



DEPARTMENT OF VETERANS AFFAIRS  
**OFFICE OF INSPECTOR GENERAL**

*Office of Healthcare Inspections*

VETERANS HEALTH ADMINISTRATION

Deficiencies in a Cardiac  
Research Study at the VA  
St. Louis Health Care  
System

Missouri



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## Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to determine the validity of allegations regarding deficiencies and delays in the cardiac care of five patients, one of whom died, at the John Cochran Division of the VA St. Louis Health Care System (facility), Missouri.

The OIG reviewed the patients' electronic health records (EHRs) and determined that further review of the following allegations was warranted:

- A research study cardiologist (research cardiologist) failed to provide follow-up cardiac care for a research patient (Patient A).
- A cardiology fellow failed to provide follow-up care and correctly interpret electrocardiogram (ECG) results for four patients (Patients B, C, D, and E).<sup>1</sup>

The OIG also identified additional concerns:

- The facility's Subcommittee on Research Safety and the Institutional Review Board failed to ensure a research team's adherence to a research plan and completion of specific research study requirements.<sup>2</sup>
- The Director of the Cardiac Stress Test Laboratory provided inconsistent instructions related to a stress test laboratory procedure.

The OIG substantiated that a research cardiologist failed to initiate cardiac follow-up care based on Patient A's positive stress-test result and failed to notify the patient or primary care provider of the results. Cardiac imaging that was ordered after the positive stress test was part of the research study protocol; it was not ordered in response to the positive stress-test results. The research cardiologist did not initially recognize that only the ordering provider was electronically notified of test results. The research cardiologist considered the primary care provider

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<sup>1</sup> VHA Handbook 1400.01, *Resident Supervision*, December 19, 2012. A fellow is a post-residency physician, who is pursuing studies in a specialized field of medicine. This handbook was rescinded on November 7, 2019, and replaced with VHA Directive 1400.01, *Supervision of Physician, Dental, Optometry, Chiropractic, and Podiatry Residents*, November 7, 2019. The handbook and directive have the same or similar language regarding fellows. The specific care concerns expressed in the allegations regarding the fellow were failure to manage follow-up care and difficulty reading ECGs.

<sup>2</sup> VHA Handbook 1200.08, *Safety of Personnel Engaged in Research*, March 6, 2009. The Subcommittee on Research Safety manages different aspects of research safety. The handbook was rescinded and replaced by VHA Directive 1200.08, *Safety of Personnel and Security of Laboratories Involved in VA Research*, April 24, 2019. The Institutional Review Board is a formally organized group or board assigned to perform oversight of human subject research in accordance with regulations. VHA Handbook 1200.05 (2), *Requirements for the Protection of Human Subjects in Research*, November 12, 2014, amended June 29, 2017. The handbook was rescinded and replaced by VHA Directive 1200.05, *Requirements for the Protection of Human Subjects in Research*, January 7, 2019. The handbook and directive have the same or similar language regarding the Institutional Review Board.

responsible to address the patient's follow-up care as the cardiologist was the researcher. Based on the complexity of Patient A's cardiac history and other co-morbidities, as well as the absence of an autopsy, the OIG was unable to determine whether timelier follow-up or other interventions would have prevented or delayed Patient A's death. The OIG learned that not long after Patient A's death, the facility's Chief of Cardiology initiated several process improvements to ensure communication of positive stress-test results and provide follow-up care when indicated.

The OIG did not substantiate that the cardiology fellow failed to manage follow-up care for four patients with positive stress tests and was unable to determine if the cardiology fellow had difficulty making an accurate initial interpretation of the ECGs. Documentation of the cardiology fellow's initial interpretation prior to conferring with supervising providers was not required by the Veterans Health Administration. The OIG determined that supervising providers were involved with the cardiology fellow's patient encounters, follow-up care was provided when indicated, and ECG interpretations were validated by the supervising provider (an attending cardiologist).

The OIG determined the facility's Subcommittee on Research Safety and the Institutional Review Board met oversight requirements related to the informed consent process, annual review of the study, and reporting of serious adverse events; however, the research team was not adhering to the research study plan, and primary providers were inconsistently alerted to their patient's enrollment in the research study.<sup>3</sup> The research study plan identified steps to contact the primary provider, discuss potential patient's participation, and obtain approval. Members of the research team informed the OIG that primary providers were notified of patient enrollment by adding them as an additional signer to the consent documentation or a note titled Clinical Warning in the EHR. However, the OIG review of a randomized sample of research participants' EHRs did not find evidence of cosignature or discussion. During interviews, the OIG determined that neither the research cardiologist nor the research study coordinator recognized that the additional signer was not added to the notes and believed the requirement was met.

The OIG determined there were inconsistencies between the instructions provided by the Director of the Cardiac Stress Test Laboratory for new cardiology fellows and the protocol used by facility staff for a stress test laboratory procedure that had the potential to create confusion and possibly introduce increased risk of errors. The OIG determined that a stress test laboratory protocol did not include elements required in the facility policy for establishing internal policy and standard operating procedures. Through an interview with the Director of the Cardiac Stress

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<sup>3</sup> VHA Handbook 1058.01, *Research Compliance Reporting Requirements*, June 15, 2015. In research with human subjects, a serious adverse event is any untoward event that results in death, a life-threatening experience, hospital admission or prolonged stay, significant disability or incapacity, "or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome." The primary provider is the provider who placed the initial consult for a stress test (for example the primary care provider or the patient's primary cardiologist).

Test Laboratory, the OIG learned that the protocol that was created and implemented prior to the Director's appointment did not follow the facility process for establishing internal policies. Minor updates that would not require organizational review had been made to the protocol since that time.

The OIG made six recommendations to the Facility Director related to ensuring research providers take action on stress-test results; conducting a retrospective review of patients enrolled in the study for result notification and follow-up care; reviewing Patient A's care to determine if a disclosure is warranted; aligning content of a stress test laboratory educational material with protocol; ensuring the stress test laboratory protocol is written and approved according to policy; and directing the facility's Institutional Review Board to ensure research study personnel adhere to the research study plan and communicate enrollees' involvement to primary providers.

## Comments

The Veterans Integrated Service Network and System Directors concurred with the findings and recommendations and provided acceptable action plans (see appendixes B and C). The OIG considers all recommendations open and will follow up on the planned and recently implemented actions to ensure that they have been effective and sustained.



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## **Abbreviations**

EHR	electronic health record
ECG	electrocardiogram or electrocardiography
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



## Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to determine the validity of allegations regarding deficiencies and delays in cardiac care of five patients, one of whom died, at the John Cochran Division of the VA St. Louis Health Care System (facility), Missouri.

## Background

The facility is part of Veteran Integrated Service Network (VISN) 15 and consists of two divisions in St. Louis, Missouri. VA classifies the facility as a Level 1a high complexity facility. From October 1, 2017, through September 30, 2018, the facility served 58,378 patients and had a total of 337 hospital operating beds including inpatient, domiciliary, and community living center beds. The facility has operative surgical capabilities, an ambulatory care unit, intensive care units, outpatient psychiatry clinics, primary care clinics, specialty care including cardiology, and an expanded laboratory. The facility has a Research and Education Program with over 125 active studies. The facility is affiliated with the St. Louis University School of Medicine and Washington University School of Medicine.

## Clinical Consults

A clinical consult is a request for services on behalf of a patient. A provider requests an opinion, advice, or expertise regarding the evaluation or management of a patient-specific problem and another provider responds to the request.<sup>4</sup> The consult process provides a method of coordinating patient care among different services.<sup>5</sup> VA facilities use software in the electronic health record (EHR) to enter, receive, schedule, and document information for consults. The software generates an automatic notification (alert) in the EHR that notifies the ordering provider when updates are made to the consult including results which may contain actionable clinical information. In cases when an ordering provider may not be available to review results, a surrogate provider may be designated in the EHR to receive the alert.<sup>6</sup>

## Stress Test

A stress test provides information about the heart's response to an increased workload. During stress testing, a patient, who is able to exercise, walks or runs on a treadmill or pedals a

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<sup>4</sup> In the context of this report, the term provider refers to a physician or licensed independent practitioner.

<sup>5</sup> VHA Directive 1232(2), *Consult Processes and Procedures*, August 24, 2016.

<sup>6</sup> VHA Technical Manual, Computerized Patient Record System (CPRS) V. 1. 0. November 2018.

stationary bike to increase the heart rate.<sup>7</sup> For patients who have lower extremity limitations, an arm exercise test may be completed.<sup>8</sup> Electrocardiography (ECG) is done while the patient is exercising to monitor the patient's cardiac function.<sup>9</sup> Patients who are unable to exercise may undergo a pharmacological stress test wherein a medication is administered to increase the workload of the heart.<sup>10</sup> The facility uses the consult process to order stress tests for patients.

## Clinical Trial Research Study

The Arm Exercise Versus Pharmacologic Stress Testing for Clinical Outcome Prediction (study) is a clinical trial research study performed at the facility. The purpose of the study is to evaluate and compare arm exercise stress testing to treadmill or pharmacological stress testing in terms of diagnosing and predicting cardiac disease.<sup>11</sup> Participants complete these three different stress tests in a random order on different days. After completing the stress tests, the patient has a computed tomography calcium scoring test and angiography scan. The computed tomography calcium scoring test determines the amount of calcium in the arteries of the heart. The computed tomography angiography scan provides images that show how well blood is flowing through

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<sup>7</sup> National Institutes of Health, National Heart, Lung, and Blood Institute, *Stress Test*. <https://www.nhlbi.nih.gov/health-topics/stress-testing>. (The website was accessed on September 3, 2019.)

<sup>8</sup> Mayo Clinic, *Arm ergometer provides alternative to conventional stress testing*. To complete an arm exercise stress test, a patient sits in a chair and rotates a fulcrum, such as the pedals of a bicycle, to increase the heart's workload. website. <https://www.mayoclinic.org/medical-professionals/cardiovascular-diseases/news/arm-ergometer-provides-alternative-to-conventional-stress-testing/mac-20429419>. (The website was accessed on August 28, 2019.)

<sup>9</sup> Mayo Clinic, *Electrocardiogram*. An ECG, also commonly referred to as an EKG, is a test used to detect problems and monitor heart rhythms and status. <https://www.mayoclinic.org/tests-procedures/ekg/about/pac-20384983>. (The website was accessed on May 23, 2019.) The term, ECG, is used throughout this report for both electrocardiography and electrocardiogram.

<sup>10</sup> National Institutes of Health, National Heart, Lung, and Blood Institute, *Stress Test*. <https://www.nhlbi.nih.gov/health-topics/stress-testing>. (The website was accessed on September 3, 2019.)

<sup>11</sup> Mayo Clinic, *Stress Test*. A stress test, such as the one done in the study, consists of a patient receiving medication that increases blood flow in the heart prior to myocardial perfusion imaging (an x-ray to track blood flow through the heart) to assess for heart disease. Providers recommend stress tests to diagnose coronary artery disease (damage or disease to an artery due to a buildup of cholesterol or plaque), heart rhythm irregularities, or guide treatment of heart disorders. The test may also be used to support clinical management. <https://www.mayoclinic.org/tests-procedures/stress-test/about/pac-20385234>. (The website was accessed on September 5, 2019.)

vessels in the heart muscle to detect coronary artery blockage.<sup>12</sup> Of note, none of the stress tests or scans are new procedures or experimental. Participants are identified when a referring provider enters a cardiology consult for a stress test. The patient is evaluated and enrolled when study criteria are met, the patient agrees to participate, and the patient's primary provider approves of the enrollment.

## Allegations and Related Concerns

On March 20, 2019, the OIG Hotline Division received a complaint alleging deficiencies and delays in cardiac care of five patients including one patient who subsequently died (Patient A). The OIG reviewed the patients' EHRs and determined that further review of the following allegations was warranted:

- A research study cardiologist (research cardiologist) failed to provide follow-up cardiac care for Patient A.<sup>13</sup>
- A cardiology fellow failed to provide follow-up care after positive stress tests and failed to correctly interpret ECG results for four patients (Patients B, C, D, and E).<sup>14</sup>

On April 2, 2019, the OIG opened a hotline inspection. During the inspection, the OIG team identified additional concerns related to a cardiology research study's processes, as well as inconsistent guidance provided from the Director of the Cardiac Stress Test Laboratory to facility stress test laboratory staff and cardiology fellows:

- The facility Subcommittee on Research Safety and the Institutional Review Board oversight failed to ensure a research team's adherence to a research plan and completion

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<sup>12</sup> American College of Cardiology CardioSmart, *Understanding Coronary Artery Calcium (CAC) Scoring*. Excessive calcium buildup in the coronary arteries is a sign of heart disease. Knowing the amount of calcium can assist in determining a person's risk of having a heart attack. <https://www.cardiosmart.org/Heart-Conditions/High-Cholesterol/Content/Coronary-Artery-Calcium-Scoring>. (The website was accessed on September 8, 2019.) Johns Hopkins, *Computed Tomography Angiography (CTA)*. A computed tomography scan is an "[x]-ray that uses a computer to [take] cross sectional images of [the] body." A computed tomography angiography combines the scan with an injection of dye that lights up blood vessels and tissues and can identify blockage or damage. <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/computed-tomography-angiography-cta>. (The website was accessed on September 2, 2019.)

<sup>13</sup> The research cardiologist was the primary investigator of the study and a facility staff cardiologist.

<sup>14</sup> VHA Handbook 1400.01, *Resident Supervision*, December 19, 2012. A fellow is a post-residency physician, who is pursuing studies in a specialized field of medicine. This handbook was rescinded on November 7, 2019, and replaced with VHA Directive 1400.01, *Supervision of Physician, Dental, Optometry, Chiropractic, and Podiatry Residents*, November 7, 2019. The handbook and directive have the same or similar language regarding fellows. The specific care concerns expressed in the allegations regarding the fellow were failure to manage follow-up care and difficulty reading ECGs.

of specific research study requirements while overseeing the Arm Exercise Versus Pharmacologic Stress Testing for Clinical Outcome Prediction study.<sup>15</sup>

- The Director of the Cardiac Stress Test Laboratory gave inconsistent instructions related to the regadenoson stress test laboratory procedure provided to facility cardiology fellows and a protocol used by facility staff.<sup>16</sup>

## Scope and Methodology

The OIG initiated the inspection on April 2, 2019. A site visit, conducted from June 25 through June 27, 2019, included a tour of the stress test laboratory.

Interviews were conducted with cardiologists, a primary care provider, cardiology fellows, a research cardiologist, research study co-investigators, the Acting Associate Chief of Staff for Primary Care, nursing staff, a nurse manager, an assistant nurse manager, a medical technologist, a facility Institutional Review Board member, and a research study coordinator. The OIG team reviewed electronic mail messages and attachments related to processes and procedures in the stress test laboratory. The OIG team was unable to speak with the primary care provider who was assigned to Patient A during the time of the care reviewed.<sup>17</sup>

The OIG team reviewed the EHRs of the five patients specified in the allegations. Relevant documents were reviewed: Veterans Health Administration (VHA) policies; facility policies and procedures including the stress test laboratory protocol book; and peer reviews on the care of Patient A. A review of research study documents included the study proposal, study plan, approval memorandum, informed consent, facility Research and Development Committee

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<sup>15</sup> VHA Handbook 1200.08, *Safety of Personnel Engaged in Research*, March 6, 2009. The Subcommittee on Research Safety manages different aspects of research safety. The handbook was rescinded and replaced by VHA Directive 1200.08, *Safety of Personnel and Security of Laboratories Involved in VA Research*, April 24, 2019. VHA Handbook 1200.05(2), *Requirements for the Protection of Human Subjects in Research*, November 12, 2014, amended June 29, 2017. An Institutional Review Board is a formally organized group or board assigned to perform oversight of human subject research in accordance with regulations. The handbook was rescinded and replaced by VHA Directive 1200.05, *Requirements for the Protection of Human Subjects in Research*, January 7, 2019. The handbook and directive have the same or similar language regarding the Institutional Review Board.

<sup>16</sup> RxList, *Lexiscan®*. Regadenoson is the generic name of the medication Lexiscan® which is used to stress the heart by increasing blood flow in the arteries and is given to patients unable to perform an exercise stress test. <https://www.rxlist.com/lexiscan-side-effects-drug-center.htm>. (The website was accessed on September 2, 2019). The medication will be referred to as regadenoson throughout the report.

<sup>17</sup> The primary care provider retired from the facility prior to the initiation of the OIG review. The OIG team was unsuccessful in acquiring the provider's telephone number.

minutes, and facility Institutional Review Board serious adverse event form and minutes.<sup>18</sup> To determine if research team members communicated with the patients' primary providers about enrollment in the study, the OIG reviewed a random sample of 40 (out of 99) research participants' EHRs for research consent forms and an EHR note titled Clinical Warning for evidence of cosignature or discussion.<sup>19</sup>

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.

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<sup>18</sup> Merriam Webster, *Informed Consent*. Informed consent occurs when a patient signs a formal agreement giving permission for a medical procedure after receiving information about the risks and benefits. <https://www.merriam-webster.com/dictionary/informed%20consent>. (The website was accessed on September 2, 2019.) VHA Handbook 1058.01, *Research Compliance Reporting Requirements*, June 15, 2015. A serious adverse event in research with human subjects is any untoward event that results in death, a life-threatening experience, hospital admission or prolonged stay, significant disability or incapacity "or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome." In this report, the OIG used the term adverse clinical outcome.

<sup>19</sup> The research participants reviewed were enrolled in the study between June 21, 2018, and June 10, 2019. The Clinical Warning note in the research patient's EHR stated the patient was enrolled in the study and included the date of enrollment. The note also provided the names of the research cardiologist and the research study coordinator as points of contact for concerns or questions.

## Patient A Case Summary

Patient A who was in their 50s had a medical history significant for [hypertension](#), [hyperlipidemia](#), [coronary artery disease](#) treated with a [coronary artery bypass graft surgery](#) after multiple heart [stents](#), [peripheral arterial disease](#) treated with multiple lower extremity [revascularization procedures](#), left above the knee amputation, [hyponatremia](#), and [hidradenitis](#).<sup>20</sup> The patient received medications to manage cardiac disease that included aspirin, [atenolol](#), [lisinopril](#), and [rosuvastatin](#).

On a summer day in 2018 (day 1), the patient contacted a primary care registered nurse at the Manchester Avenue VA Clinic in St. Louis, Missouri, and reported tingling in the left ear to the left shoulder, and chest discomfort of one week's duration. The patient believed the tingling was secondary to the medication, [dapson](#), and stopped the medication.

On day 3, the patient was seen by a primary care provider to address the previously reported complaints. The primary care provider documented in the EHR that the patient's chest pain occurred two weeks prior to the office visit. The pain was described as [midsternal](#) without [radiation](#) and not associated with shortness of breath or cough. The primary care provider noted the patient's tingling sensations did not resolve with discontinuation of dapson.

Following the medical exam, the primary care provider ordered consults for [vascular](#) surgery to evaluate the blood vessels in the patient's neck, an ECG to evaluate electrical stimuli in the heart, and a treadmill [stress test with nuclear imaging](#) to evaluate the heart. The ECG was performed, and it showed a normal [sinus rhythm](#). The ECG result was verified by an assigned [cardiologist](#) reviewer.

The same day, a research cardiologist reviewed the consult request for the treadmill stress test, determined the patient was a candidate for the research study, and contacted the patient regarding participation in the research study. The patient agreed to participate in the study. Almost three weeks later, on day 21, the patient signed an informed consent and attempted a treadmill stress test. The research cardiologist's EHR note indicated that the patient, who was an amputee, did not bring the lower leg prosthesis for the treadmill stress test: "[the patient] has been experiencing left groin pain because of the hidradenitis, has not worn [the] left lower extremity prosthesis for several months, and did not bring it for the treadmill [stress] test." The relevant note states "[The patient] was stable and we attempted a single leg treadmill warm-up at about 1 [mile per hour,] but it became apparent that a single leg stress test would not be feasible." The consult was discontinued. The research cardiologist planned a regadenoson stress test for approximately three weeks later.

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<sup>20</sup> The OIG uses the singular form of they (their) in this instance to protect the patient's privacy.

In addition to undergoing a [cardiology](#) evaluation, the patient was also evaluated for hidradenitis. The patient was seen by the facility's [dermatology](#), [anesthesia](#), and general surgery services to evaluate and treat hidradenitis of the [axilla](#), [perineum](#), and groin area.

Two days after the attempted stress test (day 23), the patient had bilateral axillary surgery to remove cysts and explore the perineum to rule out a fistula. Scarring and pitting in the perineum were found, but there was no fistula.

As planned, a regadenoson stress test with myocardial perfusion imaging was performed on day 39 and was negative for evidence of myocardial [ischemia](#).

Approximately three weeks after the negative regadenoson stress test (day 58), a vascular consult was completed and showed 50 to 79 percent [stenosis](#) in the right [internal carotid artery](#) and less than 50 percent stenosis in the left internal carotid artery. Significant stenosis was noted in both the right and left [external carotid arteries](#). No significant stenosis was found in the right or left [common carotid arteries](#).

The research cardiologist entered a consult for an arm exercise stress test. The test, performed on day 71, showed a "strongly positive ECG response to arm exercise to an endpoint of fatigue with concurrent angina at 97% [age-predicted peak heart rate](#)."<sup>21</sup> The medical technician noted in the EHR that the patient was discharged from the stress test laboratory in stable condition. Following this positive stress test, no additional cardiology visits were found in the EHR. On day 93, three weeks after the arm stress test with angina, the research cardiologist entered an order for a computed tomography angiography. The test was scheduled to be completed three weeks later but was canceled and rescheduled for early 2019. Documentation in the EHR states Patient A died at home on day 115, six weeks after the arm exercise stress test, before the scheduled date for the computed tomography angiography.

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<sup>21</sup> A positive response to an ECG Stress test can include: chest pain, difficulty breathing, abnormal heart rate or blood pressure response, or changes in the ECG. In this patient's case, there were ECG changes suggesting that certain portions of the patient's heart may not have been appropriately oxygenated during exercise.

## Inspection Results

### 1. Failure to Initiate Follow-Up Care for Patient A

The OIG substantiated that a research cardiologist failed to initiate cardiac follow-up care based on Patient A's positive stress-test result. However, follow-up care was ordered as part of a research protocol. The research cardiologist did not notify Patient A or the primary care provider of the positive stress-test result. The OIG determined that the failure to communicate that the stress test was positive may have resulted in a missed opportunity to make clinical management decisions related to follow-up care. Cardiology leaders reported that prior to the OIG review, process changes were implemented in the stress test laboratory to ensure follow-up care and improve communication with primary care providers.

VHA Directive 1088 states the ordering provider is responsible for initiating clinical action and follow-up for orders placed by that provider.<sup>22</sup> *VHA Communication of Test Results Toolkit* states that "ordering providers are responsible for all test results they order regardless of their VA designation... [f]or instance, all subspecialists are responsible for test results ordered by them and should not rely only on the primary care provider in order to do so, unless a pre-existing mutually agreeable and clear arrangement has been made between the two parties."<sup>23</sup> Staff reported that to assist with this process, the facility EHR is set up to send an alert to notify ordering providers when consults they have ordered are complete. VHA Directive 1088 also requires the ordering provider or designee to document that the test results were communicated to the patient.<sup>24</sup> The study plan did not address who was responsible to take action or define actions to be taken by the providers when patients enrolled in the study had a positive stress test.

### Failure to Provide Follow-Up Cardiac Care for Patient A

The OIG team reviewed Patient A's EHR and determined that the primary care provider entered a cardiology consult for a treadmill stress test (to evaluate cardiac symptoms). The patient was enrolled in the research study. The research cardiologist ordered two additional stress tests (regadenoson and an arm exercise) for study comparison. The treadmill stress test was to occur first, followed by regadenoson and arm exercise. The treadmill stress test was attempted on day 21, almost three weeks after the cardiology consult was entered; however, the patient was

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<sup>22</sup> VHA Directive 1088, Communicating Test Results to Providers and Patients, October 7, 2015.

<sup>23</sup> Shear, J. Mercer, R., Thaker, K. et al. *VHA Communication of Test Results Toolkit*, April 2012. This document is located on an internal VHA website and is not available to the general public. The toolkit provides guidance for facility staff to meet the requirements of VHA Directive 1088.

<sup>24</sup> VHA Directive 1088.

unable to complete the test.<sup>25</sup> The consult was discontinued and the ordering provider, in this case the primary care provider, would have been notified of the discontinuation and lack of results.

On day 39, the regadenoson stress test with myocardial perfusion imaging was performed as the second test of the study protocol. Documentation at the time of the test showed the last chest pain reported by the patient occurred seven weeks prior. The stress test ECG results were negative, and imaging showed normal cardiac perfusion and normal left ventricular function.<sup>26</sup> A negative stress test did not trigger a need for additional follow-up for this patient.

EHR documentation showed that just over one month later (day 71), prior to the arm exercise stress test, the research cardiologist noted the patient reported chest pain five days earlier. However, additional information detailing this chest pain was not found in the EHR note. The research cardiologist proceeded with the test. During the test the patient experienced “chest discomfort” with ECG changes that resolved within 15 minutes. The patient was discharged. The results of the test were documented as consistent with intermediate cardiac risk noting a strong positive ECG response with concurrent angina.<sup>27</sup>

The OIG determined that, as the ordering provider, the research cardiologist was the only provider alerted to the results of the regadenoson and arm exercise stress tests and imaging. EHR documentation did not provide evidence that the research cardiologist discussed the results of either test with the patient or the primary care provider, nor did the research cardiologist initiate any follow-up care at the time of the positive stress test.

On day 93, the research cardiologist ordered a calcium scoring test and computed tomography angiography. The reason cited for the angiography was “research study participant” and gave no indication that the test was part of the patient’s care management in response to a positive stress

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<sup>25</sup> EHR documentation indicates that the patient had left groin pain and did not bring a lower extremity prosthesis; the cardiologist determined a single leg stress test was not possible.

<sup>26</sup> American Heart Association, *How the Healthy Heart Works*. The left ventricle is the chamber of the heart that pumps oxygenated blood to tissues all over the body, except for the lungs. <https://www.heart.org/en/health-topics/congenital-heart-defects/about-congenital-heart-defects/how-the-healthy-heart-works>. (The website was accessed on September 16, 2019.)

<sup>27</sup> Intermediate cardiac risk is based on the Duke treadmill score in which three independent variables (exercise time, ST segment deviation on an ECG, and angina) are considered and given point values to interpret the stress test. A score between 4 and minus (-)10 indicates intermediate risk for and management of coronary artery disease. D. Mark, M.D., M.P.H., L. Shaw, B.A. et. al. “Prognostic Value of a Treadmill Exercise Score in Outpatients with Suspected Coronary Artery Disease,” *New England Journal of Medicine*. (September 19, 1991): 325(12):849-53. <https://www.ncbi.nlm.nih.gov/pubmed/1875969>. (The website was accessed on September 11, 2019.) During the six weeks prior to Patient A’s death, Patient A had three non-cardiology clinician exams at the facility. There was no EHR documentation that Patient A complained of or reported chest pain at these exams.

test. As the ordering provider, the research cardiologist had the responsibility to initiate action and arrange follow-up care to address the positive stress test.<sup>28</sup>

The American College of Cardiology/American Heart Association Practice Guidelines recommend that patients whose exercise stress-test results are considered intermediate risk be referred for additional testing, either cardiac catheterization or an angiography for cardiac imaging. The guidelines do not define a timeline for the follow-up testing unless left ventricular dysfunction is present, in which case, a prompt referral for cardiac catheterization is recommended.<sup>29</sup> Although Patient A's regadenoson stress test with myocardial perfusion imaging, completed on day 39, showed normal ventricular function, two cardiologists who reviewed the patient's EHR stated the patient should have had some type of follow-up care sooner than it was initiated.<sup>30</sup>

During an interview with the research cardiologist, the OIG inquired about the patient's need for follow-up care. The research cardiologist thought the patient needed follow-up care but not urgently and that in this case, the primary care provider would be responsible to ensure appropriate treatment and follow-up, not the researcher.<sup>31</sup> While discussing the case with the OIG, the research cardiologist realized that the ordering provider of the arm exercise stress test would be the only provider alerted to the positive results. The OIG asked the research cardiologist if the primary care provider was contacted. The research cardiologist did not remember calling the primary care provider but indicated a call may have occurred. The OIG did not find EHR documentation that the positive stress-test result was communicated to the patient's primary care provider or the patient. Due to the patient's medical history and the positive stress-test results, the OIG would have expected to see communication of these results to both the patient and the patient's primary care provider and earlier initiation of clinical action for

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<sup>28</sup> VHA Directive 1088; *VHA Communication of Test Results Toolkit*. Examples of follow-up care include notifying the primary care provider to oversee the care needed and placing a consult for cardiology clinic.

<sup>29</sup> R. Gibbons, M.D., G.J. Balady, M.D., F.A.C.C., et. al. American College of Cardiology/American Heart Association Practice Guidelines, Guidelines for Exercise Testing, *Journal of American College of Cardiology*. Vol 30, No 1 July 1997:260–315. <http://www.onlinejacc.org/content/accj/30/1/260.full.pdf>. (The website was accessed on September 11, 2019.)

<sup>30</sup> A cardiologist gave examples of possible follow-up as an appointment at a cardiology clinic and review of the patient's medications.

<sup>31</sup> The research cardiologist explained appropriate treatment as a medication management and life style modification.

follow-up care. Additionally, the OIG did not find that facility staff reviewed the case to determine if disclosure to the patient and patient's family was warranted.<sup>32</sup>

The OIG further inquired about the order for the computed tomography angiography to understand the rationale for the time frame (22 days after the positive stress test) in which the order was entered. The research cardiologist informed the OIG that the computed tomography angiography was not ordered at the time the positive stress test occurred in part because the computed tomography scanner, designated for use to complete the study angiography, was under repair and the sole radiologist trained to interpret the results was not available at that time.

Based on the complexity of Patient A's cardiac history and other co-morbidities, as well as the absence of an autopsy, the OIG was unable to determine whether timelier follow-up and intervention would have prevented or delayed Patient A's death.

### **Cardiology Leaders' Process Improvements**

The OIG learned that the following changes were implemented in the cardiology stress test laboratory to ensure follow-up care for patients with a positive stress test and communication of stress-test results to primary care providers:

- The Chief of Cardiology directed that a patient with a positive stress test will have a cardiology consult placed by the provider administering the test prior to the patient leaving the stress test laboratory. The primary care provider or the primary cardiologist or both will be added as an additional signer to the stress test note to ensure follow-up care.
- The Director of the Cardiac Stress Test Laboratory will review all stress tests to ensure that patients with positive stress tests have follow-up care in place and the results have been communicated to the primary care provider.
- The Chief of Cardiology established a Data Safety Monitoring Board (Board) comprised of four cardiologists and a nurse practitioner. The purpose of the Board was to monitor research patients' stress-test results and ensure any patient with a positive result had follow-up care including communication of results to the patient and primary care provider. Additionally, the OIG learned that the Board would complete a retrospective review of all patients enrolled in the study to date to ensure patients with positive stress-

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<sup>32</sup> VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. Disclosure of adverse events is a discussion that takes place between a provider and patient or patient's personal representative about the occurrence of a harmful or potentially harmful adverse event. A patient's clinician may inform the patient or the patient's representative about clinically significant events that occurred (clinical disclosure). A more formal process may be pursued during which "facility leader(s), together with clinicians and others as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred...and provide specific information about the patient's rights and recourse" (institutional disclosure).

test results had follow-up and results were communicated to the patients and primary care providers.

## **2. Alleged Inadequate Care Provided by a Cardiology Fellow**

The OIG did not substantiate that a cardiology fellow failed to manage follow-up care for four patients who had positive stress tests. The four patients received follow-up care. The OIG was unable to determine if the cardiology fellow had difficulty making an accurate initial interpretation of the ECGs because there was no written documentation of this analysis. However, documentation of the cardiology fellow's analysis was not required. The supervising provider was responsible for overseeing the care provided by the cardiology fellow including ensuring (1) follow-up care, if indicated; (2) correct ECG interpretation; and (3) documentation of the result.

### **Alleged Failure to Provide Follow-up Care**

In reviewing the four patients' EHRs to determine if patients with positive stress tests received follow-up care, the OIG team applied VHA guidance recognizing a supervising provider as responsible for oversight of the care provided by the cardiology fellow.<sup>33</sup> VHA requires supervising providers be involved with a cardiology fellow's patient encounters in all clinical settings, and documentation of the involvement must be evident in the patient's EHR.<sup>34</sup> The supervising provider was an attending cardiologist in each case.

The OIG confirmed that supervising providers oversaw the care provided by the cardiology fellow for the four identified patients. The cardiology fellow's notes contained either a supervising provider's cosignature or an addendum written by a supervising provider verifying involvement with the care documented and provided by the cardiology fellow. The OIG found evidence that follow-up care, when indicated, occurred and did not identify additional concerns with the care provided by the cardiology fellow for the four cases reviewed.

### **Alleged Failure to Correctly Interpret ECG Results**

VHA is not prescriptive as to who is responsible for interpreting an ECG; and the facility does not have a written policy defining ECG processes. However, during interviews with staff, the OIG learned the following practice was in place for the interpretation of ECGs for patients in the stress test laboratory. The ECG machine prints out a copy of the cardiac rhythm. The cardiology

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<sup>33</sup> VHA Handbook 1400.01.

<sup>34</sup> VHA Handbook 1400.01. Acceptable documentation of the supervising providers involvement with patient care includes the supervising provider writing a progress note, the supervising provider writing an addendum to the cardiology fellow's note, the supervising provider cosigning a cardiology fellow's note, and the cardiology fellow documenting the name of the supervising provider, the supervising provider's oversight responsibility, and the discussion regarding the patient's assessment and treatment plan in the EHR.

fellow interprets the cardiac rhythm and verbally confers with the supervising provider. This conversation is part of the educational process for the cardiology fellow and the oversight responsibility of the supervising provider. The resulting ECG interpretation is then documented in the EHR note. All computerized ECG printouts are then interpreted by another cardiologist to confirm and finalize the interpretation. Once this is completed, the results are finalized, uploaded, and available in the EHR.

The OIG reviewed the patients' EHR notes and ECGs involving care provided by the cardiology fellow. Because the initial ECG interpretation by the cardiology fellow was presented verbally, it was not reflected in the EHR. However, the OIG found evidence of the supervising provider's and cardiology fellow's real time ECG interpretation in all four cases. Although the OIG could not evaluate the cardiology fellow's initial interpretation of the ECG, collaboration between the supervising provider and cardiology fellow in assessing the ECG was evident in the documentation.

### **3. Research Compliance and Oversight**

During the initial review of documents pertaining to the study, the OIG identified concerns regarding the research team's adherence to the study plan as well as VHA required facility oversight of research studies. The concerns included the consent process, annual review of the study by both the facility's Subcommittee on Research Safety and the Institutional Review Board, reporting of research study serious adverse events, and research team communication with the primary provider related to patients' enrollment.<sup>35</sup> Based on EHR reviews, additional documentation, and information provided by the research staff, the OIG determined that the informed consent process, annual review of the study, and reporting of serious adverse events met requirements; however, the OIG did not find consistent documentation of communication with the patients' primary providers about enrollment in the study.

#### **Adherence to the Research Study Plan**

The study's approved plan states that prior to scheduled stress test procedures, the research cardiologist or the research study coordinator will contact the primary provider of the patient who qualifies for the study to discuss the patient's participation in the study. "The purpose of these communications will be to discuss the protocol, ensure provider approval, and ascertain whether potential participants have exclusion criteria."<sup>36</sup> The plan also states that the results have

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<sup>35</sup> The primary provider is the provider who placed the initial consult for a stress test (for example, the primary care provider or the patient's primary cardiologist).

<sup>36</sup> Exclusion criteria includes a patient's inability to perform the arm ergometer exercise; acute coronary syndrome; heart block; severe reversible airway disease; resting ECG abnormalities that interfere with reliable interpretation of a stress ECG; allergies to contrast; or significant renal disease.

important prognostic and diagnostic value and may assist in guiding providers to order additional evaluation and treatments, medications, and procedures.

The OIG requested, but did not receive, facility evidence documenting discussions regarding patients' enrollment into the study and approval by their primary providers. While conducting interviews with research study personnel, the OIG learned that notification to the primary provider occurs when the primary provider is added as an additional signer to the research participation consent form or to an EHR note titled Clinical Warning. Interviewees described this action as a notification of participation rather than a discussion.

An OIG review of the study enrollees' EHRs to verify documentation of notification found that none of the 40 participants selected for review had evidence that a primary provider was added as an additional signer. The records reviewed lacked evidence of discussion with a primary provider, approval for study participation, or acknowledgment by the primary provider of the patient's enrollment prior to the study occurring. During interviews, the OIG determined that neither the research cardiologist nor the research study coordinator recognized that the additional signer was not added to the notes and believed the requirement was met. Clinical Warning notes were completed by the research study coordinator after the patients' involvement in the study.<sup>37</sup>

The OIG team concluded that the research team was not adhering to the study plan. The lack of notification to primary providers regarding study enrollment introduced the likelihood that primary providers and study participants might not have fully benefited from the additional information acquired from their involvement in the study.

#### **4. Stress Test Instruction Inconsistencies**

During interviews, the OIG heard inconsistent responses regarding the administration of the pharmacological stress test (regadenoson). This prompted the OIG team to review the regadenoson stress test information provided in an email as orientation material for new cardiology fellows and facility cardiology attending staff.<sup>38</sup>

The OIG team determined cardiology fellows were to receive two instructional handouts that contained conflicting guidance regarding the acceptable systolic blood pressure prior to administration of the medication and parameters for administering a reversal agent (if

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<sup>37</sup> The OIG reviewed 34 patient Clinical Warning notes; 30 of the notes were signed between 25 and 270 days after the first study test.

<sup>38</sup> The OIG reviewed information that included: Protocol for Adult Lexiscan® Stress for Elucidation of Myocardial Ischemia from the stress test laboratory protocol book, and Lexiscan/Regadenoson and Cardiac Stress Testing—Pharmacologic Stress Testing and Contraindications, a handout on stress test with references for distribution to the fellows.

necessary).<sup>39</sup> The stress test laboratory staff received information from a facility protocol book that did not align with the guidance available to the fellows.<sup>40</sup> During an interview, the Director of the Cardiac Stress Test Laboratory stated that the instructional material was to be made available to the fellows through the university and minor updates were made to the protocol book that had been in use by staff prior to assuming the directorship. The OIG team concluded that the contradictions in instructions provided to cardiology fellows and facility staff had the potential to create confusion and possibly introduce increased risk of errors when administering the regadenoson stress test.

The OIG reviewed the facility policy that provided guidance for establishing internal policies and standard operating procedures.<sup>41</sup> The facility's policy outlined specific elements (references, review dates and rescissions, who is responsible to maintain the policy, and evidence that the protocol went through the concurrence process) to be included when preparing facility policy or a standard operating procedure.<sup>42</sup> These elements ensure that the guidance provided to staff reflects current, evidence-based practices to provide quality care. The OIG determined the stress test laboratory regadenoson protocol did not include any of the identified elements required by facility policy.

## Conclusion

The OIG substantiated that after Patient A had a positive stress test during the study, the research cardiologist did not initiate follow-up care based on the positive stress test or notify the patient or primary care provider of the results. The research cardiologist stated the primary provider was responsible for addressing follow-up care rather than a researcher. Prior to interviews with the OIG, the research cardiologist did not recognize that the ordering provider (the research cardiologist) was the only provider who was alerted to the positive stress-test results. Based on the complexity of Patient A's cardiac history and other co-morbidities, as well as the absence of an autopsy, the OIG was unable to determine whether more timely follow-up or other interventions would have prevented or delayed Patient A's death.

While on-site, the OIG learned the Chief of Cardiology initiated several process changes for patients with positive stress-test results to ensure that follow-up care and communication of the

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<sup>39</sup> Centers for Disease Control and Prevention, *About High Blood Pressure*. Systolic blood pressure is the pressure exerted on blood vessels when the heart pushes blood through the body. It is represented by the top number of a blood pressure reading. <https://www.cdc.gov/bloodpressure/measure.htm>. (The website was accessed on August 14, 2019.)

<sup>40</sup> The facility's stress test laboratory protocol book is a binder that contains step-by-step instructions to perform each procedure.

<sup>41</sup> Facility Memorandum 00-34, *Medical Center Publication Management*, April 1, 2018. A standard operating procedure provides instruction for completing a task within a service or program area (such as a protocol).

<sup>42</sup> Facility Memorandum 00-34. The concurrence process includes multiple steps and is reviewed by subject matter experts to ensure the information is accurate.

stress-test results occurred. Additionally, a retrospective review of all patients enrolled in the study to date was planned to ensure patients with positive stress-test results had follow-up and results were communicated to the patients and primary care providers.

The OIG did not substantiate that a cardiology fellow failed to manage follow-up care for four patients with positive stress tests. The OIG was unable to determine if the cardiology fellow had difficulty making an accurate initial interpretation of the ECGs prior to conferring with supervising providers. Although the facility's process did not include documentation of the cardiology fellow's initial ECG interpretation, the OIG determined that supervising providers were involved with the cardiology fellow's patient encounters, follow-up care was provided when indicated, and ECG interpretations were validated by the supervising provider prior to documentation in the EHR.

The OIG's review of the research study plan identified steps to contact the primary provider to discuss potential enrollee patient's participation in the study and obtain the primary provider's approval. The conversation would alert the primary provider that additional study results would be available in the EHR, possibly providing prognostic and diagnostic value. However, the OIG determined that neither the research cardiologist nor the research study coordinator was adhering to the study plan.

The OIG team identified inconsistencies between the instructions for the regadenoson stress test laboratory procedure that were available to cardiology fellows and the protocol used by facility staff. These inconsistencies provided conflicting information regarding acceptable blood pressure parameters prior to a pharmacological stress test and when to administer a reversal agent if necessary. Contradictions in protocols and instructions provided to facility staff creates potential confusion and possibly introduces risk for error. The research study protocol for the regadenoson stress test provided to stress test laboratory staff did not adhere to the facility policy requirements for establishing internal policy and standard operating procedures (such as protocols).

## **Recommendations 1–6**

1. The VA St. Louis Health Care System Director makes certain the Chief of Staff ensures research providers take action based on stress-test results to include coordination of care and notification to primary providers as warranted.
2. The VA St. Louis Health Care System Director ensures that a full retrospective review of patients enrolled, to date, in the Arm Exercise Versus Pharmacologic Stress Testing for Clinical Outcome Prediction study with positive stress tests received communication of their test result and follow-up care if indicated.
3. The VA St. Louis Health Care System Director ensures that a review of Patient A's case is completed to determine if disclosure is warranted.

4. The VA St. Louis Health Care System Director makes certain that the Institutional Review Board ensures adherence to the research study plan related to communication to the primary provider of patient enrollment in the study.

5. The VA St. Louis Health Care System Director ensures alignment of content for the regadenoson stress test protocols and education provided to staff and healthcare trainees.

6. The VA St. Louis Health Care System Director ensures the stress test laboratory regadenoson protocol meets VA St. Louis Health Care System Memorandum 00-34 requirements.

## Appendix A: Patients B–E Case Summaries

### Patient B

Patient B, who was in their 70s, had a history of cardiovascular disease and a planned admission to the facility for medical management of an abnormal heart rhythm. As part of the patient's treatment plan, a treadmill stress test was ordered to evaluate the patient's heart rate response to exertion. The cardiology fellow assessed the patient prior to the treadmill stress test and found no contraindications to perform the evaluation. During the treadmill stress test the patient experienced dizziness prior to reaching the maximum heart rate and the test was stopped; consequently, the test results were inconclusive. The supervising provider reviewed and documented concurrence with the cardiology fellow's assessment and summary of the patient's care. The patient received follow-up care (placement of a pacemaker) three days later.

### Patient C

Patient C, who was in their 70s, had a history of cardiovascular disease. An exercise stress test was ordered by the primary cardiologist. The patient was identified as a candidate for the study and agreed to participate. Additional stress tests were ordered by the research cardiologist and scheduled over the next several months. The patient completed the first two stress tests. The primary cardiologist was notified of the positive results from the first stress test. The OIG could not find documentation that the primary cardiologist was notified of the results from the second stress test. The cardiology fellow assessed the patient prior to the third stress test (regadenoson) and performed the evaluation. After the administration of regadenoson, the patient had a decrease in blood pressure and complained of chest pain.<sup>43</sup> The patient was treated with aminophylline (a medication that reverses the effects of regadenoson) and given fluids; within a few minutes, the blood pressure returned to baseline, and the chest pain resolved.<sup>44</sup> The patient's primary cardiologist was notified of the events. A cardiology follow-up appointment occurred within a week.

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<sup>43</sup> Mayo Clinic website, *Regadenoson*. Anticipated side effects of regadenoson include chest pain, labored breathing, nausea, and sweating. The mechanism of regadenoson dilates the blood vessels which can cause a decrease in blood pressure. <https://www.mayoclinic.org/drugs-supplements/regadenoson-intravenous-route/side-effects/drg-20071632>. (The website was accessed on December 31, 2019.)

<sup>44</sup> Henzolova MJ et al. *ASNC imaging Guidelines for SPECT nuclear cardiology procedures: Stress, protocols, and tracers*. J Nuclear Cardiology, 2016. <https://www.asnc.org/files/Guidelines%20and%20Quality/ASNC%20SPECT%20ProtocolsTracers%20Guidelines2016.pdf>. (The website was accessed on September 16, 2019.)

## **Patient D**

Patient D, who was in their 50s and had a history of diabetes and cardiovascular disease, was referred for a cardiology evaluation. The patient was scheduled for a stress test. The cardiology fellow assessed the patient prior to the treadmill stress test and did not identify contraindications to testing. The patient had no complications during the treadmill stress test and the results were negative. The supervising provider examined the patient, reviewed the cardiology fellow's interpretation of the stress-test results, and documented concurrence. The results of the stress test were discussed with the patient and no further testing was indicated.

## **Patient E**

Patient E, who was in their 40s with a history of hypertension, hyperlipidemia, and obstructive sleep apnea, reported chest pain to a primary care provider who ordered a treadmill stress test. The cardiology fellow assessed the patient prior to the treadmill stress test and found no contraindications to perform the evaluation. During the test, the patient had heart rhythm changes without chest pain and tolerated the procedure. The treadmill stress test was assessed as abnormal. The supervising provider reviewed and documented concurrence with the cardiology fellow's assessment and summary of the patient's care. A follow-up cardiology appointment occurred approximately a month later and no further cardiac work up was indicated.

## Appendix B: VISN Director Memorandum

### Department of Veterans Affairs Memorandum

Date: February 20, 2020

From: Director, VA Heartland Network (10N15)

Subj: Healthcare Inspection—Alleged Deficiencies and Delays in Cardiac Care at the VA St. Louis VA Health Care System, Missouri

To: Director, Office of Healthcare Inspections (54HL05)  
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. In response to the findings of OIG Healthcare Inspection—Alleged Deficiencies and Delays in Cardiac Care at the VA St. Louis VA Health Care System, Missouri, the facility has taken actions to address the six (6) recommendations.
2. I have reviewed and concur with the report, findings, recommendations and actions submitted by the facility. Monitoring of completion and sustainment of the actions will be done.

*(Original signed by:)*

William P. Patterson, MD, MSS  
Network Director, VA Heartland Network  
VISN 15

## Appendix C: Facility Director Memorandum

### Department of Veterans Affairs Memorandum

Date: February 19, 2020

From: Director, VA St. Louis Health Care System (657/00)

Subj: Healthcare Inspection—Alleged Deficiencies and Delays in Cardiac Care at the VA St. Louis VA Health Care System, Missouri

To: Director, VA Heartland Network (10N15)

1. In response to the findings of OIG Healthcare Inspection—Deficiencies in a Cardiac Research Study at the VA St. Louis VA Health Care System, Missouri, the facility has taken actions to address the six (6) recommendations.
2. The VA St. Louis Health Care System appreciates the opportunity to respond to this inspection. We take these recommendations seriously, and will continue to provide exceptional quality care to each of our Veterans.

*(Original signed by:)*

Keith Repko  
Medical Center Director  
VA St Louis Health Care System

## Facility Director Response

### Recommendation 1

The VA St. Louis Health Care System Director makes certain the Chief of Staff ensures research providers take action based on stress-test results to include coordination of care and notification to primary providers as warranted.

Concur.

Target date for completion: September 30, 2020

### Director Comments

The Chief of Staff in collaboration with the both the Medicine and Research Services implemented a process to ensure that research providers take the following steps based on positive stress-test results: 1) Notify patients of abnormal stress-test results, and document their notification into the electronic health record (EHR); and 2) Add the Primary Care Provider (PCP) as an additional signer as a means of notifying them of the positive results and recommendations for coordinating care. Reporting of research patients' positive stress-test results will be monitored by the Data Safety Monitoring Board (DSMB) with results reported monthly to the Medicine Service and Institutional Review Board (IRB) with a goal of 95% compliance for six months.

### Recommendation 2

The VA St. Louis Health Care System Director ensures that a full retrospective review of patients enrolled, to date, in the Arm Exercise Versus Pharmacologic Stress Testing for Clinical Outcome Prediction study with positive stress tests received communication of their test result and follow-up care if indicated.

Concur.

Target date for completion: Completed February 11, 2020

### Director Comments

A full retrospective review was conducted on patients enrolled in the Arm Exercise Versus Pharmacologic Stress Testing for Clinical Outcome Prediction study who had positive stress tests. Of the 119 Veterans included in the study and excluding the two patients reviewed by the OIG in this report, twenty-four had positive stress tests. 100% patients (24/24) were notified of their positive stress test findings and received appropriate follow-up care.

## **OIG Comment**

The OIG considers this recommendation open to allow the submission of documentation to support closure.

## **Recommendation 3**

The VA St. Louis Health Care System Director ensures that a review of Patient A's case is completed to determine if disclosure is warranted.

Concur.

Target date for completion: Completed February 11, 2020

## **Director Comments**

Patient A's death was thoroughly reviewed by the facility's Peer Review Committee (PRC) and the Chief of Staff (COS) to determine whether the death met criteria for an institutional disclosure under VHA Directive 1004.08, Disclosure of Adverse Events. Their review found that the Veteran was informed of the positive stress test which reflected stable coronary artery disease which the patient was aware of, therefore, the facility concluded that an Institutional Disclosure was not warranted.

## **OIG Comment**

The OIG considers this recommendation open to allow the submission of documentation to support closure.

## **Recommendation 4**

The VA St. Louis Health Care System Director makes certain that the Institutional Review Board ensures adherence to the research study plan related to communication to the primary provider of patient enrollment in the study.

Concur.

Target date for completion: September 30, 2020

## **Director Comments**

The research study team submitted a modification request to change the way Primary Care Providers are notified of enrolled Veterans in the study from what is described in the study plan to notification through use of the additional signer option of IMED [iMedConsent™ software consent form] consent. This request will be considered by the Institutional Review Board at March 2020 meeting. The Institutional Review Board will monitor adherence to the research

study plan related to communication to the primary provider of patient enrollment with a goal of 95% compliance for six months.

### **Recommendation 5**

The VA St. Louis Health Care System Director ensures alignment of content for the regadenoson stress test protocols and education provided to staff and healthcare trainees.

Concur.

Target date for completion: March 1, 2020

#### **Director Comments**

A review of the stress tests reports for all study participants demonstrated no evidence of harm or untoward events related to the discordant regadenoson protocols. The consensus of those conducting the review (Research, Medicine and Stress Lab Director) did conclude that developing a single regadenoson protocol would simplify the training for the cardiology fellows and imaging staff. The regadenoson protocol was revised accordingly, and all Stress Lab staff, fellows, and healthcare trainees will be educated on the single protocol.

#### **OIG Comment**

The OIG considers this recommendation open to allow the submission of documentation to support closure

### **Recommendation 6**

The VA St. Louis Health Care System Director ensures the stress test laboratory regadenoson protocol meets VA St. Louis Health Care System Memorandum 00-34 requirements.

Concur.

Target date for completion: Completed February 14, 2020

#### **Director Comments**

The Stress Lab Director and Cardiology Nurse Manager utilized the standard operating procedure template to establish a standard operating procedure that meets requirements of MCM 00-34

#### **OIG Comment**

The OIG considers this recommendation open to allow the submission of documentation to support closure.

## Glossary

**age-predicted peak (maximum) heart rate.** The number of beats per minute the heart is working at its maximum usually estimated as 220 minus the person's age.<sup>45</sup>

**anesthesia.** A medicine called an anesthetic is used to reduce or prevent pain during a medical procedure.<sup>46</sup>

**atenolol.** A medication used to control high blood pressure and “works by relaxing blood vessels and slowing [the] heart rate to improve blood flow and decrease blood pressure.”<sup>47</sup>

**axilla.** The area known as the armpit.<sup>48</sup>

**cardiologist.** A physician or provider who has special training and skills “treating and preventing diseases of the heart and blood vessels.”<sup>49</sup>

**cardiology.** The study of the heart and disease that affect its function.<sup>50</sup>

**common carotid artery.** “[T]he part of either carotid artery between its point of origin and its division into the external and internal carotid arteries.”<sup>51</sup>

**coronary artery bypass graft surgery.** A procedure that uses a piece of healthy vein from somewhere else in the body to create a way around a blocked area of the coronary artery and improve blood flow to the heart.<sup>52</sup>

**coronary artery disease.** Occurs when the arteries that supply blood to the heart become narrowed and hardened reducing blood flow potentially leading to chest pain or a heart attack.<sup>53</sup>

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<sup>45</sup> Merriam-Webster Dictionary, *Medical Definition of maximum heart rate.* <https://www.merriam-webster.com/medical/maximum%20heart%20rate>. (The website was accessed on September 2, 2019.)

<sup>46</sup> U.S National Library of Medicine, *Anesthesia.* <https://medlineplus.gov/anesthesia.html>. (The website was accessed on September 2, 2019.)

<sup>47</sup> U.S National Library of Medicine, *Atenolol.* <https://medlineplus.gov/druginfo/meds/a684031.html>. (The website was accessed on September 5, 2019.)

<sup>48</sup> Merriam-Webster Dictionary, *Definition of armpit.* <https://www.merriam-webster.com/dictionary/armpit>. (The website was accessed on September 2, 2019.)

<sup>49</sup> American College of Cardiology CardioSmart, *What is a Cardiologist.* <https://www.cardiosmart.org/Heart-Basics/What-is-a-Cardiologist>. (The website was accessed on September 9, 2019.)

<sup>50</sup> Merriam Webster Dictionary, *Definition of cardiology.* <https://www.merriam-webster.com/dictionary/cardiology#note-1> (The website was accessed on September 30, 2019.)

<sup>51</sup> Merriam-Webster Dictionary, *Definition of common carotid artery.* <https://www.merriam-webster.com/medical/common%20carotid%20artery> (The website was accessed on October 1, 2019.)

<sup>52</sup> Johns Hopkins, *Coronary Artery Bypass Graft Surgery.* <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/coronary-artery-bypass-graft-surgery>. (The website was accessed on September 5, 2019.)

<sup>53</sup> U.S National Library of Medicine, *Coronary Artery Disease.* <https://medlineplus.gov/coronaryarterydisease.html> (The website was accessed on June 14, 2019.)

**dapsone.** A medication used to treat chronic skin dermatitis.<sup>54</sup>

**dermatology.** The branch of medicine that involves the skin and its diseases.<sup>55</sup>

**external carotid artery.** The outer branch of the carotid that supplies the face, tongue, and outer parts of the head with blood.<sup>56</sup>

**hidradenitis.** Is inflammation of a sweat gland.<sup>57</sup>

**hyperlipidemia.** Refers to elevated levels of fats in the blood.<sup>58</sup>

**hypertension.** Also known as high blood pressure, is when the “force of the blood against...artery walls is high enough that it may eventually cause health problems, such as heart disease.”<sup>59</sup>

**hyponatremia.** An abnormally low concentration of sodium in the blood. Sodium helps regulate the amount of water in your cells and helps maintain normal blood pressure.<sup>60</sup>

**internal carotid artery.** The inner branch of the carotid artery that supplies the brain, eyes, and other internal parts of the head.<sup>61</sup>

**ischemia.** A deficient supply of blood to a body part that is due to obstruction of the inflow of oxygenated blood from the heart.<sup>62</sup>

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<sup>54</sup>Merriam-Webster Dictionary, *Definition of dapsone*. <https://www.merriam-webster.com/dictionary/dapsone>. (The website was accessed on August 27, 2019.)

<sup>55</sup> Merriam-Webster Dictionary, *Definition of dermatology*. <https://www.merriam-webster.com/dictionary/dermatology#examples>. (The website was accessed on September 2, 2019.)

<sup>56</sup> Merriam-Webster Dictionary, *Medical Definition of external carotid artery*. <https://www.merriam-webster.com/medical/external%20carotid%20artery>. (The website was accessed on September 2, 2019.)

<sup>57</sup>Merriam-Webster Dictionary, *Medical Definition of hidradenitis*. <https://www.merriam-webster.com/medical/hidradenitis>. (The website was accessed on August 27, 2019.)

<sup>58</sup> Merriam-Webster Dictionary, *Definition of hyperlipidemia*. <https://www.merriam-webster.com/dictionary/hyperlipidemia>. (The website was accessed on August 26, 2019.)

<sup>59</sup> Mayo Clinic, *High Blood Pressure (Hypertension)*. <https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/symptoms-causes/syc-20373410>. (The website was accessed on September 6, 2019.)

<sup>60</sup> Mayo Clinic, *Hyponatremia*. <https://www.mayoclinic.org/diseases-conditions/hyponatremia/symptoms-causes/syc-20373711>. (The website was accessed on September 8, 2019.)

<sup>61</sup> Merriam-Webster Dictionary, *Medical Definition of internal carotid artery*. <https://www.merriam-webster.com/medical/internal%20carotid%20artery>. (The website was accessed on September 2, 2019.)

<sup>62</sup> Merriam-Webster Dictionary, *Definition of ischemia*. <https://www.merriam-webster.com/dictionary/ischemia>. (The website was accessed on September 2, 2019.)

**lisinopril.** A medication used to treat high blood pressure and heart failure and “works by decreasing certain chemicals that tighten the blood vessels, so blood flows more smoothly and the heart can pump blood more efficiently.”<sup>63</sup>

**midsternal.** Describes the middle line of the breastbone located in the center of the chest.<sup>64</sup>

**nuclear stress test.** “[A]n imaging method that uses radioactive material to show how well blood flows” during rest and activity into the heart muscle.<sup>65</sup>

**perineum.** The area between the anus and the posterior part of the external genitals.<sup>66</sup>

**peripheral arterial disease.** Is damage or dysfunction of the arteries outside the heart resulting in decreased blood flow.<sup>67</sup>

**radiate.** To spread out from a central point in all directions.<sup>68</sup>

**revascularization procedure.** A surgical procedure that produces additional blood supply to a body part.<sup>69</sup>

**rosuvastatin.** A medication used to lower cholesterol.<sup>70</sup>

**sinus rhythm.** The rhythm of the heart produced by impulses from the sinoatrial node.<sup>71</sup>

**stenosis.** A narrowing or constriction of the diameter of a bodily passage or orifice.<sup>72</sup>

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<sup>63</sup> U.S National Library of Medicine, *Lisinopril*. <https://medlineplus.gov/druginfo/meds/a692051.html>. (The website was accessed on September 5, 2019.)

<sup>64</sup> U.S. National Library of Medicine website, *Pectus excavatum repair – series – Normal anatomy*. [https://medlineplus.gov/ency/presentations/100035\\_1.htm](https://medlineplus.gov/ency/presentations/100035_1.htm). (The website was accessed on December 31, 2019.) Merriam-Webster Dictionary, *Definition of sternum*. (The website was accessed on December 31, 2019.)

<sup>65</sup> U.S National Library of Medicine, *Nuclear Stress Test*. <https://medlineplus.gov/ency/article/007201.htm>. (The website was accessed on August 26, 2019.)

<sup>66</sup> Merriam-Webster Dictionary, *Definition of perineum*. <https://www.merriam-webster.com/dictionary/perineum>. (The website was accessed on September 2, 2019.)

<sup>67</sup> Merriam-Webster Dictionary, *Medical Definition of peripheral arterial disease*. <https://www.merriam-webster.com/medical/peripheral%20arterial%20disease>. (The website was accessed on August 26, 2019.)

<sup>68</sup> Oxford Learner’s Dictionary, *Radiate*. <https://www.oxfordlearnersdictionaries.com/us/definition/english/radiate>. (The website was accessed on August 28, 2019.)

<sup>69</sup> Merriam-Webster Dictionary, *Definition of revascularization*. <https://www.merriam-webster.com/dictionary/revascularization>. (The website was accessed on August 26, 2019.)

<sup>70</sup> U.S National Library of Medicine, *Rosuvastatin*. <https://medlineplus.gov/druginfo/meds/a603033.html>. (The website was accessed on September 5, 2019.)

<sup>71</sup> Merriam-Webster Dictionary, *Definition of sinus rhythm*. <https://www.merriam-webster.com/dictionary/sinus%20rhythm>. (The website was accessed on September 2, 2019.)

<sup>72</sup> Merriam-Webster Dictionary, *Definition of stenosis*. <https://www.merriam-webster.com/dictionary/stenosis>. (The website was accessed on September 2, 2019.)

**stent.** A short metal or plastic tube inserted into an artery to keep it open.<sup>73</sup>

**vascular.** A system of blood vessels that carry blood throughout the body.<sup>74</sup>

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<sup>73</sup> Merriam-Webster Dictionary, *Medical Definition of stent*. (The website was accessed on August 26, 2019.)

<sup>74</sup> Merriam-Webster Dictionary, *Definition of vascular*. (The website was accessed on September 2, 2019.)

## OIG Contact and Staff Acknowledgments

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