patient's perioperative experience: preoperative, intraoperative, and postoperative and determined that care provided during the three phases was consistent with guidelines, directives, and Facility policy related to the care of a surgical patient.⁴⁰

Preoperative

The OIG reviewed requirements of the preoperative phase, which included obtaining the patient's history and informed consent, conducting a physical examination and other preoperative assessments, as well as insertion of

- Catheters for hemodynamic monitoring,
- A bladder catheter to measure urine, and
- A probe to provide images for a TEE.⁴¹

Patient safety measures were instituted, such as procurement of necessary equipment, positioning of the patient, surgical skin preparation, and a time out.⁴²

Intraoperative

During the maintenance of anesthesia in the intraoperative phase,⁴³ the patient's oxygenation, ventilation, circulation (perfusion), and temperature were continually monitored.⁴⁴ In order to place the patient on CPB, venous and aortic catheters were inserted. The cardioplegia catheters were also inserted; one into the right atrium and a second one into the ascending aorta to infuse the cold cardioplegia solution.

⁴⁰ The preoperative phase begins when the patient is informed of the need for surgery, makes the decision to have the surgery and ends when the patient is transferred to the operating room bed. The intraoperative phase includes the surgical procedure. The postoperative phase includes the immediate recovery period and continues until the patient resumes usual activities.

⁴¹ Kaneko et al., *Mitral Valve Replacement*.

⁴² VHA Handbook 1004.01. *Informed Consent for Clinical Treatments and Procedures*. August 14, 2009, revised September 20, 2017; VHA Directive 1039. *Ensuring Correct Surgery and Invasive Procedures*. July 26, 2013. A "time out" is "when the surgeon, anesthesiologist, and nursing staff utilize a checklist and concur verbally that they have the correct patient identify, procedure to be performed, site of procedure, valid consent form, patient position, procedure site marked appropriately, pertinent medical images confirmed, correct medical implant, preoperative antibiotics, deep vein thrombosis prevention, availability of blood and special equipment." See also, AORN, 2015 *Guidelines for Perioperative Practice, Guideline for Positioning the Patient* (revised April 2017) and 2014 *Guideline for Preoperative Patient Skin Antisepsis*.

⁴³ The intraoperative phase begins when the patient is transferred to the operating room and ends when the patient is transferred to a post-anesthesia care unit or another area such as Intensive Care.

⁴⁴ VHA Handbook 1123. *Anesthesia Service*. March 7, 2007. This VHA Handbook was scheduled for recertification on or before the last working day of March 2012, but has not been recertified.

The OIG reviewed the EHR, the vital signs, and monitoring parameters recorded during the procedure and determined the key indicators were within normal limits (WNL) during the procedure. The anesthesiologists recorded the patient's oxygenation, ventilation, and circulation before, during, and after the CPB.⁴⁵ Circulation was monitored by (1) the left radial arterial monitor that measures blood pressure, (2) the pulmonary artery catheter that can be used to measure cardiac output, and (3) recorded urinary output that is measured to evaluate kidney perfusion.⁴⁶ According to an interview, the urinary catheter bag was placed at the head of the bed, near the anesthesiologist.

The patient was placed on the CPB, and the perfusionist continued to monitor the oxygenation, circulation, and patient's temperature. During interviews, the surgeon, anesthesiologist, and perfusionist reported varied recollections of communications throughout the procedure.

The OIG reviewed the anesthesia and perfusion intraoperative records and determined the patient's oxygenation values were WNL. The surgeon documented the patient's mixed venous oxygenation saturation (SvO₂) was normal after CPB.⁴⁷

The anesthesiologist recalled that, within 35 minutes of the patient going on CPB, urinary output was reduced. The perfusionist and anesthesiologist had different recollections as to whether they discussed the urine output with each other; however, the perfusionist documented that a diuretic was administered. Soon after, 100cc of urine output was recorded on the perfusion record. A second diuretic that is routinely given during cardiac surgery was also administered by the perfusionist. The urine output was not discussed with the surgeon because the anesthesiologist stated lower urine output is common when patients go on CPB as a result of the change in the flow to the kidneys. The intraoperative anesthesia record reflected a total of 700 milliliters of urine output during the surgery. The surgeon recalled the first indication that "something wasn't right" was when the perfusionist was checking the urinary catheter bag and thought it was blocked. In the review of the intraoperative anesthesia report, the OIG determined that urine output was reduced, but WNL.⁴⁸

When the surgeon partially withdrew the clamp from the aorta, lower pressure was found in the aorta. The patient's low blood pressure was treated with intravenous medications. As routine

⁴⁵ Oxygenation is the supplying of oxygen to the patient or patient's tissues. [Merriam Webster.com](https://www.merriam-webster.com/dictionary/oxygenation). (The website was accessed on June 1, 2018.); Ventilation is "the circulation and exchange of gases in the lungs...basic to respiration." [Merriam Webster.com](https://www.merriam-webster.com/dictionary/ventilation). (The website was accessed on December 14, 2017.)

⁴⁶ Cardiac output is "the amount of blood the heart pumps in 1 minute." Vincent J-L. Understanding cardiac output. *Critical Care*. 2008;12(4):174. doi:10.1186/cc6975.

⁴⁷ Normal Values: oxygen saturation (95–100 percent), SvO₂ (60–75 percent). Elaine K. Dailey and John S. Schroeder, *Techniques in Bedside Hemodynamic Monitoring*, 5th ed. (St. Louis: Mosby-Year Book 1994), 422.

⁴⁸ See Young Song and Dong Wook Kim et al.

practice, two chest tubes were placed for drainage. The patient's chest was closed, and the patient was discharged to the ICU.

The surgeon noted that until the end of the case, the blood pressure (left radial arterial monitor), flow pressures (cardiac output), and SvO₂ were WNL.⁴⁹ The surgeon did not recall any issues reported during initiation or maintenance of CPB.

Postoperative

Cardiothoracic patients are transported directly to the ICU from the OR following the procedure.⁵⁰ The anesthesiologist provides a complete report of the patient's intraoperative and post-procedure status and other pertinent information to the ICU nurse. A patient hand off is performed and documented on the anesthesia record. The surgical staff is responsible for completing a postoperative note and writing orders.⁵¹

The OIG reviewed the EHR and noted the anesthesiologist documented that a call was placed to the ICU nurse approximately one hour prior to transfer. Information reported included specifics about the procedure, allergies, medications, and, drainage catheters, or tubes remaining in the patient. The patient was transported to the ICU.

The ICU nurse recorded vital signs, including arterial blood pressure, pulmonary artery pressures, SvO₂, oxygenation, cardiac output, intravenous fluids and medications, and urinary and chest tube output at intervals consistent with Facility policy. The blood pressure was low per arterial blood pressure readings and blood pressure cuff. IV medications were given to improve blood pressure.

Issue 2: Alleged Misplacement of the CPB Catheter at the Beginning of Surgery

The OIG did not substantiate that the CPB catheter was "misplaced" at the beginning of surgery. The OIG found documentation in the EHR, and confirmed during staff interviews, that the CPB catheter was placed by the surgical fellow under the supervision of the attending cardiothoracic surgeon. Review of the EHR and interviews determined the cannulation and initiation of CPB appeared unremarkable, and no issues were reported to the surgeon regarding the function or position of the CPB catheter during initiation and maintenance of CPB.

The surgeon told the OIG that a problem with the CPB catheter was discovered towards the end of the procedure, when the cross-clamp was removed and there was lower pressure in the aorta.

⁴⁹ Wasnick et al., 2011. Chapter 2. *Hemodynamics and Cardiac Anesthesia*. Mixed SvO₂ "represents the venous hemoglobin saturation in the pulmonary artery after the mixing of venous blood from the superior vena cava, the inferior vena cava, and the coronary sinus."

⁵⁰ The postoperative phase begins with the patient's transfer to the post-anesthesia care unit or Intensive Care.

⁵¹ Facility Policy Memorandum 112-02. *Post Anesthesia Care Unit-Phase I*, September 22, 2014.

The surgeon suggested the location of the CPB catheter may have resulted in poor perfusion of the brain (brain anoxia). Evidence is not available to determine the cause and length of time of the malposition of the CPB catheter during the surgery. The patient's subsequent death, however, is indicative of insufficient blood flow to the brain for a significant period of time.

The CPB catheter is intended to maintain a position within the ascending aorta and any migration out of the aorta (for example, entering a blood vessel branching off the aorta such as the subclavian artery) would represent malpositioning. During CPB, the patient's blood flow is preserved using two catheters: (1) a venous catheter, which takes deoxygenated blood to the CPB machine and (2) an arterial catheter, which returns oxygenated blood to the body.

As seen in Figure 1, the CPB catheter is placed in the ascending aorta where it is in a position to feed (perfuse) the head (through the right and left common carotid arteries), the left arm (through the left subclavian artery), and the lower body (through the descending aorta). If the CPB catheter is placed too close to an artery branching off the aorta, the blood flow from the catheter can be captured by that artery, diverting blood necessary to carry oxygen to vital organs and tissue in other areas of the body.

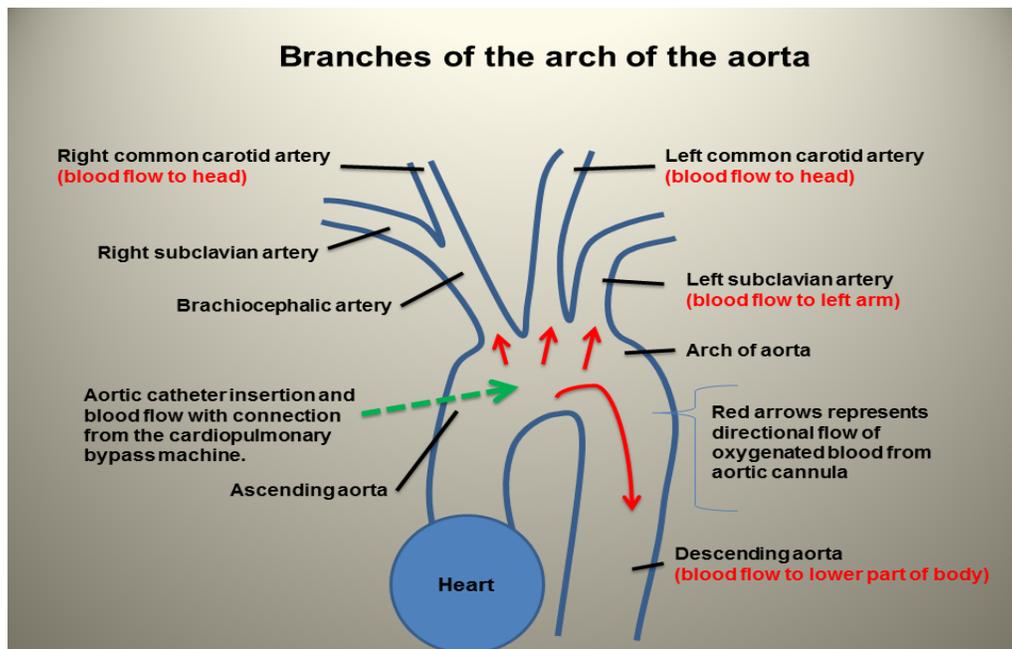


Figure 1. CPB Catheter Site and Placement in the Ascending Aorta
Source: VA OIG staff illustration

Prior to the initiation of CPB, the CPB catheter is placed at a predetermined depth and sutured in place by the surgeon or a surgical fellow. Although rare, a complication can occur after the patient goes on the CPB where pressures associated with blood flow cause the CPB catheter to migrate downstream toward the left subclavian artery.

Figure 2 illustrates blood flow while a patient is on CPB. If the catheter is fully captured by the left subclavian artery, the pressure readings on the perfusion monitor attached to the left arm would be very high, making it unlikely that the malpositioned catheter would escape detection. If the CPB catheter is placed or migrated close to the left subclavian artery without being fully captured, pressure readings might not be high enough for providers to detect that blood is being diverted to the left arm and away from the head and the rest of the body.

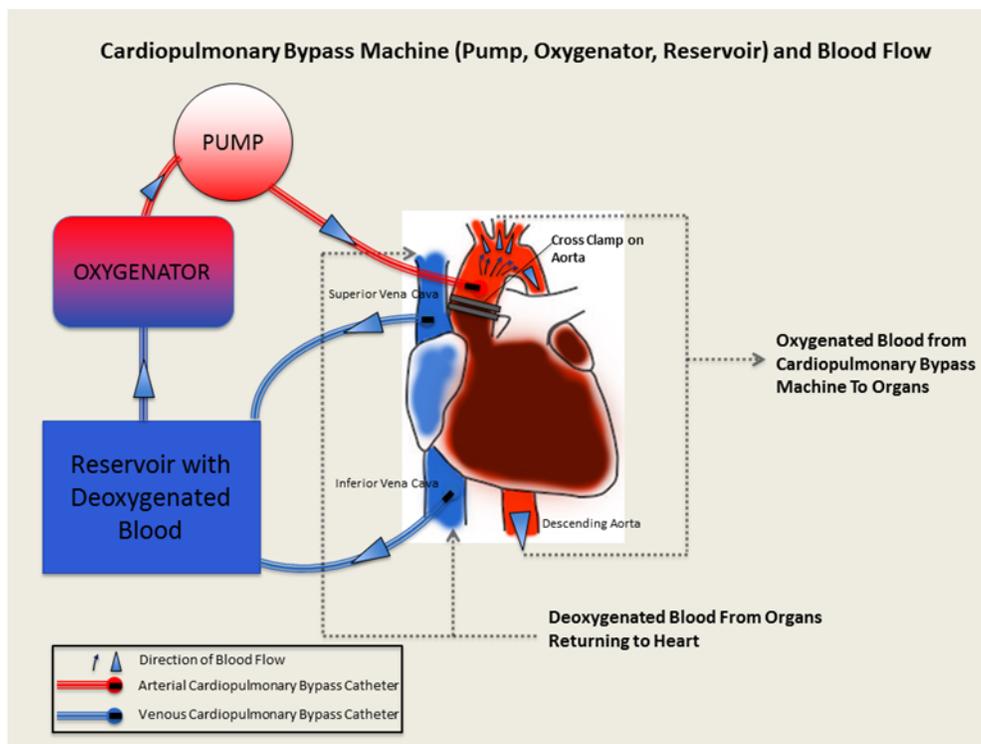


Figure 2. Blood flow while a Patient is on CPB

Source: VA OIG staff illustration

The OIG was told in interviews that at the beginning of the procedure, the surgical fellow placed the CPB catheter in a standard fashion under the supervision of the surgeon. The anesthesiologist conducted a TEE and interpreted the images as showing that the CPB catheter was in proper position. According to the physician's interpretation of the TEE and other information available at the start of the procedure, it did not appear that the catheter was improperly placed at that time. The anesthesiology and surgical team members reported in interviews that a TEE was performed at the beginning of surgery and that it showed the CPB catheter was in the aorta and not the left subclavian artery.

The Facility provided copies of the TEE images from the surgery. The OIG reviewed the images and obtained an interpretation from a subject matter expert from another VA facility. After a TEE probe is placed, the surgical team is able to view dynamic, real-time TEE video images of

the patient's anatomical structures and evaluate blood flow through the heart on a computer screen.

In addition to reviewing the video images, two still images were captured from the TEE video, but, upon review, were inconclusive as to where the catheter was located. The subject matter expert who reviewed the still images could not opine that the failure to capture the correct placement of the catheter on a still photo from a dynamic image was equivalent to the failure to place the catheter correctly. A dissection of the aorta was not seen in the postoperative images, one of the complications of catheter (cannula) placement.

If the catheter migrated during the procedure, the question becomes whether clinical signs of poor perfusion were sufficient to alert surgery, anesthesia, and/or perfusion providers of the need to institute timely interventions. Providers were monitoring indicators of perfusion: (a) blood pressure, (b) oxygen saturation levels, and (c) urine output. The patient's blood pressure, which was being monitored, in part, through an intra-arterial catheter in the left arm, appeared normal. The CPB catheter was most likely very close to, if not in, the left subclavian artery, and perfusing the left arm, even though it was failing to adequately perfuse the rest of the body and the brain. Oxygen levels as documented in anesthesia and perfusion intraoperative records were WNL. The OIG noted the perfusionist administered a diuretic (a medication used to increase the flow of urine) and there was a response approximately 20 minutes later. The total urine output during surgery was 700 milliliters. The anesthesiologist told the OIG that the patient's urine output was not discussed with the surgeon and that lower urine output is common when patients go on CPB. The OIG determined that when considered with other indicators of perfusion (blood pressure and oxygen levels), which appeared to be within normal limits, the providers' assessment of the patient's urine output during CPB was reasonable.

Issue 3: Alleged Abandonment by the Anesthesiologist during Surgery

The OIG did not substantiate that the patient was abandoned by an anesthesiologist during surgery. VHA Handbook 1123, *Anesthesia Service*, March 7, 2007, requires qualified anesthesia personnel to be physically "present in the room throughout the conduct of all general anesthetics, regional anesthetics, and monitored anesthesia care." To achieve optimum patient safety, the American Society of Anesthesiologists (ASA) sets standards of care and responsibilities for anesthesiologists, who direct the anesthesia care team.⁵² The ASA standards also require that a medically-directing anesthesiologist be "immediately available," defined as being "in physical proximity that allows the anesthesiologist to re-establish direct contact with the patient to meet

⁵² ASA, *Statement on the Anesthesia Care Team*, Committee of Origin: Anesthesia Care Team. Approved by the ASA House of Delegates on October 26, 1982, and last amended on October 16, 2013.

medical needs and any urgent or emergent clinical problems. These responsibilities may also be met through coordination among anesthesiologists of the same group or department.”⁵³

Facility OR staff and the anesthesiologist reported during interviews that the anesthesiologist was present for critical points: induction,⁵⁴ placement of the CPB catheter (also known as cannulation),⁵⁵ application of the cross-clamp to the aorta prior to CPB, removal of the cross-clamp, and removal of the CPB catheter. An OR staff member told the OIG that documenting the presence of surgical and anesthesia staff at all times in the OR room was not routine. Staff and the anesthesiologist also told the OIG that it was routine for the anesthesiology resident to take responsibility for the patient when the anesthesiologist takes a break in the immediate vicinity. According to staff interviews and a review of the record, the OIG determined that both an anesthesiologist and an anesthesiology resident were present during the procedure for critical and required times.

Issue 4: Other Findings Regarding Quality Management Processes

The OIG reviewed the Facility’s quality management processes and records. VHA’s safety program goals are to prevent harm to patients and build a culture of safety. Requirements include “reviewing adverse events to identify underlying causes and implementing changes needed to reduce the likelihood of recurrence.”⁵⁶ The required processes include conducting a root cause analysis (RCA), peer reviews, and disclosures.

The OIG determined that the patient’s death met the definition of a sentinel event and that the Facility did not complete an RCA.⁵⁷ An “RCA is a specific type of focused review that is used for all adverse events,” and is required to be completed within 45 days.⁵⁸ VHA Handbook 1050.01 requires that adverse events that are catastrophic in severity, such as those resulting in unanticipated death, are considered to be reviewable sentinel events and warrant immediate investigation and response.⁵⁹ Facility policy also requires an individual RCA be “performed for

⁵³ ASA Definition of “Immediately Available” When Medically Directing, Committee of Origin: Economics. Approved by the ASA House of Delegates October 17, 2012, and last amended on October 15, 2014.

⁵⁴ “The induction of anesthesia refers to the transition from an awake to an anaesthetized state.” *British Journal of Hospital Medicine*, May 2013, Vol 74, No 5.

⁵⁵ A cannula is a tube for insertion into a vessel, duct, or cavity.

⁵⁶ VHA Handbook 1050.01 *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This VHA Handbook was scheduled for recertification on or before the last working date of March 2016 and has not been recertified.

⁵⁷ Sentinel events are “a type of adverse event defined by [The Joint Commission] as unexpected occurrences involving death, serious physical or psychological injury, or risk thereof.” VHA Handbook 1050.01.

⁵⁸ VHA Handbook 1050.01.

⁵⁹ VHA Handbook 1050.01.

any incident that meets Joint Commission criteria to be a reviewable sentinel event.”⁶⁰ Although the Chief of Staff told the OIG that an investigation was completed by Patient Safety staff, other Facility leaders indicated an RCA had not been completed. The Patient Safety Manager did not provide evidence of documentation of a structured review or report.

OIG Update: *Upon receipt of the draft report in September 2018, the Facility provided the OIG documentation of a fact-finding review that was conducted by a Facility team. The Facility team determined there were no systemic issues and therefore, decided not to conduct an RCA.*

As discussed earlier, Facility surgical and anesthesia staff had varied recollections of communications throughout the procedure. Failures in communication are shown by The Joint Commission to be one of the top three most frequent root causes for sentinel events (2004 through 2015).⁶¹ The Facility medical bylaws stated that each clinical service “develop policies and procedures to assure effective management, ethics, safety, communication, and quality within the Service.”⁶² An RCA review of events by the Facility at the time the surgery outcome was known would have allowed for more accurate recollection and identification of possible individual and systems modifications.

The Facility staff conducted internal and external peer reviews on the cardiac surgeon. The OIG determined the University of Michigan staff, who contracted with the Facility to provide the anesthesiologist’s services for this patient, conducted a review on the anesthesiologist but declined to provide the results of the review to the Facility. The University staff did not consider the review to be a peer review.

OIG Update: *Upon receipt of the draft report in September 2018, the Facility provided the OIG documentation of a fact-finding review that was conducted by a Facility team. The Facility focused on the surgeon during the review.*

VHA Directive 2010-025, *Peer Review for Quality Management*, requires a peer review for a “death during or within 30 days of a surgical procedure.”⁶³ A peer review is a confidential, nonpunitive process for evaluating health care provided by an individual provider. Peer reviews are part of a facility’s quality management program, and results “cannot be used for personnel

⁶⁰ Facility Policy Memorandum 00-17, *Adverse Events, Sentinel Events, and Close Calls*, July 14, 2015.

⁶¹ Sentinel event statistics updated, released through end of 2015. The Joint Commission. Published March 2, 2016.

⁶² Facility Policy Memorandum 00-18, *Medical Staff Bylaws and Rules and Regulations of Veterans Health Administration (VHA)*, October 7, 2014.

⁶³ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. The directive expired June 30, 2015, and has not been updated. A peer is “a health care professional who has similar or more advanced education, training, experience, licensure, or clinical privileges or scope of practice to the provider being reviewed.” VHA Directive 2010-025.

actions, such as: reassignment, changes in privileges, performance pay determinations, [or] disciplinary actions.”⁶⁴

The OIG determined the Facility completed a clinical disclosure to the patient’s family. According to VHA policy, a clinical disclosure is a process by which the patient’s physician meets with the patient or patient’s representative to share “that a harmful or potentially harmful adverse event has occurred.” The Facility did not, however, complete an institutional disclosure to assist the family in determining actions and recourse as needed. An institutional disclosure is a formal process by which Facility leaders together with physicians and others, as appropriate, “inform the patient or the patient’s personal representative that an adverse event has occurred during the patient’s care that resulted in or is reasonably expected to result in death or serious injury” and provide specific information about the patient’s rights and recourse.⁶⁵

VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, states that disclosure is warranted for sentinel events to inform patients and their families of unanticipated outcomes that occurred during care.⁶⁶ Facility policy also required institutional disclosures in cases resulting in serious injury or death. The policy required specific documentation for institutional disclosures in the EHR by the Patient Safety Manager, Risk Manager, Quality Manager, or the Chief of Staff.⁶⁷

The OIG determined that the surgeon described in the EHR what could be defined as a “clinical disclosure” to the patient’s family. The Chief of Staff reported that an institutional disclosure was discussed with the Patient Safety Manager and that according to policy, an institutional disclosure should have been done, but they did not want to reactivate the pain for the family.

The surgeon and the anesthesiologist told the OIG that they have modified their practice to assist in timely identification of the need for further interventions to prevent a similar occurrence in the future including

- Surgeon checks to make sure the surgical fellow has properly placed the CPB catheter at the beginning of the procedure,
- Surgeon advances the CPB catheter 5 cm from the insertion point into the aorta,
- Prior to initiating bypass, a bolus of saline is injected and visualized with the TEE to determine the aorta catheter placement and directional flow of blood,

⁶⁴ VHA Directive 2010-025.

⁶⁵ VHA Handbook 1004.08.

⁶⁶ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, corrected copy, October 2, 2012. The directive expired on or before the last day of October 2017 and has not been updated.

⁶⁷ Facility Policy Memorandum 11-35, *Disclosure of Unanticipated Patient Outcomes*, December 31, 2012.

- Anesthesiologist places the arterial catheter in the patient's right radial artery or a femoral artery,⁶⁸ and
- Anesthesiologist takes additional TEE images of the CPB catheter placement.

The OIG determined that the surgeon and/or anesthesiologists have implemented individual modifications in their practice. While these modifications might be successful or improve patient care, these modifications were not determined or endorsed through a systematic quality review. A peer review and a systematic quality review by the Facility, particularly an RCA, would have allowed for more accurate and rapid communication of actual causes of harm to this patient, and improved care for other patients at the Facility.

⁶⁸ The OIG did not find evidence-based literature to support the insertion of the catheter into a specific artery.

Conclusion

The OIG was unable to substantiate that the patient received inappropriate care during cardiac surgery that ultimately led to death, due to a lack of available evidence related to how or when the CPB catheter became misplaced.

The OIG did not substantiate that the CPB catheter was misplaced at the beginning of surgery leading to body and brain anoxia during surgery. The physicians reported that they performed a TEE at the beginning of the procedure and confirmed that the CPB catheter was in the aorta and not in the left subclavian artery. The cardiac surgeon told the OIG a problem with the CPB catheter was discovered towards the end of the procedure, when the cross-clamp was removed from the aorta and there was lower pressure. The surgeon suggested location of the CPB catheter may have resulted in poor perfusion of the brain. Evidence is not available to determine how long the catheter was malpositioned during the surgery, other than the patient's death, which indicated a significant period of time elapsed while the patient's brain was receiving insufficient blood flow.

The OIG did not substantiate that the patient was abandoned by an anesthesiologist during surgery. All staff interviewed who were in the OR during the time of surgery recalled the anesthesiologist and/or the anesthesiology resident being present for the critical and required times.

The OIG determined the patient's death met the definition of a sentinel event and that the Facility did not complete an RCA as required. The OIG determined that the Facility conducted internal and external peer reviews for the surgeon. The University of Michigan, who contracted with the Facility to provide the anesthesiologist's services for this patient, conducted a review on the anesthesiologist but declined to provide the results of the review to the Facility. The University did not consider the review to be a peer review.

The OIG determined the Facility completed a clinical disclosure to the family but did not complete an institutional disclosure as required by VHA to assist the family in determining actions and recourse as needed.

The OIG determined that the surgeon and/or anesthesiologists have implemented individual modifications in their surgical practice. While these modifications might be successful or improve patient care, these modifications were not determined or endorsed through a systematic quality review. A peer review and a systematic quality review by the Facility, particularly an RCA, would have allowed for more accurate and rapid communication of actual causes of harm to this patient and improved care for other patients at the Facility.

The OIG made two recommendations.

Recommendations 1–2

1. The Veterans Integrated System Network 10 Director ensures the VA Ann Arbor Healthcare System Director complies with Veterans Health Administration policies regarding requirements for root cause analysis, peer review, and institutional disclosure.
2. The VA Ann Arbor Healthcare Facility Director applies quality management processes to evaluate modifications made by the anesthesiologist and surgeon for cardiothoracic surgeries and determines if modifications should be implemented system-wide.

Appendix A: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: August 31, 2018

From: Network Director, VISN 10 (10N10)

Subj: Healthcare Inspection— Quality of Care Concerns Regarding a Patient Who Had Cardiac Surgery at the VA Ann Arbor Healthcare System, Michigan

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

1. I have reviewed and concur with the responses to each recommendation provided in the Healthcare Inspection Quality of Care Concerns Regarding a Patient Who had Cardiac Surgery at the VA Ann Arbor Healthcare System, Michigan.
2. The facility will ensure that the corrective action plans are implemented with continued oversight.
3. If you have any questions, please contact Jane Johnson, VISN 10 Quality Management Officer, at (513) 247-2838.

(Electronic Signature on File)

Robert P. McDivitt, FACHE

Comments to OIG's Report

Recommendation 1

The Veterans Integrated System Network 10 Director ensures the VA Ann Arbor Healthcare System Director complies with Veterans Health Administration policies regarding requirements for root cause analysis, peer review, and institutional disclosure.

VISN Response: Concur

Target Date: October 1, 2018

Director Comments

Patient Safety will track sentinel events, root cause analysis, and peer reviews to ensure institutional disclosures are completed, as required by the Directive.

Appendix B: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: September 20, 2018

From: Director, VA Ann Arbor Healthcare System (506/00)

Subj: Healthcare Inspection—Quality of Care Concerns Regarding a Patient Who Had Cardiac Surgery at the VA Ann Arbor Healthcare System, Michigan

To: Director, Veterans in Partnership (10N10)

1. We appreciate the opportunity to review the draft report of recommendations from the OIG Quality of Care Concerns Regarding a Patient Who Had Cardiac Surgery at the VA Ann Arbor Healthcare System, Michigan.
2. Please find the attached corrections to the draft report. The supportive documentation for the requested corrections is also attached. In addition, a response to each recommendation is provided in the report for your review. We have already initiated corrective actions.
3. If you have questions regarding the responses to the recommendations in the report feel free to call me at 734-845-5458 or Cynthia Paterson, Patient Safety Manager, 734-845-5191.

(Electronic Signature on file)

Ginny L. Creasman, Pharm.D., FACHE
Medical Center Director
VA Ann Arbor Healthcare System

Comments to OIG's Report

Recommendation 2

The VA Ann Arbor Healthcare System Director applies quality management processes to evaluate modifications made by the anesthesiologist and surgeon for cardiothoracic surgeries and determines if modifications should be implemented system-wide.

Facility Response: Concur

Target date for completion: September 15, 2018

Director Comments

Patient Safety will apply quality management processes to evaluate modifications made by anesthesiologist and surgeon for cardiothoracic surgeries and determine if modifications should be implemented system-wide.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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