



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Alleged Deficiencies Related
to the Cardiac
Catheterization and
Electrophysiology
Laboratories at the Jesse
Brown VA Medical Center
Chicago, Illinois



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations regarding concerns with cardiology procedures at the Jesse Brown VA Medical Center (facility), Chicago, Illinois.

The allegations included the following:

- Complications occurred in the Cardiac Catheterization and Electrophysiology Laboratories resulting in at least one patient death.¹
- An anesthesiologist voiced concerns about the increased need to intervene in the cardiac catheterization lab.
- The Chief of Anesthesiology had concerns about “all the code blues that are occurring in the cath lab [Cardiac Catheterization Laboratory].”
- The Chief of Staff is aware of issues in the Cardiac Catheterization Laboratory and “nothing has been done.”
- The interventional cardiologist is not present during scheduled procedures and fellows perform the procedures independently.²

The OIG also evaluated facility leaders’ responses to the reports of deficiencies in the Cardiac Catheterization and Electrophysiology Laboratories.

The OIG substantiated that complications occurred in 13 of the 22 patients reviewed who underwent cardiac catheterization and electrophysiology procedures at the facility.³ Two of the patients with complications died—a patient who underwent a cardiac catheterization and a critically-ill patient who underwent an electrophysiology procedure.⁴ The OIG reviewed the electronic health records of the 13 patients for adverse clinical outcomes and determined that the complications, including the two deaths, were not due to deficiencies in care or a failure to follow Veterans Health Administration (VHA) policy, and were consistent with known risks associated with cardiac procedures.⁵

¹ The original allegation referenced “injuries.” The OIG used the term *complications* to more accurately reflect outcomes and data tracking.

² Within the context of the medical field, fellows are physicians who participate in education or research in a medical specialty after completion of medical training.

³ The 22 patients included nine patients named in the original allegation, and an additional 13 patients identified by the OIG through VHA Corporate Data Warehouse data for the period January 1, 2017, to April 30, 2019.

⁴ The OIG identified that the second patient died following an electrophysiology procedure. The OIG found that facility leaders performed appropriate quality reviews of this patient’s death.

⁵ Within the context of this report, the OIG considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level care.

The OIG also determined that, in response to the death of the patient who underwent a cardiac catheterization procedure (subject patient), facility leaders followed VHA and local policy, and initiated both required and voluntary internal and external quality reviews. The OIG found that on the date of the subject patient's death, a facility staff member submitted a patient safety incident report regarding the death, and the medical team completed a clinical disclosure. Facility leaders also completed an issue brief, which alerted the Veterans Integrated Service Network (VISN) of the adverse event. Facility leaders also voluntarily reported the death to The Joint Commission as a sentinel event.

On June 12, 2019, facility leaders (including the Acting Chief of Staff, Acting Chief of Clinical Affairs, and Chief of Medicine) and VISN leaders, met with the National Cardiology Program Office and agreed that the National Cardiology Program Office would conduct a site review. The VISN Quality Management Officer told the OIG that the site visit would be in lieu of a root cause analysis to “yield a more comprehensive review of the program versus an RCA [root cause analysis]. It allows for SMEs [subject matter experts] of the program to conduct an assessment of the entire program with feedback for any improvements, if any.” The National Cardiology Program Office's site visit occurred on August 14, 2019, and did not make any major recommendations or identify quality of care concerns.⁶

The facility does not have an internal cardiothoracic surgery program and uses area hospitals to perform those surgeries when needed. The August 2019 VHA National Cardiology Program site visit report did not identify the lack of onsite cardiothoracic surgery as a quality of care concern. The report addressed the facility cardiac complication rate and identified no clinical care concerns. The OIG reviewed VHA National Cardiology Program data and interviewed the Chief of Cardiology and found that the rates for major complications were not higher than national levels.

The OIG did not substantiate that an anesthesiologist had concerns about the need to intervene in the Cardiac Catheterization Laboratory nor that the Chief of Anesthesiology had concerns about “all the code blues that are occurring in the [Cardiac Catheterization Laboratory].” However, the OIG found that the Chief of Anesthesiology had a concern about the pre-procedural workup of the subject patient and that the concern was addressed with facility leaders.

The OIG found that the facility's Cardiopulmonary Resuscitation Committee meeting minutes lacked a way to identify a specific patient code event that the committee evaluated; however, a June 18, 2019, OIG Comprehensive Healthcare Inspection Program made a recommendation that

⁶ The minor recommendations cited did not pertain to allegations related to this report. The recommendations addressed staffing, salaries, use of university affiliated providers for procedures, and equipment upgrades for the electrophysiology lab.

the committee review each resuscitative episode; therefore, this report will make no further recommendations related to the Cardiopulmonary Resuscitation Committee.⁷

The OIG substantiated that the Acting Chief of Staff was aware of issues in the Cardiac Catheterization Laboratory, but did not substantiate that “nothing has been done.” The Acting Chief of Staff was aware of the subject patient’s death and the eight other patients identified in the allegation and partook in both the internal and external reviews.

The OIG did not substantiate that an interventional cardiologist was not present during scheduled procedures or that fellows performed procedures independently.

The OIG made no recommendations.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the report (see appendixes B and C). No further action is required.



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⁷ VA Office of Inspector General, *Comprehensive Healthcare Inspection of the Jesse Brown VA Medical Center, Chicago, Illinois*, Report No. 18-04673-138, June 18, 2019.

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Abbreviations

CART	Clinical Assessment Reporting and Tracking
CPR	cardiopulmonary resuscitation
EHR	electronic health record
NSTEMI	non-ST segment elevation myocardial infarction
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted an inspection in response to allegations related to the Cardiac Catheterization and Electrophysiology Laboratories and facility leaders' responses at the Jesse Brown VA Medical Center (facility), Chicago, Illinois.

Background

The facility, part of Veterans Integrated Service Network (VISN) 12, comprises the Jesse Brown VA Medical Center and four community clinics located in Chicago, and Chicago Heights, Illinois; and Crown Point, Indiana. The facility is affiliated with the Northwestern University Feinberg School of Medicine and the University of Illinois College of Medicine, and served over 49,000 patients in 2018.¹ The Veterans Health Administration (VHA) classifies the facility as a Level 1b tertiary center.

Cardiology

Cardiology is a subspecialty of internal medicine that studies abnormalities, diseases, and normal function of the heart, and the effect of cardiac disorders and diseases on the body.²

Cardiac Catheterization

Cardiac catheterization is a medical procedure used to assess and treat heart conditions.³ During a cardiac catheterization, an [interventional cardiologist](#) uses cardiac catheters, contrast dye, and x-ray to visualize the coronary arteries and heart valves, and to measure the pressure and blood flow in the heart. If the interventional cardiologist identifies a narrowed or blocked artery, a [percutaneous coronary intervention](#) may be performed.⁴

Electrophysiology Studies

Electrophysiology studies are tests used to assess abnormal heart rhythms. During a study, an electrophysiologist inserts a specialized electrode catheter that records the heart's electrical

¹ Patients served from October 1, 2017, to September 30, 2018.

² American College of Cardiology, *What is a Cardiologist?* <https://www.cardiosmart.org/Heart-Basics/What-is-a-Cardiologist>. (The website was accessed on April 19, 2019.)

³ National Heart, Lung and Blood Institute. *Cardiac Catheterization*. <https://www.nhlbi.nih.gov/health-topics/cardiac-catheterization>. (The website was accessed on April 19, 2019.)

⁴ American Heart Association. *Cardiac Catheterization*. https://www.heart.org/HEARTORG/Conditions/HeartAttack/SymptomsandDiagnosisofHeartAttack/Cardiac-Catheterization_UCM_451486_Article.jsp. (The website was accessed on April 19, 2019.)

activity. Based on the test results, the electrophysiologist determines whether further intervention such as an [ablation](#), [pacemaker](#), [defibrillator](#), or surgery is necessary.⁵

VA Clinical Assessment Reporting and Tracking Program

The VA Clinical Assessment Reporting and Tracking (CART) Program’s purpose is to “monitor and enhance the quality and safety of invasive cardiac procedures for veterans through clinical analytics and information technology.”⁶ Interventional cardiologists and electrophysiologists document patient and procedural information in CART including major [adverse events](#) and complications. Clinicians can document procedure data in CART, which is accessible through the patient’s electronic health record (EHR).⁷ The CART National Program Director and the facility’s Chief of Cardiology provided the OIG with the CART program’s definitions of major adverse events, complications, contrast reactions, and access site injury complications that may occur during cardiac catheterization and electrophysiology laboratory procedures (see table 1).

⁵ American Heart Association, *Electrophysiology Studies*. <https://www.heart.org/en/health-topics/arrhythmia/symptoms-diagnosis--monitoring-of-arrhythmia/electrophysiology-studies-eps>. (The website was accessed on June 20, 2019.)

⁶ U.S. Department of Veterans Affairs, *About CART Program*. September 17, 2018. <https://www.va.gov/healthcareexcellence/cart/about.asp>. (The website was accessed on July 11, 2019.) VHA Directive 2005-062, *Cardiac Assessment Reporting and Tracking System for Cardiac Catheterization Laboratories*, December 13, 2005. This directive was in effect during the timeframe of some of the events discussed in this report; it was rescinded and replaced by VHA Directive 1158, *Cardiac Assessment Reporting and Tracking System for Cardiac Catheterization Laboratories*, February 6, 2019. VHA Directive 2005-062 used the term and abbreviation Cardiac Assessment Reporting and Tracking System for Cardiac Catheterization Laboratories (CART-CL) and the VHA Directive 1158 uses Clinical Assessment Reporting and Tracking (CART) Program for Invasive Cardiac Procedures.

⁷ VHA Directive 2005-062. VHA Directive 1158, contains the same or similar language related to documentation. U.S. Department of Veterans Affairs, *About CART Program*, September 17, 2018. <https://www.va.gov/healthcareexcellence/cart/about.asp>. (The website was accessed on July 11, 2019.)

Table 1. CART Categories of Major Adverse Events and Complications for Coronary Angiography and Percutaneous Coronary Intervention

Major Adverse Events	Other Complications		
Periprocedural death	Acute cardiogenic shock	Anaphylactic shock	Access site dissection
Periprocedural stroke	Acute pulmonary edema	Acute respiratory distress	Access site perforation
Unplanned cardiac surgery	Coronary artery dissection	Hives	Access site hematoma
Unplanned additional percutaneous coronary intervention	Coronary perforation		Retroperitoneal hemorrhage
	Emergent escalation of mechanical support		Limb ischemia
	New cardiac tamponade		Vascular injury requiring surgery repair

Source: *OIG-compiled list from CART National Program Office and facility information*⁸

Prior OIG Report

In a June 18, 2019, report, *Comprehensive Healthcare Inspection of the Jesse Brown VA Medical Center, Chicago, Illinois*, the OIG determined the facility did not review 6 of 10 OIG-selected resuscitative episodes at the facility. One recommendation made to the Facility Director that is relevant to this report was to ensure

the Cardiopulmonary Resuscitation (CPR) Committee reviews each resuscitative episode under the facility’s responsibility and monitors the CPR Committee’s compliance.⁹

Allegations

On February 22, 2019, the OIG received several allegations related to cardiology procedures at the facility:

- Complications occurred in the Cardiac Catheterization and Electrophysiology Laboratories resulting in at least one patient death.¹⁰
- An anesthesiologist voiced concerns about the increased need to intervene in the cardiac catheterization lab.
- The Chief of Anesthesiology has concerns about “all the code blues that are occurring in the cath lab [Cardiac Catheterization Laboratory].”

⁸ The listed complications pertain only to cardiac catheterization procedures. Categories and definitions for complications for electrophysiology procedures are in early testing in the CART program.

⁹ VA Office of Inspector General, *Comprehensive Healthcare Inspection of the Jesse Brown VA Medical Center, Chicago, Illinois*, Report No. 18-04673-138, June 18, 2019.

¹⁰ The original allegation referenced “injuries.” The OIG used the term *complications* to more accurately reflect outcomes and data tracking.

- The Chief of Staff is aware of issues in the Cardiac Catheterization Laboratory and “nothing has been done.”
- The interventional cardiologist is not present during scheduled procedures and fellows perform the procedures independently.

The OIG also evaluated facility leaders’ responses to the reports of deficiencies in the Cardiac Catheterization and Electrophysiology Laboratories.

Scope and Methodology

The OIG initiated the inspection on March 21, 2019, and conducted a site visit May 13–16, 2019. The review included select data and documents from January 1, 2017, through April 30, 2019.

The OIG team interviewed facility leaders including the Acting Chief of Staff, Acting Chief of Clinical Affairs and the Chiefs of Anesthesiology, Cardiology, Cardiac Catheterization Laboratory, Electrophysiology, and Medicine. The OIG team interviewed the facility interventional cardiologists; electrophysiologists; anesthesiologists; a cardiology [fellow](#); a cardiology nurse manager; three cardiology nurses; the Patient Safety Manager; the Risk Manager; the Clinical Guidelines Coordinator; a performance improvement coordinator; a quality, safety, and value coordinator; and a clinical nurse specialist.

The OIG reviewed VHA and facility policies, CART reports, VISN reports, system data, electronic patient event report data, Joint Patient Safety Reporting data, [issue briefs](#), pertinent medical literature, and other relevant documents. The OIG reviewed the meeting minutes of the following committees: CPR; Patient Safety; Quality Leadership Council; Cardiac Catheterization Laboratory Performance Improvement; Medical Executive Council; Peer Review; Moderate Sedation; Operative and Other Invasive Procedures Committee; Radiation Safety; and Reusable Medical Equipment.

During the site visit, the OIG conducted a physical inspection of the Cardiac Catheterization and Electrophysiology Laboratories.

The OIG reviewed 22 EHRs to determine if there were deficiencies in care:

- Nine patients identified in the original allegation (including the subject patient described in the case summary).
- Thirteen patients with cardiac-procedure complications identified by the OIG after a review of the January 1, 2017–April 30, 2019, cardiac catheterization and electrophysiology CART procedure and CPR notes.

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 determine whether an alleged event or action took place when there is insufficient evidence.

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 subject patient was a veteran in their 40s with a medical history of [hypertension](#), [asthma](#), [orthopnea](#), [paroxysmal nocturnal dyspnea](#), and [non-ST segment elevation myocardial infarction \(NSTEMI\)](#).¹¹

In summer 2018, the patient presented to the facility's Emergency Department with complaints of shortness of breath, wheezing, chest tightness, and a dry cough for three days. The patient described the chest tightness as a [substernal](#), sharp, and pressure-like pain lasting for approximately 10 minutes, which worsened when laying back, lessened with leaning forward; and was unlike the pain associated with the NSTEMI in spring 2017. The patient reported a four-month noncompliance with prescribed medications as the patient had lost insurance coverage. The patient received asthma medications in the Emergency Department and reported symptomatic improvement.

A chest x-ray completed in the Emergency Department showed a "possibility of underlying [pericardial effusion](#)." An [electrocardiogram](#) showed a [left bundle branch block](#), and a [transthoracic echocardiogram](#) revealed a small posteriorly located pericardial effusion without evidence of tamponade and a 30 percent [ejection fraction](#). The same day, the Internal Medicine Service admitted the patient to a [telemetry](#) unit. The patient received medication to promote [diuresis](#) and started [colchicine](#) due to a presumptive diagnosis of [pericarditis](#) based upon the chest pain and clinical history.

The patient remained at the facility for four days, and although the patient's chest pain initially improved, it reoccurred. The patient's shortness of breath continued to improve with minimal diuresis, and the internal medicine provider found no evidence of fluid overload on exam or the transthoracic echocardiogram. Upon discharge, the patient's diagnoses included: pericarditis, posterior located pericardial effusion, and [heart failure with reduced ejection fraction](#). The discharging provider documented follow-up for primary care and cardiology.

Eight days after discharge, at a scheduled primary care appointment, the provider discussed the patient's elevated blood pressure and advised the patient to return for a repeat blood pressure

¹¹ The OIG uses the singular form of their (they/them) to protect the patient's privacy.

check and if agreeable would start [losartan](#). Seventeen days later, the patient attended an appointment with the clinical pharmacist for blood pressure and heart failure medication management. The patient reported a cough and nightly wheezing for the previous two to three days. The clinical pharmacist ordered an [albuterol](#) nebulizer and advised the patient to seek emergent care if symptoms worsened or persisted. The patient had follow-up appointments scheduled for 18 days later with the primary care provider and cardiologist.

Eight days prior to the patient's scheduled follow-up appointments, they presented to the facility's Emergency Department with progressive shortness of breath, unresponsive to treatment at home. The patient reported compliance with diuretic therapy and restricted fluid intake as directed after the last hospitalization. The Medicine Service admitted the patient, and the patient responded well to methylprednisolone, nebulizer therapy, and diuresis. The patient was discharged home the next day, with a plan for primary care, cardiology, and pulmonology follow-up.

One week after discharge, the patient attended their previously scheduled follow-up appointments with primary care and cardiology. The patient reported an improvement in shortness of breath and pericarditis pain to the primary care provider. The cardiologist recommended a [cardiovascular magnetic resonance imaging](#) study, a decrease in [furosemide](#) dosage, an increase in [metoprolol](#), an aspirin regimen taper, and a follow-up appointment.

Approximately three weeks after the follow-up appointments, cardiovascular magnetic resonance imaging revealed [cardiomyopathy](#), severe global [hypokinesis](#), a left ventricular ejection fraction of 20–25 percent, a moderate pericardial effusion, a moderate right [pleural effusion](#), a small left pleural effusion, and a [delayed enhancement pattern](#) nonischemic in etiology and consistent with [myocarditis and myopericarditis](#).

The following day, the patient met with a pulmonologist who recommended a [pulmonary function test](#) and an in-lab sleep study to evaluate for [obstructive sleep apnea](#). One week later, the patient participated in a two-day sleep study, which resulted in a recommendation to schedule the patient for a therapeutic sleep study with a [continuous positive airway pressure](#) device. Eighteen days after the in-lab sleep study, the patient underwent the two-day therapeutic sleep study. Following the study, a pulmonary fellow ordered a continuous positive airway pressure device.

Eight days after the completion of the therapeutic sleep study, a transthoracic echocardiogram showed a moderately dilated left ventricle, severe global hypokinesis, an ejection fraction of 20–25 percent, a moderate to large circumferential pericardial effusion, and no definitive evidence of cardiac tamponade.

The patient attended a follow-up cardiology appointment 12 days after the transthoracic echocardiogram, and reported feeling “fatigued and winded” for periods of two to three days, dizziness without [syncope](#) multiple times a day, and chest pain once or twice a week without a

clear trigger. The provider recommended a repeat transthoracic echocardiogram to evaluate the progression of the pericardial effusion and scheduled it for 13 days later. The patient had a follow-up appointment planned with the cardiology nurse practitioner for one week after the scheduled repeat transthoracic echocardiogram.

Four days before the scheduled repeat transthoracic echocardiogram, the patient presented to the Emergency Department with complaints of chest pressure, and the Medicine Service admitted the patient to a telemetry unit. At the time of admission, the patient was on a tapered aspirin regimen prescribed for pericarditis. The Emergency Department provider ordered diuretics and [ketorolac](#). The [rheumatology](#) service met with the patient and ruled out an autoimmune etiology for the patient's pericarditis. The rheumatologist discussed the possibility of [sarcoidosis](#), but radiologic imaging was not consistent with this disease. The next day, an interventional cardiologist reviewed the echocardiogram completed on the same date and recommended further imaging and [pericardiocentesis](#) for both therapeutic and diagnostic purposes. The cardiologist discussed the possibility of a heart transplant workup at another facility with the patient. The attending physician discharged the patient two days after being admitted and entered a consult to schedule a right [heart catheterization](#) and possible pericardiocentesis; the procedures were scheduled for 13 days after discharge.

One day before his scheduled procedures, the patient attended a pulmonary follow-up visit. The pulmonologist concurred with the plan for a right [heart catheterization](#) and reported that it may help evaluate for sarcoidosis as the etiology of the patient's heart failure.

The next day, the patient presented to the facility for a left and right heart catheterization and a pericardiocentesis. A pre-procedure echocardiogram confirmed "a moderate sized pericardial effusion, primarily posterior but with some anterior extension." During the cardiac catheterization, elevated right sided pressures suggested a pericardial effusion. The interventional cardiologist inserted the pericardiocentesis needle and advanced it toward the [pericardium](#). At that point in the procedure, the interventional cardiologist noticed "blood in the syringe" and injected [agitated saline](#) through the needle with ultrasound guidance. This confirmed that the needle did not enter the heart and was in the targeted pericardial space.

As the interventional cardiologist further advanced the guide wire, the patient's heart rate slowed, and the patient became unresponsive. The cardiac catheterization team initiated CPR and called a [code blue](#). A certified registered nurse anesthetist intubated the patient, and a respiratory therapist placed the patient on mechanical ventilation. With assistance from the intraprocedural [sonogram](#), the interventional cardiologist identified a pericardial effusion and made multiple attempts to aspirate the contents. Although the medical team performed [advanced cardiac life support](#), the resuscitation was unsuccessful.

An autopsy revealed 550 milliliters of blood in the patient's pericardial sac, pericardial hematoma (consistent with tamponade), perforation at the anterior right ventricle, multiple puncture wounds to the heart including to the right ventricle, and [cardiomegaly](#) with non-

ischemic cardiomyopathy. The Cook County Medical Examiner's Office documented the cause of death as cardiac arrest, cardiomyopathy, and heart failure, and the manner of death as natural.

Inspection Results

1. Alleged Deficiencies in Cardiac Catheterization and Electrophysiology Patient Care

The OIG substantiated that complications occurred in 13 of the 22 patients reviewed who underwent cardiac catheterization and electrophysiology procedures at the facility. Two of the patients with complications died.¹² The OIG reviewed the EHRs of the 13 patients for adverse clinical outcomes and determined that the complications, including the deaths, were not due to deficiencies in care or a failure to follow VHA policy, and were consistent with known risks associated with cardiac procedures.¹³

Facility Leaders' Responses to Subject Patient's Death

The subject patient died in late fall 2018, during a planned pericardiocentesis procedure in the Cardiac Catheterization Laboratory. The OIG determined that, in response to the death, facility leaders followed VHA and local policy, and initiated both required and voluntary internal and external quality reviews.

VHA and facility policy mandates disclosure of adverse events to patients or their personal representatives. Clinical disclosure of a harmful or potentially harmful event is the process in which the patient's provider informs the patient or the patient's personal representative of the adverse event that has occurred during the patient's care.¹⁴ VHA also requires facility leaders to draft and submit an issue brief to the VISN with event description.¹⁵ Further, VHA requires facility directors to ensure clinical staff perform a mortality review of inpatient hospitalization deaths.¹⁶

¹² One of the patients who died was the subject patient who underwent a cardiac catheterization; the second was a critically-ill patient who underwent an electrophysiology procedure.

¹³ Within the context of this report, the OIG considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level care.

¹⁴ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. This handbook was rescinded and replaced by VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018, and contains the same or similar language related to clinical disclosures. Facility Policy 00-16-15, *Patient Safety Program*, January 1, 2016. This policy was rescinded and replaced by Facility Policy 00-16-22, *Patient Safety Program*, March 2019, and contains similar language related to clinical disclosures.

¹⁵ VA Deputy Under Secretary for Health Operations and Management, *10N Guide to VHA Issue Briefs*, June 26, 2017.

¹⁶ VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

VHA requires that facilities report adverse events and [sentinel events](#) to the National Center for Patient Safety.¹⁷ Facility policy mandates the patient safety manager to report adverse and sentinel events to the VISN patient safety officer and the VA National Center for Patient Safety, and to consult with the VISN to determine if a report will be made to [The Joint Commission](#). Facility policy also required employees to report any adverse events, including those that may warrant a [root cause analysis](#), through the patient incident reporting system.¹⁸

Internal and External Reporting

The OIG examined patient safety event reports and found that on the same day the patient died, a facility staff member submitted a patient safety incident report regarding the subject patient's death. Following the subject patient's death, the facility performed required and voluntary reviews of the event (see appendix A).

The OIG found that on the date of the patient's death, the medical team completed a clinical disclosure. Facility leaders completed an issue brief, which alerted the VISN of the adverse event. One week later, facility leaders, with VISN guidance, voluntarily reported the death to The Joint Commission as a sentinel event.

Since December 31, 2006, VHA has required Cardiac Catheterization Laboratory clinical staff report all pre-procedure and procedure data in CART.¹⁹ The CART National Program Safety Committee automatically reviews facility reported major adverse events. This is in addition to, and independent of, the facility's peer review program.²⁰

The CART National Program Safety Committee evaluated and completed a quality review on February 14, 2019, regarding the subject patient's death, and identified that the interventional cardiologist did not clearly document the indications for a pericardiocentesis. On March 4, 2019, The Joint Commission closed the case. On March 13, 2019, the Cardiology Morbidity and Mortality committee presented and discussed the subject patient's death. On the same day, the Peer Review Committee completed an internal quality review (see appendix A).

The OIG reviewed the autopsy, which revealed a "right ventricle perforation and massive blood accumulation within pericardial cavity." The interventional cardiologist who performed the

¹⁷ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

¹⁸ Facility Policy 00-16-15, *Patient Safety Program*, January 1, 2016. This policy was rescinded and replaced by Facility Policy 00-16-22, *Patient Safety Program*, March 2019, and contains similar language related to patient safety event reporting.

¹⁹ VHA Directive 2005-062, *Cardiac Assessment Reporting and Tracking System for Cardiac Catheterization Laboratories*, December 13, 2005. This directive was rescinded and replaced by VHA Directive 1158, *Cardiac Assessment Reporting and Tracking System for Cardiac Catheterization Laboratories*, February 6, 2019, and contains the same or similar language related to the CART program.

²⁰ Periprocedural death, stroke, emergent coronary artery bypass grafting, and unplanned percutaneous coronary intervention are major adverse events automatically reviewed. CART, Safety Committee: Coronary Procedures, no date.

cardiac catheterization procedure described the autopsy findings as expected since the patient was undergoing chest compressions while a needle was moved into a one-centimeter space to remove fluid. Consistent with CART definitions of complications, the Chief of the Cardiac Catheterization Laboratory stated right ventricular perforation is a known complication of pericardiocentesis, and CART also identifies it as such.

The OIG found that the subject patient received reasonable clinical assessment and treatment. The OIG determined that the subject patient experienced an adverse clinical outcome but determined that the outcome was consistent with known risks associated with the cardiac procedure and was not due to suboptimal treatment or deficiencies in care.

Additional Patients' Complications

Eight Remaining Patients Identified in Original Allegation

The OIG reviewed the EHRs of the eight patients who, per the complainant, experienced complications related to cardiac catheterization and electrophysiology procedures (see appendix B):

- Two patients who underwent a coronary angiography had complications related to the procedure, including one major adverse event (an unplanned percutaneous coronary intervention).
- Five patients who underwent electrophysiology procedures had complications related to the procedure, including two major adverse events. (One patient died in the recovery room following cardiac arrest; one patient required an unplanned percutaneous coronary intervention.)
- One patient underwent a coronary angiography procedure and did not experience a complication related to the procedure.

Additionally, the OIG found that six of the eight patients experienced an adverse clinical outcome—three of the six patients experienced a worsening prognosis, two patients experienced a need for a higher level of care, and one patient died.

Thirteen Patients Identified through CART Data

The OIG retrieved CART data from the VHA Corporate Data Warehouse for the period of January 1, 2017, to April 30, 2019, and found 13 additional patients with documented complications, including major adverse events.²¹

²¹ The OIG reviewed the data for 17 patients and identified that one patient was the subject cardiac patient and three patients were reported in the original allegation. The OIG reviewed the EHRs of the remaining 13 patients.

The OIG further analyzed the EHRs of the 13 patients and made the following determinations:

- Five patients who underwent coronary angiography procedures had complications and no major adverse events.
- Seven patients who underwent percutaneous coronary intervention procedures had complications and no major adverse events.
- One patient who underwent a coronary angiography procedure had no complications and no major adverse events.²²

Additionally, the OIG found that 6 of the 13 patients experienced an adverse clinical outcome—five patients experienced a worsening prognosis and one patient experienced a need for a higher level of care.

Based on the OIG review of the EHR and CART data for 22 patients, the OIG determined that complications related to cardiac catheterization and electrophysiology procedures did occur, including the major adverse events of two patient deaths and two unplanned percutaneous coronary interventions.²³ The OIG determined, however, that the complications were within an expected range of occurrence and providers adhered to risk adverse measures. Although the OIG found that 13 of the 22 patients reviewed experienced adverse clinical outcomes, the OIG determined that the outcomes were consistent with known risks associated with the cardiac procedures and were not due to suboptimal treatment or deficiencies in care.²⁴

CART Reporting Limitations

As of February 6, 2019, VISN and facility leaders are collectively responsible to review CART annual data reports that identify complication outliers.²⁵ According to the CART National Program Director, the VISN Chief Medical Officer or Chief of Cardiology may request a CART program review of patient complications other than major adverse events, called an ad-hoc review.

The CART National Program Director told the OIG that since the inception of the CART program in 2006, the expectation has been that providers complete the clinical documentation,

²² While reported as a complication in CART, the OIG found that the procedure for this patient was not performed due to an occluded vein.

²³ The OIG identified that a second patient died following an electrophysiology procedure. The OIG found the facility leaders performed appropriate quality reviews of this patient's death.

²⁴ The OIG identified adverse clinical outcomes in seven of the nine patients named in the original complaint (including the subject patient), and 6 of the 13 patients identified in the review of CART data.

²⁵ VHA Directive 1158.

including complications.²⁶ However, the CART National Program Office recognized that complications may not have consistently been reported. A revision to the CART application “forced” clinicians to document complications data prior to finalizing the report. The CART National Program Director further explained that the deployment of the revision began in late 2017 and that the facility implemented the changes on March 23, 2018.

2. Alleged Concerns of Anesthesiologists

The OIG did not substantiate that an anesthesiologist expressed concerns about the need to intervene in the cardiac catheterization lab. The OIG team interviewed the anesthesiologist identified in the allegation and found no concerns related to interventions in the Cardiac Catheterization Laboratory.

The OIG did not substantiate that the Chief of Anesthesiology had concerns about “all the code blues that are occurring in the [Cardiac Catheterization Laboratory].” The OIG determined that the Chief of Anesthesiology did not have concerns about the quality of care or code blue events in the Cardiac Catheterization Laboratory but did have a concern about the pre-procedural workup of the subject patient.

The complainant alleged that the Chief of Anesthesiology expressed concerns at a February 2019 meeting about “all the code blues” that occurred in the Cardiac Catheterization Laboratory. Per VHA requirements, the director of the CPR committee or the committee members review all code blues.²⁷ Facility policy mandated the Chief of Anesthesiology chair the committee and that the committee review all code events and address any performance issues.²⁸

The Chief of Anesthesiology remembered a meeting with the Acting Chief of Staff, the Acting Chief of Clinical Affairs, and the Chief of Medicine to discuss two codes in the Cardiac Catheterization Laboratory, which had occurred within the last calendar year. The Chief of Anesthesiology was unable to recall specific patient names discussed or if minutes of the meeting were documented.

The Chief of Anesthesiology informed the OIG of being “asked to be there because I was the chairperson of the CPR Committee,” and the only concern discussed by the Chief of Anesthesiology at the meeting pertained to the subject patient’s pre-procedural workup. The

²⁶ VHA Directive 2005-062 required VHA facilities that have cardiac catheterization laboratories fully implement and utilize the Cardiac Assessment Reporting Tracking-Cardiac Catheterization Laboratories program for data entry and report generation, including pre-procedure, procedure, and Percutaneous Coronary Intervention modules no later than December 31, 2006.

²⁷ VHA Directive 1177, *Cardiopulmonary Resuscitation*, August 28, 2018.

²⁸ Facility Policy 11-10-17, *Cardiopulmonary Resuscitation (CPR)*, October 9, 2014. This policy was rescinded and replaced by Facility Policy 11-10-22, *Cardiopulmonary Resuscitation (CPR)*, March 2019, and contains similar language related to committee responsibilities.

Chief of Anesthesiology stated finding it unusual but not impossible for a cardiac patient with an [American Society of Anesthesiology II physical status classification assignment](#) to undergo an interventional cardiology procedure. The Chief further stated that the concerns were addressed in meetings with facility leaders.²⁹ In addition, the Chief of Anesthesiology told the OIG about not having concerns regarding the quality of care or code blue events in the Cardiac Catheterization Laboratory.

The OIG reviewed CPR meeting minutes to determine if the committee reviewed the subject patient's code and other codes that had occurred in the Cardiac Catheterization Laboratory. Since the committee did not document specific patient identifiers in the minutes, the OIG was unable to determine the identity or location of the patients discussed. Additionally, a previous OIG report determined that the facility did not review 6 of 10 OIG selected resuscitative episodes at the facility and likely missed opportunities to review codes for patient care issues. The OIG Comprehensive Healthcare Inspection Program team made one recommendation regarding the review of codes, thus this report does not address the actions of the CPR Committee.³⁰

The OIG also reviewed all facility code blue events that had occurred in the Cardiac Catheterization Laboratory between January 1, 2017, and April 30, 2019. The OIG found that two of six code blue events occurred during cardiac catheterization procedures and involved patients provided in the allegation. Of the two code blue events reviewed, the OIG did not identify clinical care concerns.

3. Chief of Staff's Awareness and Actions Taken

The OIG substantiated that the Acting Chief of Staff was aware of issues in the Cardiac Catheterization Laboratory including the subject patient's death. The OIG did not substantiate that "nothing has been done." The OIG found that the Acting Chief of Staff and other facility leaders participated in both the internal and external quality reviews.

VHA and facility policy required an internal quality management review for deaths associated with an adverse event or treatment complication.³¹ Facility policy also required a consultation

²⁹ Cleveland Clinic, *Anesthesia Physical Classification System*, 2015.

<https://my.clevelandclinic.org/health/articles/12976-anesthesia-physical-classification-system>. (The website was accessed on July 2, 2019.) The American Society of Anesthesiology categorizes classifications into four designations. ASA I indicates a healthy patient. ASA II indicates a patient with mild to moderate systemic disease. ASA III indicates a patient with severe systematic disease and ASA IV indicates a patient with severe disease that is life threatening. The facility leaders addressed this issue through multiple internal and external reviews (see appendix A).

³⁰ VA Office of Inspector General, *Comprehensive Healthcare Inspection of the Jesse Brown VA Medical Center, Chicago, Illinois*, Report No. 18-04673-138, June 18, 2019.

³¹ VHA Directive 1190. Facility Policy 11-30-21, *Peer Review for Quality Management*, June 2018.

with the VISN to discuss adverse events that meet The Joint Commission's definition of a sentinel event.³²

The Acting Chief of Staff reported to the OIG being aware of the subject patient's death and participated in facility reviews of the Cardiac Catheterization Laboratory.

On the same day of the subject patient's death, facility leaders alerted the VISN with an issue brief. A week later, the facility reported the death as a sentinel event to The Joint Commission. The Acting Chief of Staff told the OIG that shortly after the subject patient's death, facility leaders including the Chief of Anesthesiology, met to discuss the code event. In this meeting, the Acting Chief of Staff and the Acting Chief of Clinical Affairs reported that the death prompted a retroactive review of all "untoward events" that occurred in the Cardiac Catheterization and Electrophysiology Laboratories within the past two years.

Facility clinical leaders reviewed the CPR and peer review committees meeting minutes, identified eight procedures in the Cardiac Catheterization and Electrophysiology Laboratories with complications, and on January 11, 2019, sent the eight patient names to the VISN's Chief Medical Officer and Chief Quality Management Officer. Additionally, on February 6, 2019, the VISN provided the patient names and procedure dates to the CART National Program Office for an ad-hoc review.³³ The CART National Program Office provided the ad-hoc review report to the Chief of Cardiology on April 9, 2019. The ad-hoc report noted complications occurred; however, the CART National Program Office did not recommend a site visit.

On May 7, 2019, the Chief of Cardiology developed an action plan based on the recommendations contained in the CART program's review. The Acting Chief of Staff approved the action plan. The action plan encompassed six areas of improvement to include; comprehensive pre-procedural assessment and timeliness of procedural documentation, retroperitoneal hemorrhage and [pneumothorax](#) prevention, management of procedural anticoagulation, and invasive hemodynamic tests for ischemia. As of July 19, 2019, facility leaders and managers completed all items identified in the action plan.

National Cardiology Program Site Visit

On June 12, 2019, VISN and facility leaders (including the Acting Chief of Staff, Acting Chief of Clinical Affairs, and Chief of Medicine), met with the National Cardiology Program Office

³² Facility Policy 00-16-15, *Patient Safety Program*, January 1, 2016.

³³ Facility leaders provided eight patients for the ad-hoc review that included the name of the subject patient as well as the names of seven of the eight patients provided in the allegation. The procedure for the remaining ninth patient occurred after January 11, 2019, and therefore was not in the ad-hoc review list of patients. Although the facility did not send it to CART program for further review, the patient went through the facility's patient safety reporting processes. Furthermore, the Chief of Cardiology determined the issue to be a known complication and handled appropriately by the provider.

and agreed that the National Cardiology Program Office would conduct a site review. The VISN Quality Manager Officer told the OIG that the site visit would be in lieu of a root cause analysis to “yield a more comprehensive review of the program versus an RCA [root cause analysis]. It allows for SMEs [subject matter experts] of the program to conduct an assessment of the entire program with feedback for any improvements, if any.” The National Cardiology Program Office’s site visit occurred on August 14, 2019, and did not identify any major recommendations or quality of care concerns.³⁴

Cardiothoracic Surgery

The facility does not have an internal [cardiothoracic surgery](#) program and uses area hospitals to perform those surgeries when needed. The August 2019 VHA National Cardiology Program site visit report did not identify the lack of onsite cardiothoracic surgery as a quality of care concern.

Complication Rates

The CART National Program Director told the OIG that complications are interpreted “in the context of clinical and procedural complexity, however, as using raw complication rates to draw conclusions about interventional quality has been demonstrated to lead to significant risk aversion and decreased access to interventional services without improving the quality of cardiovascular care.” The August 2019 VHA National Cardiology Program site visit report addressed the facility cardiac complication rate and identified no clinical care concerns, citing that the 30-day post percutaneous coronary intervention mortality rate is “numerically higher than, but not statistically different than the national median.” The OIG reviewed CART data and interviewed the Chief of Cardiology and found that the rates for major complications were not higher than national levels.

4. Presence of Attending Interventional Cardiologist

The OIG did not substantiate that an interventional cardiologist was not present during scheduled procedures or that fellows performed procedures independently.

VHA and facility policy require [direct supervision](#) of fellows performing procedures, and EHR documentation must identify the supervising provider.³⁵

The facility participated in a three-year cardiovascular disease fellowship training program in which fellows performed procedures in the Cardiac Catheterization and Electrophysiology

³⁴ The minor recommendations cited did not pertain to allegations related to this report. The recommendations addressed benefits of increased staffing, salaries, use of university affiliated providers for procedures, and equipment upgrades for the electrophysiology lab.

³⁵ VHA Handbook 1400.01, *Resident Supervision*, December 19, 2012. Facility Policy 11-01-21, *Resident Supervision Policy*, January 2018.

Laboratories. During fellowship, supervising providers gradually allow fellows more autonomy as skills increase.³⁶ The OIG reviewed EHRs of the nine patients provided in the allegation and interviewed facility leaders, cardiologists, and cardiology staff. The OIG found no reported or documented instances of fellows performing cardiac catheterization and electrophysiology procedures without direct supervision.

Conclusion

The OIG substantiated that complications occurred in 13 of the 22 patients reviewed who underwent cardiac catheterization and electrophysiology procedures at the facility. Two of the patients with complications died.³⁷ The OIG reviewed the EHRs of the 13 patients for adverse clinical outcomes and determined that the complications, including the deaths, were not due to deficiencies in care or a failure to follow VHA policy, and were consistent with known risks associated with cardiac procedures.³⁸

The facility does not have an internal cardiothoracic surgery program and uses area hospitals to perform those surgeries when needed. The August 2019 VHA National Cardiology Program site visit report did not identify the lack of onsite cardiothoracic surgery as a quality of care concern. The report addressed the facility cardiac complication rate and identified no clinical care concerns. The OIG reviewed VHA National Cardiology Program data and interviewed the Chief of Cardiology and found that the rates for major complications were not higher than national levels.

Following an autopsy, the cause of death of the subject patient was determined to be cardiac arrest, secondary to cardiomyopathy and heart failure. Upon the patient's death, facility leaders initiated both mandated and voluntary reviews and adhered to VHA and local policy initiating both internal and external reviews.

The OIG did not substantiate that an anesthesiologist had concerns about the need to intervene in the Cardiac Catheterization Laboratory. Also, the OIG did not substantiate that the Chief of Anesthesiology had concerns about "all the code blues that are occurring in the [Cardiac Catheterization Laboratory]." However, the OIG found that the Chief of Anesthesiology had a concern about the pre-procedural workup of the subject patient and met with other clinical facility leaders to discuss this concern.

³⁶ Accreditation Council for Graduate Medical Education, *ACGME Program Requirements for Graduate Medical Education in Interventional Cardiology (Internal Medicine)*, Chicago: ACGME, 2017.

³⁷ One of the patients who died was the subject patient who underwent a cardiac catheterization; the second was a critically-ill patient who underwent an electrophysiology procedure.

³⁸ Within the context of this report, the OIG considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level care.

CPR Committee meeting minutes lacked a way to identify which patient code event the committee evaluated; however, a June 18, 2019, OIG Comprehensive Healthcare Inspection Program inspection recommended that the CPR Committee review each resuscitative episode; therefore, this report will make no further recommendations pertaining to the CPR Committee.

Two patient code blue events occurred during a cardiac catheterization procedure within a two-year timeframe; however, the OIG did not identify clinical concerns associated with the two code events.

The OIG substantiated that the Acting Chief of Staff was aware of issues in the Cardiac Catheterization Laboratory. The OIG did not substantiate that “nothing has been done.” The Acting Chief of Staff was aware of the subject patient’s death and of the eight other events that occurred in the Cardiac Catheterization and Electrophysiology Laboratories. The Acting Chief of Staff participated in meetings with facility clinical leaders, facility leaders, and VISN leaders to discuss the care provided to the subject patient and the eight other patients identified in the original allegation.

The OIG did not substantiate that an interventional cardiologist was not present during scheduled procedures or that fellows performed procedures independently. The OIG reviewed EHRs of the nine patients provided in the original allegation and interviewed facility leaders, cardiologists, and cardiology staff. The OIG found no reported or documented instances of fellows performing cardiac catheterization or electrophysiology procedures without supervision during cardiac catheterization and electrophysiology procedures.

The OIG made no recommendations.

Appendix A: Timeline of Facility Response to the Subject Patient's Death

Below is an overview and timeline of facility leaders' response to the subject patient's death.

Date	Action
Late fall 2018	Subject patient's death.
Same day late fall 2018	Medical team completed clinical disclosure.
Same day late fall 2018	Issue Brief sent to VISN.
Same day late fall 2018	Patient safety event documented in the Joint Patient Safety Reporting system.
One week later	Sentinel event report sent to The Joint Commission.
One week later	External quality management review initiated.
1/9/2019	VISN subject matter expert discussion of subject patient's death.
1/11/2019	Facility sent eight patient names to the VISN to forward to the CART National Program Office for an ad-hoc review.
1/16/2019	VISN and facility discussion of quality management review findings.
1/18/2019	Subject patient's death discussed in the CPR Committee.
1/23/2019	The Joint Commission closed the case.
2/6/2019	VISN Chief Medical Officer provided eight patient names to the National Cardiology Program Office for expert review. National Cardiology Program Office deferred review pending results of ad-hoc CART review.
2/14/2019	Ad-hoc CART review completed.
3/13/2019	Internal quality management review completed.
3/13/2019	Morbidity and Mortality Committee reviewed subject patient's death.
3/15/2019	Internal quality management review process completed.
4/10/2019	VISN Chief Medical Officer received CART ad-hoc review results.
4/22/2019	VISN Chief Medical Officer and Quality Management Officer reviewed results of CART ad-hoc review.
4/26/2019	Meeting with VISN and facility leaders to review results of CART ad-hoc review.
5/2/2019	Meeting with VISN and facility leaders to review CART ad-hoc review recommendations. VISN leaders requested a facility action plan.
5/7/2019	Facility action plan completed and sent to the VISN.

Alleged Deficiencies Related to the Cardiac Catheterization and
Electrophysiology Laboratories at the Jesse Brown VAMC, Chicago, IL

Date	Action
6/3/2019	VISN requested that another VISN complete a clinical review of the Cardiac Catheterization Laboratory.
6/7/2019	Facility action plan shared with National Cardiology Program Office.
6/12/2019	National Cardiology Program Office to conduct review of the Cardiac Catheterization Laboratory. Previous request for another VISN review rescinded.
6/20/2019	National Cardiology Program Office will conduct site visit the week of August 12, 2019.
7/19/2019	Action plan items completed.
8/14/2019	National Cardiology Program Office's conducted site visit and did not identify any major recommendations or quality of care concerns.

Source: OIG analysis of the facility's response to the subject patient's death

Appendix B: List of Patients with Alleged Complications

Nine patient names were provided to the OIG with the allegation. The nine patients allegedly experienced complications in the Cardiac Catheterization or Electrophysiology Laboratories. This included the subject patient in addition to eight other patients.

Identifier	Type of Procedure	Documented Facility Actions	OIG Review of Complications
1	Coronary angiogram with percutaneous coronary intervention	CART review and an internal peer review completed.	The OIG determined a dissection and tamponade occurred with an emergent pericardiocentesis.
2	Biventricular pacemaker placement	CART review, internal peer review, and patient safety report completed.	The OIG determined a pneumothorax occurred and required thoracic surgery to place a chest tube .
3	Biventricular implantable cardioverter defibrillator placement	CART review completed.	The OIG determined a cardiopulmonary arrest occurred post- procedure.
	Ablation	Patient safety event reported.	The OIG determined a vascular injury occurred due to a failed femoral artery closure device and required vascular surgery.
4	Ablation	CART review, internal peer review, and patient safety event report completed.	The OIG determined a cardiopulmonary arrest and death occurred post procedure.
5	Coronary angiogram with percutaneous coronary intervention	CART review completed.	The OIG determined a cardiopulmonary arrest, coronary artery dissection, myocardial infarction, unplanned percutaneous coronary intervention, and cardiogenic shock occurred.

Alleged Deficiencies Related to the Cardiac Catheterization and
Electrophysiology Laboratories at the Jesse Brown VAMC, Chicago, IL

Identifier	Type of Procedure	Documented Facility Actions	OIG Review of Complications
6	Coronary angiogram	CART review completed.	The OIG determined a cardiopulmonary arrest occurred prior to the catheterization laboratory procedure. No complications reported.
7	Electrophysiology procedure with ablation	CART review completed.	The OIG determined a retroperitoneal bleed occurred.
8 (Subject patient)	Coronary angiogram and pericardiocentesis	CART review, internal peer review, and patient safety report completed.	The OIG determined a cardiopulmonary arrest, tamponade and death occurred.
9	Implantable cardioverter defibrillator placement	Patient safety event report completed.	The OIG determined a coronary sinus perforation, cardiogenic shock, and an emergent left heart catheterization occurred.
	Percutaneous coronary angiogram	None.	The OIG determined an additional unplanned percutaneous coronary intervention occurred.

Source: OIG-compiled list from EHR reviews

Appendix C: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: January 31, 2020

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

Subj: Healthcare Inspection—Alleged Deficiencies Related to the Cardiac Catheterization and
Electrophysiology Laboratories at the Jesse Brown VA Medical Center, Chicago, Illinois

To: Director, Office of Healthcare Inspections (54HL07)
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. I have reviewed and concur with the Healthcare Inspection— Alleged Deficiencies Related to the Cardiac Catheterization and Electrophysiology Laboratories at Jesse Brown VA Medical Center report.
2. I would like to thank the OIG Inspection team for a thorough review of the Cardiac Catheterization and Electrophysiology Laboratories at Jesse Brown VA Medical Center.
3. If additional information is needed, please contact Performance Improvement Director Deborah Barker at the Jesse Brown VA Medical Center.

(Original signed by:)

Shavetta R. Williams
Acting Network Director, VISN 12

Appendix D: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: January 29, 2020

From: Acting Director, Jesse Brown VA Medical Center (537)

Subj: Healthcare Inspection—Alleged Deficiencies Related to the Cardiac Catheterization and
Electrophysiology Laboratories at the Jesse Brown VA Medical Center, Chicago, Illinois

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

1. We have reviewed this document and accept the report as provided.
2. Should you have any additional questions, please contact the Chief, Quality, Safety and Value,
Deborah J. Barker RN, MSN, MBA.

(Original signed by:)

Christine Kleckner, MBA, RD
Acting, Medical Center Director

Glossary of Terms

ablation. Electrophysiology procedure used to correct abnormal heart rhythms by scarring or killing small parts of the heart.³⁹

advanced cardiac life support. A series of advanced interventions for patients in cardiac arrest and includes basic life support as well as airway management and the use of intravenous medications.⁴⁰

adverse events. Events connected with care or services delivered that result in harm or potential harm.⁴¹

agitated saline. Air bubbles within a solution that is visible on ultrasound images.⁴²

albuterol. A drug $C_{13}H_{21}NO_3$ used to treat asthma as an aerosol or as the sulfate in tablet form.⁴³

American Society of Anesthesiology physical status classification system. Used to evaluate a patient's comorbidities prior to selection of an appropriate anesthetic.⁴⁴

anaphylactic shock. Sudden, severe allergic reaction that can be life threatening often leading to difficulty breathing, swelling, and fainting.⁴⁵

asthma. Lung condition where airways constrict and swell.⁴⁶

biventricular. Of, relating to, or affecting both ventricles of the heart.⁴⁷

³⁹ Mayo Clinic, *Ablation*. <https://www.mayoclinic.org/tests-procedures/cardiac-ablation/about/pac-20384993>. (The website was accessed on July 3, 2019.)

⁴⁰ Nurse.org, *Everything Nurses Need to Know About ACLS, BLS & PALS Certifications 2018*. <https://nurse.org/articles/everything-nurses-need-to-know-about-acls-bls-pals/>. (The website was accessed on July 29, 2019.)

⁴¹ VHA Handbook 1004.08.

⁴² Harvard Health Publishing, *What is a Bubble Study?* <https://www.health.harvard.edu/heart-health/what-is-a-bubble-study>. (The website was accessed on July 12, 2019.)

⁴³ Merriam-Webster. *Definition of albuterol*. <https://www.merriam-webster.com/dictionary/albuterol>. (The website was accessed on September 27, 2019.)

⁴⁴ Cleveland Clinic, *Anesthesia Physical Classification System*, 2015. <https://my.clevelandclinic.org/health/articles/12976-anesthesia-physical-classification-system>. (The website was accessed on July 2, 2019.)

⁴⁵ Merriam-Webster. *Definition of anaphylactic shock*. <https://www.merriam-webster.com/dictionary/anaphylactic%20shock>. (The website was accessed on July 29, 2019.)

⁴⁶ Mayo Clinic, *Asthma*. <https://www.mayoclinic.org/diseases-conditions/asthma/symptoms-causes/syc-20369653>. (The website was accessed on July 3, 2019.)

⁴⁷ Merriam-Webster. *Medical Definition of biventricular*. <https://www.merriam-webster.com/medical/biventricular>. (The website was accessed on July 14, 2019.)

biventricular pacemaker. An electrical device that is implanted by an electrophysiologist and utilizes a battery connected by wires (called leads) to the lower chambers of the heart (ventricles) monitor the heart's rhythm and can utilize impulses to help the heart beat in a more coordinated way.⁴⁸

cardiogenic shock. A condition when the heart is suddenly unable to pump enough blood to meet the demands of the body and is often fatal.⁴⁹

cardiomegaly. An enlarged heart.⁵⁰

cardiomyopathy. Any of several structural or functional diseases of heart muscle that makes it more difficult for your heart to move blood through the body.⁵¹

cardiopulmonary arrest. Occurs when the heart has stopped beating.⁵²

cardiothoracic surgery. Surgery related to the heart and chest.⁵³

cardiovascular magnetic resonance imaging. Medical imaging technology for non-invasive assessment of the function and structure of the heart.⁵⁴

chest tube. A hollow, flexible tube put in to the chest to drain fluids or air from around the lungs, heart, or throat.⁵⁵

code blue. The announcement of a medical emergency, due to an individual's unresponsiveness, alerting providers to respond and begin resuscitative efforts.⁵⁶

⁴⁸ Cleveland Clinic, *Biventricular Pacemaker*. <https://my.clevelandclinic.org/health/treatments/16784-biventricular-pacemaker>. (The website was accessed on July 24, 2019.)

⁴⁹ Mayo Clinic, *Cardiogenic Shock*. <https://www.mayoclinic.org/diseases-conditions/cardiogenic-shock/symptoms-causes/syc-20366739>. (The website was accessed on July 24, 2019.)

⁵⁰ Mayo Clinic, *Enlarged Heart*. <https://www.mayoclinic.org/diseases-conditions/enlarged-heart/symptoms-causes/syc-20355436?p=1>. (The website was accessed on July 17, 2019.)

⁵¹ Mayo Clinic, *Cardiomyopathy*. <https://www.mayoclinic.org/diseases-conditions/cardiomyopathy/symptoms-causes/syc-20370709>. (The website was accessed July 3, 2019.)

⁵² Merriam-Webster. *Definition of cardiac arrest*. <https://www.merriam-webster.com/dictionary/cardiac%20arrest>. (The website was accessed on July 24, 2019.)

⁵³ Merriam-Webster. *Definition of cardiothoracic*. <https://www.merriam-webster.com/dictionary/cardiothoracic>. (The website was accessed on October 11, 2019.)

⁵⁴ National Heart, Lung, and Blood Institute, *Cardiac MRI*. <https://www.nhlbi.nih.gov/health-topics/cardiac-mri>. (The website was accessed July 3, 2019.)

⁵⁵ MedlinePlus, *Chest Tube Insertion*. <https://medlineplus.gov/ency/article/002947.htm>. (The website was accessed on July 24, 2019.)

⁵⁶ Merriam-Webster. *Medical Definition of code blue*. <https://www.merriam-webster.com/medical/code%20blue>. (The website was accessed on July 3, 2019.)

colchicine. An anti-gout medication used to reduce inflammation in the body and may be used for cardiac issues to include pericarditis.⁵⁷

continuous positive airway pressure. A device that delivers forced air to prevent episodic airway collapse during sleep.⁵⁸

coronary angiography. An imaging procedure that uses X-rays and a special dye (that is injected in to the blood and able to see using X-rays) to visualize the blood vessels of the heart and to determine the quality of blood flow.⁵⁹

coronary artery dissection. A complication that can occur during surgical procedures to the heart. The actual injury is a cut or tear of the wall of an artery that carries blood to the heart tissue that can lead to bleeding or blockage of the artery and reduced blood flow to the areas of the heart that the artery feeds.⁶⁰

coronary perforation. A rupture of the coronary arteries. It is also a rare complication associated with percutaneous coronary interventions (surgeries) that can lead to severe consequences including death.⁶¹

defibrillator. An electrical device that uses electrical shock to restore normal heart rhythm.⁶²

delayed enhancement pattern. A delayed enhancement pattern can occur during cardiac imaging when the injected contrast material accumulates in damaged cardiac tissue, including the myocardium. The technique is used to diagnose cardiac problems and determine treatment.⁶³

⁵⁷ Medline Plus, *Colchicine*. <https://medlineplus.gov/druginfo/meds/a682711.html>. (The website was accessed on July 10, 2019.) Mayo Clinic, *Pericarditis*. <https://www.mayoclinic.org/diseases-conditions/pericarditis/diagnosis-treatment/drc-20352514>. (The website was accessed on July 17, 2019.)

⁵⁸ MedlinePlus, *Positive Airway Pressure Treatment*. <https://medlineplus.gov/ency/article/001916.htm>. (The website was accessed on July 12, 2019.)

⁵⁹ Mayo Clinic, *Coronary Angiogram*. <https://www.mayoclinic.org/tests-procedures/coronary-angiogram/about/pac-20384904>. (The website was accessed on July 24, 2019.)

⁶⁰ ScienceDirect, *Coronary-Artery-Dissection*. <https://www.sciencedirect.com/topics/neuroscience/coronary-artery-dissection>. (The website was accessed on July 24, 2019.)

⁶¹ Mohammed Al-Mukhaini, Prashanth Panduranga, Kadhim Sulaiman, Abdulla Amour Riyami, Mohammed Deeb, and Mohamed Barkat Riyami, "Coronary Perforation and Covered Stents: An Update and Review," *Heart Views*, 12, no. 2 (April/June 2011): 63-70. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3221194/>. (The website was accessed on August 1, 2019.)

⁶² Merriam-Webster. *Definition of defibrillator*. <https://www.merriam-webster.com/dictionary/defibrillator>. (The website was accessed on July 3, 2019.)

⁶³ Arie Franco, Saeed Javidi, and Stefan G Ruehm, "Delayed Myocardial Enhancement in Cardiac Magnetic Resonance Imaging," *J Radiol Case Rep*. 2015 Jun; 9(6): 6–18. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4638378/>. (The website was accessed on July 29, 2019.)

direct supervision. When the supervising provider is physically present with the physician trainee or fellow during patient care.⁶⁴

diuresis. An increase in the excretion of urine.⁶⁵

ejection fraction. A measurement, expressed as a percentage, of how much blood the left ventricle pumps with each contraction. An ejection fraction of 60 percent means that 60 percent of the total amount of blood in the left ventricle is pushed out with each heartbeat. A normal left ventricular ejection fraction ranges from 50% to 80%.⁶⁶

electrocardiogram. A graphic outline of the heart's movement.⁶⁷

fellow. A physician who participates in further education or research in a medical specialty after completion of medical training.⁶⁸

furosemide. A medication used to treat high blood pressure and edema.⁶⁹

heart catheterization. Another term for *cardiac catheterization*. A medical procedure where a wire or thin tube is threaded through your blood vessels to reach the heart chambers and to diagnose and/or treat certain heart problems.⁷⁰

heart failure with reduced ejection fraction. Another term for *systolic failure*. The left ventricle loses the ability to normally contract.⁷¹

hematoma. A collection of clotted blood that can form anywhere in or on the body due to bleeding from a blood vessel.⁷²

⁶⁴ VHA Handbook 1400.01, *Resident Supervision*, December 19, 2012.

⁶⁵ Merriam-Webster. *Definition of diuresis*. <https://www.merriam-webster.com/dictionary/diuresis>. (The website was accessed on July 8, 2019.)

⁶⁶ Merriam-Webster. *Medical Definition of ejection fraction*. <https://www.merriam-webster.com/medical/ejection%20fraction>. (The website was accessed on July 8, 2019.)

⁶⁷ MedlinePlus, *Echocardiogram*. <https://medlineplus.gov/ency/article/003869.htm>. (The website was accessed on July 8, 2019.)

⁶⁸ Merriam-Webster. *Definition of fellow*. <https://www.merriam-webster.com/dictionary/fellow>. (The website was accessed on June 17, 2019.)

⁶⁹ MedlinePlus, *Furosemide*. <https://medlineplus.gov/druginfo/meds/a682858.html>. (The website was accessed on July 12, 2019.)

⁷⁰ National Heart, Lung and Blood Institute, *Cardiac Catheterization*. <https://www.nhlbi.nih.gov/health-topics/cardiac-catheterization>. (The website was accessed on April 19, 2019.)

⁷¹ American Heart Association, *Types of Heart Failure*. <https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/types-of-heart-failure>. (The website was accessed on July 17, 2019.)

⁷² Merriam-Webster. *Definition of hematoma*. <https://www.merriam-webster.com/dictionary/hematoma>. (The website was accessed on July 29, 2019.)

hypertension. A medical term for *high blood pressure*. A condition that occurs when there is a sustained increase of blood pushing against the artery walls.⁷³

hypokinesis. The reduced movement or contraction of a muscle.⁷⁴

implantable cardioverter defibrillator. A device that prevents sudden cardiac death by sensing abnormal heart rhythms and shocking the heart back into action with a jolt of electricity. The device is implanted by an electrophysiologist.⁷⁵

interventional cardiologist. A physician who performs invasive, catheter-based interventions to diagnose and treat coronary disease and other disorders of the heart.⁷⁶

ischemia. A state of inadequate blood supply to a part of the body which can lead to damage to the area that is being deprived.⁷⁷

issue brief. A tool used to provide information to leadership within the organization, regarding a situation, event or issue.⁷⁸

ketorolac. An anti-inflammatory medication used to relieve pain.⁷⁹

left bundle branch block. A disorder in which there is a delay or interruption in the movement of electrical signals in the left side of the heart.⁸⁰

losartan. A medication used to treat high blood pressure.⁸¹

methylprednisolone. A medication used to treat inflammation in the body.⁸²

⁷³ Mayo Clinic, *High Blood Pressure*. <https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/symptoms-causes/syc-20373410>. (The website was accessed on July 8, 2019.)

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⁷⁷ Merriam-Webster. *Definition of ischemia*. <https://www.merriam-webster.com/dictionary/ischemia>. (The website was accessed on July 29, 2019.)

⁷⁸ Deputy Under Secretary for Health for Operations and Management (10N), *Guide to Issue Briefs*, June 26, 2017.

⁷⁹ Mayo Clinic, *Ketorolac*. <https://www.mayoclinic.org/drugs-supplements/ketorolac-oral-route-injection-route/description/drg-20066882>. (The website was accessed on July 8, 2019.)

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⁸¹ MedlinePlus, *Losartan*. <https://medlineplus.gov/druginfo/meds/a695008.html>. (The website was accessed on July 12, 2019.)

⁸² Mayo Clinic, *Solu-Medrol*. <https://www.nationalmssociety.org/Treating-MS/Medications/Solu-Medrol>. (The website was accessed on July 10, 2019.)

metoprolol. A medication used to treat high blood pressure and prevent chest pain.⁸³

myocardial infarction. A medical term for *heart attack*.⁸⁴

myocarditis/myopericarditis. An inflammation of the heart muscle (or surrounding the muscle as in myopericarditis) that affects the hearts conduction system and can cause a heart attack or stroke.⁸⁵

non-ST segment elevation myocardial infarction (NSTEMI). A heart attack that occurs upon a partial blockage of the coronary artery.⁸⁶

obstructive sleep apnea. A condition caused by narrowed or blocked airways and involves pauses of breathing during sleep.⁸⁷

orthopnea. Difficulty breathing when lying down which improves when sitting up.⁸⁸

pacemaker. A device implanted in the body that uses electrical impulses to aid in correcting abnormal heart rhythms.⁸⁹

paroxysmal nocturnal dyspnea. The sensation of being short of breath while sleeping causing one to wake up.⁹⁰

percutaneous coronary intervention. A procedure performed to widen an obstructed coronary artery and involves passing a catheter through the skin into a blood vessel to reach the site of obstruction.⁹¹

⁸³ MedlinePlus, *Metoprolol*. <https://medlineplus.gov/druginfo/meds/a682864.html>. (The website was accessed on July 14, 2019.)

⁸⁴ Merriam-Webster. *Definition of heart attack*. <https://www.merriam-webster.com/dictionary/heart%20attack> (The website was accessed on August 26, 2019.)

⁸⁵ Mayo Clinic, *Myocarditis*. <https://www.mayoclinic.org/diseases-conditions/myocarditis/symptoms-causes/syc-20352539>. (The website was accessed on July 29, 2019.)

⁸⁶ Mayo Clinic, *Heart Attack*. <https://www.mayoclinic.org/diseases-conditions/heart-attack/symptoms-causes/syc-20373106>. (The website accessed on July 10, 2019.)

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⁸⁸ Merriam-Webster. *Medical Definition of orthopnea*. <https://www.merriam-webster.com/medical/orthopnea>. (The website was accessed on July 8, 2019.)

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⁹⁰ HK Walker, WD Hall, JW Hurst, editors., *Clinical Methods: The History, Physical, and Laboratory Examinations*, 3rd ed. (Boston: Butterworths,1990), Chapter 11.

⁹¹ Merriam-Webster. *Medical Definition of percutaneous coronary intervention*. <https://www.merriam-webster.com/medical/percutaneous%20coronary%20intervention>. (The website was accessed on July 7, 2019.)

pericardiocentesis. The surgical puncture of the pericardium to remove fluid.⁹²

pericarditis. Swelling and irritation of the membrane that surrounds the outer surface of the heart which can also cause chest pain.⁹³

pericardium. A sac that encases the heart.⁹⁴

pericardial effusion. Accumulation of fluid in the pericardial cavity or sac enclosing the heart.⁹⁵

periprocedural. The time period just before, during or just after a surgical or medical procedure.⁹⁶

pleural effusion. Accumulation of fluid on the outside of the lungs.⁹⁷

pneumothorax. A buildup of air or gases in the space between the membrane on the lungs and the inner chest wall leading to a collapse of the whole lung or a part of the lung reducing the ability for the lung to inflate and work.⁹⁸

pulmonary edema. A buildup of fluid in the lungs which makes it difficult to breath.⁹⁹

pulmonary function test. Tests used to measure breathing and evaluate lung function.¹⁰⁰

retroperitoneal. A space between the membrane lining the abdomen that covers the abdominal organs and the posterior abdominal wall. This space contains the kidneys, pancreas and portions of major blood vessels.¹⁰¹

⁹² Merriam-Webster. *Medical Definition of pericardiocentesis*. <https://www.merriam-webster.com/medical/pericardiocentesis>. (The website was accessed on July 8, 2019.)

⁹³ Mayo Clinic, *Pericarditis*. <https://www.mayoclinic.org/diseases-conditions/pericarditis/symptoms-causes/syc-20352510>. (The website was accessed on July 24, 2019.)

⁹⁴ Merriam-Webster. *Definition of pericardium*. <https://www.merriam-webster.com/dictionary/pericardium>. (The website was accessed on July 24, 2019.)

⁹⁵ Mayo Clinic, *Pericardial Effusion*. <https://www.mayoclinic.org/diseases-conditions/pericardial-effusion/symptoms-causes/syc-20353720>. (The website was accessed on July 8, 2019.)

⁹⁶ Merriam-Webster. *Medical Definition of periprocedural*. <https://www.merriam-webster.com/medical/periprocedural>. (The website was accessed on July 29, 2019.)

⁹⁷ Merriam-Webster. *Medical Definition of pleural effusion*. <https://www.merriam-webster.com/medical/pleural%20effusion>. (The website was accessed on July 8, 2019.)

⁹⁸ Mayo Clinic, *Pneumothorax*. <https://www.mayoclinic.org/diseases-conditions/pneumothorax/symptoms-causes/syc-20350367>. (The website was accessed on July 24, 2019.)

⁹⁹ Mayo Clinic, *Pulmonary Edema*. <https://www.mayoclinic.org/diseases-conditions/pulmonary-edema/symptoms-causes/syc-20377009>. (The website was accessed on July 29, 2019.)

¹⁰⁰ MedlinePlus, *Pulmonary Function Tests*. <https://medlineplus.gov/ency/article/003853.htm>. (The website was accessed on July 12, 2019.)

¹⁰¹ Merriam-Webster. *Medical Definition of retroperitoneum*. <https://www.merriam-webster.com/medical/retroperitoneum>. (The website was accessed on July 24, 2019.)

rheumatology. The study of musculoskeletal diseases and systemic autoimmune conditions.¹⁰²

root cause analysis. An approach, tool, or technique used to uncover the root cause of a problem.¹⁰³

sarcoidosis. An inflammatory disease in which abnormal masses or nodules consisting of inflamed tissues form within organs.¹⁰⁴

sentinel event. A patient safety event that results in death, permanent harm or severe temporary harm.¹⁰⁵

sonogram. An image, produced by ultrasound, taken of the inside of a person's body by using a special machine; also called echogram, ultrasonogram.¹⁰⁶

substernal. The location below or behind the sternum bone in the chest.¹⁰⁷

syncope. A medical term for *fainting*. A temporary loss of consciousness routinely related to insufficient blood flow to the brain.¹⁰⁸

tamponade. Tamponade or cardiac tamponade is an accumulation of fluid in the pericardium resulting in compression of the heart.¹⁰⁹

telemetry. A clinical tool for cardiac monitoring.¹¹⁰

transthoracic echocardiogram. An imaging study used to view the motion of the heart.¹¹¹

¹⁰² American College of Rheumatology, What is a Rheumatologist? <https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Health-Care-Team/What-is-a-Rheumatologist>. (The website was accessed on June 13, 2019.)

¹⁰³ American Society for Quality, *Root Cause Analysis*. <https://asq.org/quality-resources/root-cause-analysis>. (The website was accessed on June 13, 2019.)

¹⁰⁴ Merriam-Webster. *Definition of sarcoidosis*. <https://www.merriam-webster.com/dictionary/sarcoidosis>. (The website was accessed on July 8, 2019.)

¹⁰⁵ Comprehensive Accreditation Manual for Hospitals, *Sentinel Events*, E-dition, July 1, 2018.

¹⁰⁶ Merriam-Webster. *Definition of sonogram*. <https://www.merriam-webster.com/dictionary/sonogram>. (The website was accessed on July 25, 2019.)

¹⁰⁷ Merriam-Webster. *Medical Definition of substernal*. <https://www.merriam-webster.com/medical/substernal>. (The website was accessed on August 29, 2019.)

¹⁰⁸ American Heart Association, *Syncope (Fainting)*. <https://www.heart.org/en/health-topics/arrhythmia/symptoms-diagnosis--monitoring-of-arrhythmia/syncope-fainting>. (The website was accessed on July 12, 2019.)

¹⁰⁹ Merriam-Webster. *Medical Definition of cardiac tamponade*. <https://www.merriam-webster.com/medical/cardiac%20tamponade>. (The website was accessed on July 8, 2019.)

¹¹⁰ Cleveland Clinic Journal of Medicine, *Telemetry*, June 2009. <https://www.mdedge.com/ccjm/article/95096/cardiology/telemetry-overused-it-helpful-thought>. (The website was accessed on July 10, 2019.)

¹¹¹ Mayo Clinic, *Echocardiogram*. <https://www.mayoclinic.org/tests-procedures/echocardiogram/about/pac-20393856>. (The website was accessed on July 8, 2019.)

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