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Office of Healthcare Inspections

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Healthcare Inspection
Delays in Scheduling Diagnostic
Studies and Other Quality of Care
Concerns
William S. Middleton Memorial
Veterans Hospital
Madison, Wisconsin

August 29, 2017

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of Congressman Mike Coffman to assess allegations received in 2014 regarding delays in scheduling diagnostic studies and other quality of care concerns at the William S. Middleton Memorial Veterans Hospital (facility), Madison, WI. After beginning our review, we also received a request from Senator Tammy Baldwin to review the same issues. We subsequently augmented the allegations based on additional dialogue with the complainant as well as former and current employees. The allegations we received and addressed in our review are as follows:

- Echocardiograms, stress tests, and sleep studies were delayed.
- Echocardiogram in-house consults were discontinued and later resubmitted as new consults to appear timely.
- VA refused to approve Non-VA Care, including echocardiograms and stress tests, as a cost savings decision.
- A cardiologist did not sign cardiac catheterization reports.
- A cardiologist did not review an event monitor tracing report [strip] timely, which resulted in a patient having an invasive surgical procedure.
- The Pharmacy refused to give veterans a 90-day supply of clopidogrel and instead only gave a 30-day supply, contributing to patients' missed doses.

We substantiated delays in scheduling in-house echocardiograms for patients in 2013 and 2015. We reviewed 2013 and 2015 in-house echocardiogram consult requests. (See Figure 1 below.)

For 2013, we identified 2,187 in-house echocardiogram consult requests. We found that 1,200 of 2,187 in-house echocardiogram consult requests (54.9 percent) were associated with a scheduling delay. We determined that for 700 of the 1,200 in-house echocardiogram consult requests (58.3 percent) associated with a scheduling delay, patients experienced a hospitalization and/or death after the date the provider requested the consult. We reviewed the EHRs of these 700 patients and determined that 2 patients had an increased risk for sudden cardiac death due to a delay in scheduling an echocardiogram. After several months delay, both patients underwent echocardiograms followed by surgical procedures to treat their life-threatening conditions.

For 2015, we identified 2,397 in-house echocardiogram consult requests. We found that 752 of 2,397 echocardiogram consult requests (31.4 percent) were associated with a scheduling delay. We determined that for 95 of the 752 echocardiogram consult requests (12.6 percent) associated with a scheduling delay, patients experienced a hospitalization and/or death after the provider requested the consult. We reviewed the

EHRs of these 95 patients and determined that no patients experienced an adverse clinical outcome as a result of the delays.

We substantiated delays in scheduling in-house stress tests for patients. We reviewed 2013 and 2015 in-house stress test consult requests. (See Figure 1 below.)

For 2013, we identified 1,263 in-house stress test consult requests. We found that 252 of 1,263 stress test consult requests (20.0 percent) were associated with a scheduling delay. We determined that for 120 of the 252 in-house stress test consult requests (47.6 percent) associated with a scheduling delay, patients experienced a hospitalization and/or death after the date the provider requested the consult. We reviewed the EHRs of these 120 patients and determined that no patients experienced an adverse clinical outcome as a result of the delays.

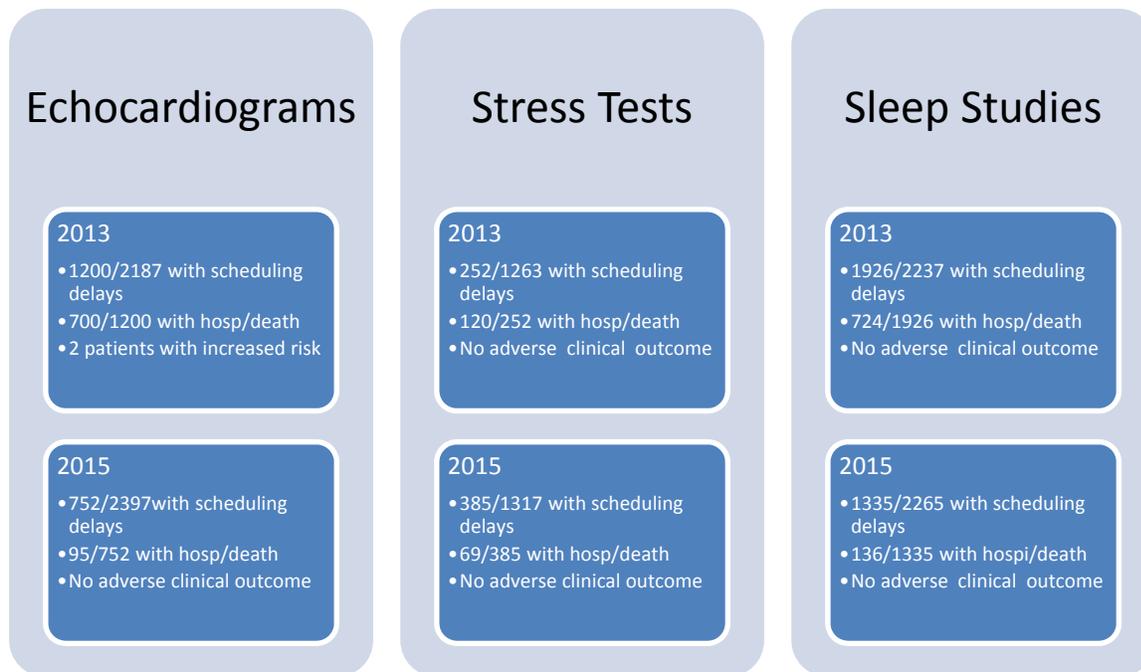
For 2015, we identified 1,317 in-house stress test consult requests. We found that 385 of 1,317 stress test consult requests (29.2 percent) were associated with a scheduling delay. We determined that for 69 of the 385 stress test consult requests (17.9 percent) associated with a scheduling delay, patients experienced a hospitalization and/or death after the provider requested the consult. We reviewed the EHRs of these 69 patients and determined that no patients experienced an adverse clinical outcome as a result of the delays.

We substantiated delays in scheduling in-house sleep studies for patients. We reviewed 2013 and 2015 in-house sleep study consult requests. (See Figure 1 below.)

For 2013, we identified 2,237 in-house sleep study consult requests. We found that 1,926 of 2,237 sleep study consult requests (86.1 percent) were associated with a scheduling delay. We determined that for 724 of the 1,926 sleep study consult requests (37.6 percent) associated with a scheduling delay, patients experienced a hospitalization and/or death after the provider requested the consult. We reviewed the EHRs of these 724 patients and determined that no patients experienced an adverse clinical outcome as a result of the delays.

For 2015, we identified 2,265 in-house sleep study consult requests. We found that 1,335 of 2,265 in-house sleep study consult requests (58.9 percent) were associated with a delay in scheduling. We determined that for 136 of the 1,335 in-house sleep study consult requests (10.2 percent) associated with a scheduling delay, patients experienced a hospitalization and/or death after the provider requested the consult. We reviewed the EHRs of these 136 patients and determined that no patients experienced an adverse clinical outcome as a result of the delays.

Figure 1: Summary of OIG Analysis of 2013 and 2015 Echocardiograms, Stress Tests, and Sleep Studies With Delayed Scheduling



Source: OIG Analysis

We substantiated that a small number of 2013 and 2015 echocardiogram consults were discontinued within 30 days then later resubmitted as new consults without explanatory documentation. We could not determine that echocardiogram consults were discontinued within 30 days and resubmitted to appear timely.¹

In 2013, we identified 2,187 echocardiogram consult request requests and found 220 of these were discontinued within 30 days and resubmitted as new consults. We found 4 of the 220 consults were discontinued and resubmitted without documentation and the remaining 216 consults were discontinued and resubmitted with supporting documentation explaining why the consult had been discontinued and resubmitted.

In 2015, we identified 2,397 echocardiogram consult request requests and found 217 of these were discontinued within 30 days and resubmitted as new consults. We found 4 of 217 consult requests were discontinued and resubmitted without documentation and the remaining 213 consults were discontinued and resubmitted with supporting documentation.

We did not substantiate that facility managers refused to approve non-VA, echocardiograms and stress tests as a cost savings decision. We reviewed 2013 and 2015 non-VA echocardiograms and stress tests consult requests to determine if facility managers refused to approve non-VA care. (See Figure 2.)

¹ VHA Consult/Request Tracking User Manual, Version 3.0, originally released December 1997, last revision February 2016. The Consult Request Tracking System allows for “Discontinued Orders,” “Order Cancellation,” and “Order Discontinued,” pages 183-184.

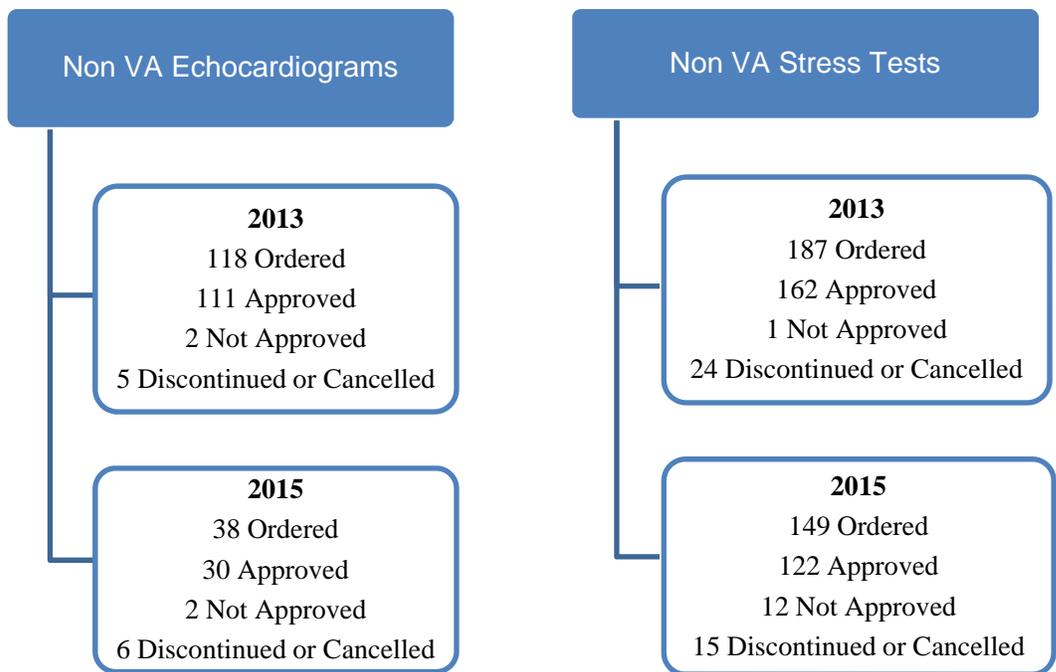
For 2013, we identified 118 non-VA echocardiogram consult requests. We found 111 of 118 non-VA echocardiogram consults (94.1 percent) were approved, 2 of 118 non-VA echocardiogram consults (1.7 percent) were not approved, and 5 of 118 non-VA echocardiogram consults (4.2 percent) were discontinued or cancelled prior to approval for non-VA care.

For 2015, we identified 38 non-VA echocardiogram consult requests. We found 30 of 38 non-VA echocardiogram consults (78.9 percent) were approved, 2 of 38 non-VA echocardiogram consults (5.3 percent) were not approved, and 6 of 38 non-VA echocardiogram consults (15.8 percent) were discontinued or cancelled prior to approval for non-VA care.

For 2013, we identified 187 non-VA stress test consult requests. We found 162 of 187 non-VA stress test consults (86.6 percent) were approved, 1 of the 187 (0.5 percent) non-VA stress test consults was not approved, and 24 non-VA stress test consults (12.8 percent) were discontinued or cancelled prior to approval for non-VA care.

For 2015, we identified 149 non-VA stress test consult requests. We found 122 of 149 non-VA stress test consults (81.9 percent) were approved, 12 of 149 non-VA stress test consults (8.1 percent) were not approved, and 15 of 149 non-VA stress test consults (10 percent) were discontinued or cancelled prior to approval for non-VA care.

Figure 2: Summary of OIG Analysis of 2013 and 2015 Non VA Echocardiograms and Stress Tests Approval Status



Source: VA OIG Analysis

We substantiated that a cardiologist did not sign cardiac catheterization reports timely; however, we did not substantiate that untimely signing of cardiac catheterization reports resulted in delayed care for three identified patients. We reviewed the EHRs of the

three identified patients. We found that a cardiologist did not sign one patient's cardiac catheterization report until 4 months after the procedure, and two patients' cardiac catheterization reports were not signed until 6 months after the procedure.

With respect to the three identified patients, documentation in the EHRs of each patient showed that managing providers were aware of the results of the catheterization procedures, and made immediate management decisions based on those results. While we did find that the catheterization reports were not signed within the required 24 hour period, we found no evidence that this caused a delay in care. In general, however, access to a report is important for the non-acute care teams managing these patients in different settings, such as a patient's primary care provider. Such access allows these providers to review, reinforce, and monitor recommended medication, dietary and lifestyle modifications made by the cardiologists based on findings from the catheterization.

We did not substantiate that a cardiologist did not timely review an event monitor tracing strip which resulted in a patient undergoing an invasive surgical procedure. According to documentation in the EHR, transmission of the tracing strip in question was unsuccessful,² the technician could not locate the tracing strip, and the tracing strip was not available for the cardiologist to review. We found that a cardiologist did not respond to a view alert related to the tracing strip in a timely fashion, but determined the delay in responding to the view alert was not a contributing factor in the patient undergoing an invasive surgical procedure.

In 2012, an event monitor was mailed to the patient. One month later, the patient had a syncopal episode and attempted to transmit a tracing strip. The next week, the patient telephoned a Cardiology clinic provider and reported the syncopal episode and transmission.

The clinic provider entered a note documenting the patient's telephone call indicating that he/she would alert technicians and a cardiologist to check if telemetry strips are available for review. One of the technicians entered a note on the day of the patient's telephone call indicating that the patient had returned the event monitor by mail (monitor #1) and there were no transmissions. The cardiologist did not timely acknowledge receipt as required by Veterans Health Administration (VHA) policy: "CPRS users must respond promptly (as defined by facility policy) to View Alerts, which notify them of documents requiring authentication."³ Physicians and other caregivers

² The EHR does not indicate why transmission was unsuccessful.

³ VHA Handbook 1907.01, *Health Information Management and Health Records*, August 25, 2006 was in effect during the time of the events discussed; it was rescinded on September 2012 and replaced with VHA Handbook 1907.01, *Health Information Management and Health Records*, July 22, 2014. The Handbooks contain the same language regarding View Alerts.

must monitor and take appropriate action on their computerized prompts for signature, currently known as “View-Alerts.”⁴

Although the cardiologist did not acknowledge receipt of the view alert until early 2013, we found documentation that the patient received another event monitor (monitor #2) one month after returning monitor #1. Despite multiple event monitor transmissions and contact with cardiology staff, over the next several weeks, tracing strips from monitor #2 did not show abnormalities that corresponded to the patient’s report of symptoms. A cardiologist recommended an implantable loop recorder in an effort to diagnose the underlining abnormality responsible for the patient’s symptoms.

Approximately 8 weeks after receiving monitor #2, the patient underwent an invasive procedure for the implantation of a loop recorder as multiple previous external event monitors had not identified heart rate and rhythm issues responsible for the patient’s symptoms.⁵ The patient was followed closely by cardiology staff over the next 3 years without identification of an etiology for intermittent symptoms. During a clinic visit in 2016, the patient asked cardiology clinic staff about removal of the loop recorder. As of early 2017, plans for removal of the loop recorder with the patient continued.

We did not substantiate that pharmacy staff refused to give veterans a 90-day supply of clopidogrel, and instead only gave a 30-day supply, and that this contributed to missed doses. Dispensing a 30-day supply reflected a change in policy regarding clopidogrel prescribing practices which resulted from new information regarding the safety and efficacy of the drug. We reviewed a Memorandum dated March 22, 2007, from the facility’s Chief of Staff and Chief of Pharmacy Service to facility providers regarding the restrictions and new ordering method for clopidogrel. According to the Memorandum, the Veterans Integrated Service Network’s leadership staff and the facility’s Pharmacy and Therapeutics Committee members approved the *Clopidogrel (Plavix®) Criteria for Use in Veteran Patients* established by the VHA Pharmacy Benefits Management Services and the Medical Advisory Panel.⁶ On April 9, 2007, facility pharmacy managers initiated a new ordering process for clopidogrel in accordance with these criteria:

- Clopidogrel will be removed from the outpatient medication tab in CPRS.
- The only way to order clopidogrel for outpatients is through a “Clopidogrel Medication Utilization Evaluation [(MUE)⁷] progress note.”

⁴Ibid. Notifications are electronic messages that provide information, or which prompt staff to act on a clinical event. Clinical events, such as unsigned or un-cosigned documents, critical laboratory value, or a change in orders, trigger a notification to be sent to all recipients identified by the corresponding package (Laboratory, CPRS, Radiology, etc.). **NOTE:** In CPRS, notifications are located on the bottom of the Patient Selection screen. In Vista, notifications are located with a prompt “View Alerts” when the user logs onto the system.

⁵ *Implantable “Loop Recorder”-A New Diagnostic Tool for Syncope of Unknown Cause*, US National Library of Medicine National Institutes of Health. <https://www.ncbi.nlm.nih.gov/pubmed/16623256>. Accessed March 22, 2017.

⁶ *Clopidogrel (Plavix®) Criteria for Use in Veteran Patients*, VHA Pharmacy Benefits Management Services and the Medical Advisory Panel. <http://www.pbm.va.gov/apps/VANationalFormulary/>. Accessed March 1, 2017.

⁷ According to the Society of Health System Pharmacists, a MUE is a performance improvement method that can focus on evaluating and improving medication-use processes. *Am J Health-Syst Pharm.* 1996; 53:1953–5. ASHP

- The MUE will ask the provider the following questions:
 - date of event
 - indication
 - remaining months of therapy
- If the indication and duration of therapy are consistent with National Criteria, the provider will be able to order clopidogrel immediately.
- Inpatient clopidogrel orders will be unaffected by this process until discharge.
- Existing prescriptions for clopidogrel are being reviewed by clinical personnel.

We reviewed the EHRs of six patients who were identified as having missed dosages due to receiving only a 30-day supply of clopidogrel. We identified that a provider had completed and submitted an MUE progress note for all six patients. The MUE note included indication and duration of therapy. We found three of the six patients received a 30-day supply of clopidogrel and three patients received a 90-day supply of clopidogrel as requested by a provider. We did not find evidence that a 30-day supply of clopidogrel contributed to missed dosages for the three patients who received a 30-day supply of clopidogrel.

We recommended that the Facility Director:

- Ensure that outpatient echocardiography and stress test consult requests are scheduled and completed in accordance with Veterans Health Administration policy.
- Ensure that sleep study consult requests are scheduled and completed within the timeframe required by Veterans Health Administration policy.
- Ensure that patients' cardiac diagnostic and procedure reports are signed within the timeframe specified by policy to ensure appropriate follow-up and patient care coordination.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes C and D, pages 29–32 for the Directors' comments.) We consider Recommendations 1 and 2 closed. We will follow up on the planned action for the remaining open recommendation until completed.



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guidelines on medication-use evaluation. American Society of Health-System Pharmacists. Accessed on December 2, 2016, from <https://www.ashp.org/DocLibrary/BestPractices/FormGdlMedUseEval.aspx>.

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of Congressman Mike Coffman to assess allegations received in 2014 regarding delays in scheduling diagnostic studies and other quality of care concerns at the William S. Middleton Memorial Veterans Hospital (facility), Madison, WI. After beginning our review, we also received a request from Senator Tammy Baldwin to review the same issues.

Background

Facility Profile. The facility is part of Veterans Integrated Service Network (VISN) 12. The facility provides tertiary medical, surgical, neurological, and psychiatric care, a full range of outpatient services, and community living center services to approximately 130,000 veterans. The facility is affiliated with the University of Wisconsin School of Medicine and Public Health.

Diagnostic Studies. Providers order diagnostic procedures or tests to confirm a diagnosis or in some cases, to prepare patients for surgery.⁸ These procedures are vital to the treatment planning process and other health care decisions. A delay in scheduling a diagnostic study may contribute to a delay in patient care and possibly adverse impact or risk for sudden death.⁹ Diagnostic studies or tests may be performed during an inpatient stay or scheduled to be performed in an outpatient setting. Those diagnostic studies or tests meant to be completed in an outpatient setting at the facility will be referred to in this report as “in-house.”

The diagnostic studies and diagnostic tools discussed in this report include:

- **Echocardiogram.** An echocardiogram is a test that uses sound waves to create detailed pictures of the heart. A physician reviews the results to evaluate the heart’s pumping action and blood flow across the heart valves.¹⁰ Types of echocardiogram procedures discussed in this report include transthoracic and transesophageal.
- **Stress Test.** A stress test provides information about the heart’s response to an increased workload. During stress testing, the patient who is able will walk or run on a treadmill or pedal a stationary bike to increase his/her heart rate. Tests are done while the patient is exercising. Patients who are unable to exercise may

⁸ National Institutes of Health, Diagnostic Procedures. <http://www.nhlbi.nih.gov/health/health-topics/topics/cm/diagnosis>. Accessed August 2, 2016.

⁹ VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009, was in effect during the time of the events discussed in this report; it was rescinded and replaced with VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015. The new Directive establishes that test results are to be communicated to patients within 7 calendar days for results requiring action and 14 days for results that do not require any action.

¹⁰ Mayo Clinic, Echocardiogram. <http://www.mayoclinic.org/tests-procedures/echocardiogram/basics/why-its-done/prc-20013918>. Accessed February 19, 2017.

undergo a pharmacological stress test wherein a medication is administered to increase the workload of the heart.¹¹

- **Sleep Study.** Untreated sleep disorders can raise the risk for heart disease, high blood pressure, stroke, and other medical conditions.¹² A polysomnogram or a sleep study is usually performed overnight at a sleep center and measures how well the patient sleeps and how the body responds to sleep problems. Brain activity, eye movements, heart rate, and blood pressure are monitored as well as the amount of oxygen in the blood, air movement through the upper respiratory tract, snoring, and chest movements.¹³
- **Cardiac Catheterization.** A cardiac catheterization is an invasive medical procedure used to diagnose heart conditions. A physician places a long, thin, flexible tube (catheter) into a blood vessel in the arm, groin (upper thigh), or neck, and threads it into the heart to measure pressures and blood flow. Contrast medium is injected through the catheter which allows visualization of the heart's coronary arteries and/or other structures.¹⁴
- **Event Monitors.** Event monitors [cardiac event recorders] are small, portable devices worn by an individual while engaged in normal daily activity to record the heart's electrical activity. Some patients have heart rhythm problems only during activities such as sleeping or physical exertion; an event monitor increases the chance of capturing these problems.¹⁵ Event monitors are generally worn for longer timeframes to try to capture infrequent problems with heart rate or rhythm. The device makes a record of an individual's electrocardiogram (ECG or EKG) when they have fast or slow heartbeats, or feel dizzy. The ECG can be sent by telephone to a receiving center or to the patient's doctor.¹⁶
- **Implantable Loop Recorder.** The implantable loop recorder is an event monitor used to establish the causes of unexplained syncope (fainting or passing out) in patients where standard conventional tests have failed to provide adequate data for diagnosis. The loop recorder is a diagnostic "pacemaker" surgically implanted under the skin of the chest. The leads of the device do not require

¹¹ Stress Test, Institutes of Health, National Heart, Lung, and Blood Institute, <http://www.nhlbi.nih.gov/health/health-topics/topics/stress>. Accessed October 28, 2016.

¹² Ibid.

¹³ Ibid.

¹⁴ Cardiac Catheterization, National Institutes of Health, National Heart, Lung, and Blood Institute. <http://www.nhlbi.nih.gov/health/health-topics/topics/cath>. Accessed October 28, 2016.

¹⁵ Holter Monitors - National Heart, Lung, and Blood Institute. <http://www.nhlbi.nih.gov/book/export/html/4873>. Accessed September 16, 2016.

¹⁶ Cardiac Event Recorder, American Heart Association. http://www.heart.org/HEARTORG/Conditions/Arrhythmia/PreventionTreatmentofArrhythmia/Cardiac-Event-Recorder_UCM_447317_Article.jsp. Accessed March 23, 2017.

endovenous (within a vein) implantation. Heart rhythm is monitored continuously on the basis of an endless loop, up to a maximum period of 14 months.¹⁷

Outpatient Scheduling Process and Procedures

According to Veterans Health Administration (VHA) Directive, patients must be able to schedule an appointment for a routine diagnostic test within 30 days of referral.¹⁸ A provider uses a clinical consultation to identify the appropriate clinic or service, the specific diagnostic study needed, and the urgency or timeframe within which the diagnostic study is to be completed.¹⁹ The urgency level may vary depending on the clinical need to diagnose and treat the patient's illness. (See Appendix B, Table 2.)

The scheduling process for a diagnostic study is typically initiated when the clinical consultation request is ordered; the preferred strategy is to schedule the appointment before the patient leaves the referring provider team area.²⁰ A scheduler is responsible for scheduling an appointment on or as close to the desired date as possible. If there is a discrepancy between the patient and provider desired date, the scheduler must contact the provider for a decision on the return appointment timeframe.²¹ When the appointment is established, the scheduler is also responsible for communicating the appointment time to the patient and assisting if the patient requests that the appointment be rescheduled or cancelled. Once the appointment is scheduled and the study completed, the clinician must enter a progress note that is associated with the consult in the patient's EHR with the results or outcome of the study. This action alerts the requesting physician that the results are available and decisions regarding additional care may be made and treatment may begin.²² This action also closes the clinical consultation process.²³

When the request for an in-house diagnostic study or service is not available in a timely manner due to capability, or accessibility, including high demand for care and geographic inaccessibility, facility providers may pursue external services. A consult for these external services may include care through other VA medical centers, other

¹⁷ Implantable Loop Recorder, National Center for Biotechnology Information. <https://www.ncbi.nlm.nih.gov/pubmed/16623256>. Accessed March 22, 2017.

¹⁸ VHA Directive 2006-041, *Veterans Health Care Service Standards- Corrected Copy*, June 27, 2006, this Directive expired June 30, 2011 and has not yet been updated.

¹⁹ VHA Directive 2008-056, *VHA Consult Policy*, September 16, 2008, was in effect during the time of the events discussed in this report; it was rescinded and replaced with VHA Directive 1232(1), *Consult Process and Procedures*, August 24, 2016, amended September 23, 2016. VHA Directive 1232(1) contains the same or similar language regarding completion of consults when the clinician enters a note.

²⁰ Ibid.

²¹ VHA Directive 2010-027, *VHA Outpatient Scheduling Processes and Procedures*, June 9, 2010, revised December 8, 2015, was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1230, *VHA Outpatient Scheduling Processes and Procedures*, July, 2016; VHA Directive 1230. The revised VHA directive uses the terms clinically indicated and/or preferred date in lieu of desired date.

²² VHA Directive 2008-056, *VHA Consult Policy*, September 16, 2008, was in effect during the time of the events discussed in this report; it was rescinded and replaced with VHA Directive 1232(1), *Consult Process and Procedures*, August 24, 2016, amended September 23, 2016. VHA Directive 1232(1) contains the same or similar language regarding completion of consults when the clinician enters a note.

²³ Ibid.

facilities as part of sharing agreements, or community providers. VHA has several mechanisms for purchasing care from community providers, including the Non-VA Care and Veterans Choice Programs.

Non-VA Care Coordination. Non-VA Care Coordination (NVCC), formerly known as Fee Basis, is medical care provided to eligible veterans outside of VA when VA facilities and services are not reasonably available. Non-VA Care may only be considered when the patient can be treated sooner than at a VA facility and the service is clinically appropriate and of high quality. A consult and pre-authorization for treatment in the community is required.²⁴

Veterans Choice Program.²⁵ The Veterans Choice Program (Choice) was implemented in October of 2014 to improve veterans' access to health care by allowing eligible veterans to use approved health care providers outside of VA without impacting existing VA health care or other VA benefits. A veteran must be enrolled in the VA health care system and meet at least one of six eligibility criteria including scheduled for an appointment at the facility greater than 30 days or current residence is more than 40 miles driving distance from the closest VA medical facility.²⁶

Allegations

In October 2014, we received a request from Congressman Mike Coffman to assess alleged delays in scheduling diagnostic studies at the facility. After beginning our review, we also received a request from Senator Tammy Baldwin to review the same issues. We subsequently augmented the allegations based on additional dialogue with the complainant as well as former and current employees. The allegations we addressed in our review are as follows:

- Echocardiograms, stress tests, and sleep studies were delayed.
- Echocardiogram in-house consults were discontinued and later resubmitted as new consults to appear timely.
- VA refused to approve Non-VA Care, including echocardiograms and stress tests, as a cost savings decision.
- A cardiologist did not sign cardiac catheterization reports.
- A cardiologist did not review an event monitor tracing report [strip] timely which resulted in a patient having an invasive surgical procedure.
- The Pharmacy refused to give veterans a 90-day supply of clopidogrel and instead only gave a 30-day supply, contributing to patients' missed doses.

²⁴ VHA Directive 1601, *Non-VA Medical Care Program*, January 23, 2013.

²⁵ The Veteran Choice Program was established by the Veterans Access, Choice, and Accountability Act of 2014.

²⁶ *Ibid.* Under this program, VA contracts with third-party administrators to purchase care from certain community providers.

Scope and Methodology

We initiated our review in October 2014 and completed our work in November 2016. We visited the facility on March 16–18, 2015. We interviewed knowledgeable individuals to clarify the allegations. We also interviewed the Chief of Staff, the Chief of Cardiology, the Chief of Pulmonary (Sleep Lab), the Chief of Pharmacy, other facility employees, and former employees with knowledge of these issues.

We reviewed VHA and facility policies and procedures, data from the VA Corporate Data Warehouse (CDW), a centralized data repository that contains VA clinical, administrative, and financial data. We also reviewed electronic health records (EHR) as described in the case summaries and Issues 1–4. Specific methodology used for each allegation is described below.

Issue 1: Delays in Scheduling Diagnostic Studies

To respond to concerns regarding diagnostic study delays, we evaluated timely completion of facility consults ordered for echocardiograms,²⁷ stress tests, and sleep studies from January 1, 2013, through December 31, 2013. To determine the progress of timely completion of these diagnostic studies and the impact of scheduling delays on patients, we also evaluated echocardiograms, stress tests, and sleep studies from January 1, 2015, through December 31, 2015.

Study Population

The study population comprised all patients at the facility who had at least one delayed consult for at least one of the diagnostic studies listed above from January 1, 2013, through December 31, 2013, and from January 1, 2015, through December 31, 2015. We identified the study population using data extracted on September 6, 2016, from the CDW.

Patients Who Experienced at Least One Diagnostic Study Delay

We determined that patients experienced a delay if at least one of the patients' consults for the selected diagnostic study was not completed within the expected timeframe. The start date for this timeframe was the later of the date that the consult was ordered or the clinically indicated date. The end date was the date that the patient had a clinic visit that was linked to the consult, the patient died, or the consult was discontinued or canceled. For additional information on the scope and methodology, see Appendix B, Tables 1 and 2.

Patients Who Experienced at Least One Hospitalization and/or Death

For patients who experienced at least one diagnostic study delay, we analyzed CDW data that included in-house and Non-VA Care. We used the data to classify patients who experienced at least one delay into two subpopulations. One subpopulation

²⁷ We did not distinguish between transthoracic and transesophageal echocardiograms when collecting the data.

included those who died or were hospitalized through September 6, 2016. Only hospitalizations at or paid for by VA were included in our review. The other subpopulation included those who did not die and were not hospitalized. For additional information on the scope and methodology, see Appendix B, Table 1.

Impact of Diagnostic Studies Delays

Our team of clinical reviewers, which included at least one nurse or physician assistant, evaluated whether there could be a relationship between each consult delay and a patient's hospitalization and/or death. We defined this "relationship" to include consult delays that could have contributed to or led to the event as well as consult delays that could have resulted in a clinically significant delay in diagnosis of and treatment for a condition. For example, we would generally conclude that a delayed stress test consult was unlikely to be related to a hospitalization to treat pneumonia. However, we would generally conclude that a delayed echocardiogram consult could be related to cardiac arrest. For those delayed consults that could have been related to clinically concerning issues, we conducted an in-depth EHR review to better understand the potential relationship. At least one physician reviewed the EHRs of patients if the initial reviewer suspected a consult delay was related to an adverse clinical outcome. For additional information on the scope and methodology, see Appendix B, Tables 1 and 2.

Issue 2: Discontinuing and Resubmitting Echocardiogram Consults

To address concerns regarding whether echocardiogram consults were discontinued then resubmitted to appear timely, we analyzed data for all patients at the facility who had at least one echocardiogram consult request discontinued or cancelled within 30 days and then a new consult for the same diagnostic study requested again within 6 months.²⁸ The study population for this concern is different from the study population for Issue 1 described above as it is inclusive of all patients who had at least one echocardiogram consult request regardless of a delay. The timeframe for this review was from January 1, 2013, through December 31, 2013, and from January 1, 2015, through December 31, 2015. We identified this study population using data extracted on November 7, 2016, from the CDW.

Issue 3: Non-VA Care for Echocardiograms and Stress Tests

To determine whether the facility refused to approve non-VA echocardiograms and stress tests, we reviewed all consult requests for non-VA echocardiogram and stress test diagnostic studies. In addition, we conducted reviews of EHRs of patients with discontinued or cancelled non-VA echocardiogram and stress test consult requests to determine the reason. The timeframe for this review was from January 1, 2013, through December 31, 2013, and from January 1, 2015, through December 31, 2015.

²⁸ *VHA Consult/Request Tracking User Manual*, Version 3.0, originally released December 1997, last revision February 2016. The Consult Request Tracking System allows for "Discontinued Orders," "Order Cancellation," and "Order Discontinued," pages 183-184.

Issue 4: Other Quality of Care Concerns

Cardiac Catheterization Reports

In response to concerns that a cardiologist did not sign cardiac catheterization reports timely, which resulted in delayed care for patients, we conducted EHR reviews of the three identified patients provided to us. We also reviewed the facility's Bylaws and Rules of the Medical Staff.²⁹

Event Monitoring Reports

In response to concerns that a cardiologist did not review an Event Monitoring report timely, which resulted in a patient having an invasive surgical procedure, we reviewed the identified patient's EHR and VHA policy regarding timely responses to View Alerts. In addition, we reviewed VHA policy regarding notifications to EHR users of documents requiring their attention for signatures.³⁰

90-Day Supply of Clopidogrel (Plavix)

In response to concerns that pharmacy staff refused to give veterans a 90-day supply of clopidogrel and instead only gave a 30-day supply, which contributed to missed doses, we interviewed the Chief of Pharmacy and facility staff with specific knowledge of the pharmaceutical distribution of clopidogrel. We reviewed formulary criteria for clopidogrel from the VA Pharmacy Benefits Management and a Memorandum dated March 22, 2007, from the Chief of Staff and Chief of Pharmacy documenting approval from the VISN's leadership and the facility's Pharmacy and Therapeutics Committee regarding the process for distributing clopidogrel. We also conducted EHR reviews of the six identified patients provided to us during interviews.

VHA Directive 2006-041, *Veterans Health Care Service Standards-Corrected Copy*, June 27, 2006, cited in this report expired June 30, 2011. We considered the policy to be in effect as it had not been superseded by more recent policy or guidance. In a June 29, 2016, memorandum to supplement policy provided by VHA Directive 6330(1),³¹ the VA Under Secretary for Health (USH) mandated the "...continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."³² The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under

²⁹ William S. Middleton VA Hospital, *Bylaws and Rules of the Medical Staff*, adopted by the Medical Staff, William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin, February 27, 2012.

³⁰ VHA Handbook 1907.01, *Health Information Management and Health Records*, dated August 25, 2006 was in effect at the time of the events discussed; it was rescinded on September 2012 and replaced with VHA Handbook 1907.01, *Health Information Management and Health Records*, dated July 22, 2014.

³¹ VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 11, 2017.

³² VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.

Secretaries for Health with ensuring "...the timely rescission or recertification of documents over which their program offices have primary responsibility."³³

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

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

³³ VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.

Inspection Results

Issue 1: Delays in Scheduling Diagnostic Studies

Echocardiograms

We substantiated delays in scheduling in-house echocardiograms for patients. (See Figure 1 below.) We reviewed 2013 and 2015 in-house echocardiogram consult requests and identified two patients whose scheduling delays increased their risk for sudden cardiac death while waiting for an echocardiogram. After several months' delay, both patients underwent echocardiograms followed by surgical procedures to treat their life-threatening conditions

2013 Echocardiograms

For 2013, we identified 2,187 in-house echocardiogram consult requests. We found that 1,200 of 2,187 in-house echocardiogram consult requests (54.9 percent) were associated with a scheduling delay. According to VHA Directive, "all clinical consultations must be acted on by scheduling an appointment within VA established timeframes and resolved efficiently taking into account individual health care needs."³⁴

We determined that for 700 of the 1,200 in-house echocardiogram consult requests (58.3 percent) associated with scheduling delays, patients experienced a hospitalization and/or death after the date the provider requested the consult. We reviewed the EHRs of these 700 patients and determined that 2 patients (see brief case summaries below) had an increased risk for sudden cardiac death due to a delay in scheduling an echocardiogram.

Patient 1

The patient was in his 60s when he presented to his primary care provider (PCP) in 2013 (Day 1), complaining of frequent syncopal (fainting) episodes. The provider placed three cardiology consults: one for an Outpatient Cardiology Consult, one for a Holter monitor, and one for an echocardiogram. Although all three consults were requested as routine, within the free text of the echocardiogram consult, the provider indicated that the request for the echocardiogram was "urgent." A staff cardiologist responded to the Outpatient Cardiology Consult on the same day as the request without seeing the patient. The cardiologist documented that she agreed with the PCP's assessment and plan, which included a Holter monitor and echocardiogram. If findings from those studies were abnormal, the cardiologist recommended that the PCP resubmit a consult to the Outpatient Cardiology Service.

³⁴ VHA Directive 2008-056, *VHA Consult Policy*, September 16, 2008, was in effect during the time of the events discussed in this report; it was rescinded and replaced with VHA Directive 1232(1), *Consult Process and Procedures*, August 24, 2016, amended September 23, 2016.

The echocardiogram was scheduled for Day 76. The Holter monitor analysis was completed on Day 55. The cardiologist who analyzed the Holter monitor results did not identify evidence of heart block or significant pauses, but noted the patient had several episodes of tachycardia (fast heart rate) and frequent ventricular ectopy (abnormal electrical impulse originating from the bottom of the heart). A medication was recommended to address the ectopy, and the cardiologist again recommended proceeding with the echocardiogram as ordered. On Day 71, the echocardiogram appointment for Day 76 was cancelled by the clinic, with a note explaining the cancellation was due to “critical staffing” issues. It was rescheduled for Day 202.

On Day 119, the patient was seen by a staff cardiologist. The patient reported continued and frequent syncopal episodes. The cardiologist made some adjustments to a medication dose and advised the patient to reduce his intake of caffeine and increase his intake of water. In addition, she noted, “needs echo ASAP [as soon as possible].” On Day 190, the patient was evaluated by a neurosurgeon after an angiogram (imaging study) of his carotid arteries indicated occlusion of the left internal carotid artery and bilateral vertebral artery stenosis (narrowing). Based on the patient’s history of multiple syncopal episodes and new complaints of numbness and weakness, he was admitted to the hospital for acute medical management.

On Day 192, the echocardiogram was performed. Findings from the study indicated the patient had a severe cardiomyopathy (a disease of the heart muscle which impairs the pumping function of the heart) with a left ventricular ejection fraction measured at 20–25 percent (55 percent or higher is considered normal). He underwent cardiac catheterization on Day 195, which revealed significant coronary artery disease. Based on the severity of his cardiomyopathy which placed him at risk for sudden cardiac death, the patient was discharged with a temporary defibrillator (a device that treats life-threatening arrhythmias) until a permanent defibrillator could be placed.

This patient had a history of frequent syncopal episodes and the delay in getting an echocardiogram to appropriately diagnose the etiology of his syncope placed him at risk for sudden cardiac death.

Patient 2

The patient was in his 70s with a past medical history significant for hypertension and aortic valve stenosis (narrowing of a heart valve). In 2013, his PCP placed a routine consult for an echocardiogram. The provider documented in the consult request that the valve disease had “possible advance,” and the patient had “occasional dyspnea [shortness of breath].” Approximately 5 months later, the patient was transferred by ambulance from a VHA community based outpatient clinic (CBOC) to the facility’s Emergency Department (ED) after he complained of chest pain, dizziness and weakness to the CBOC provider. He was also noted to have an abnormal EKG, potentially suggestive of angina (chest pain). The patient was sent home after being examined by an ED physician with instructions to follow up with his PCP. The following day, the PCP placed a consult to the Cardiology Service. A staff cardiologist responded to the consult, documenting that the patient would need an echocardiogram to further evaluate the aortic valve.

About 6 weeks later, the patient presented to his PCP complaining of persistent episodes of lightheadedness and dizziness that were lasting hours which was a significant increase in duration from previous episodes. Three weeks later, an echocardiogram was completed and showed that the patient's aortic stenosis was now severe and a referral was made for cardiothoracic surgery to evaluate him for possible valve replacement. Three months later, the patient underwent aortic valve replacement surgery without complications.

Although this patient had a prolonged history of symptomatic aortic stenosis and possible advanced disease, an echocardiogram was not completed for 7 months after the initial consult request. This delay increased the patient's risk for sudden cardiac death.

2015 Echocardiograms

For 2015, we identified 2,397 in-house echocardiogram consult requests. We found that 752 of 2,397 echocardiogram consult requests (31.4 percent) were associated with a scheduling delay. We determined that with 95 of the 752 echocardiogram consult requests (12.6 percent) associated with a scheduling delay, patients experienced a hospitalization and/or death after the provider requested the consult. We reviewed the EHRs of these 95 patients and determined that no patients experienced an adverse clinical outcome as a result of the delays.

Analysis of Echocardiograms

We noted a 23.5 percent improvement in scheduling in-house echocardiograms and a 45.7 percent decrease in the number of echocardiogram consults associated with a scheduling delay and a patient hospitalization and/or death when comparing 2013 and 2015 consult scheduling and patient data specific to hospitalizations and/or death. In 2013, we found two patients whose scheduling delays increased their risk for sudden cardiac death while waiting for the echocardiogram. In 2015, we did not identify patients whose scheduling delays increased their risk for sudden cardiac death.

Stress Tests

We substantiated delays in scheduling in-house stress tests for patients. We reviewed 2013 and 2015 in-house stress test consult requests and did not find documentation of an adverse clinical outcome related to delays in scheduling patients for a stress test. (See Figure 1 below.)

2013 Stress Tests

For 2013, we identified 1,263 in-house stress test consult requests. We found that 252 of 1,263 stress test consult requests (20.0 percent) were associated with a scheduling delay. According to VHA Directive, "all requests for clinical consultations

should be clinically completed within VHA timeliness standards and resolved efficiently taking into account individual health care needs.”³⁵

We determined that for 120 of the 252 in-house stress test consult requests (47.6 percent) with a scheduling delay, patients experienced a hospitalization and/or death after the date the provider requested the consult. We reviewed the EHRs of these 120 patients and determined that no patients experienced an adverse clinical outcome as a result of the delays.

2015 Stress Tests

For 2015, we identified 1,317 in-house stress test consult requests. We found that 385 of 1,317 stress test consult requests (29.2 percent) were associated with a scheduling delay. We determined that for 69 of the 385 stress test consult requests (17.9 percent) with scheduling delays, patients experienced a hospitalization and/or death after the provider requested the consult. We reviewed the EHRs of these 69 patients and determined that no patients experienced an adverse clinical outcome as a result of the delays.

Analysis of Stress Tests

We noted a 9.3 percent increase in scheduling delays for in-house stress test consult requests and a 29.7 percent decrease in the number of delayed stress test consults associated with a patient hospitalization and/or death when comparing 2013 and 2015 consult scheduling and patient data specific to hospitalizations and/or death. We did not identify patients whose scheduling delays were associated with an adverse clinical outcome.

Sleep Studies

We substantiated delays in scheduling in-house sleep studies for patients. We reviewed 2013 and 2015 in-house sleep study consult requests and did not find evidence of an adverse clinical outcome related to delays in scheduling patients for a sleep study. According to VHA Directive, “all requests for clinical consultations are clinically completed with results consistent with VHA timeliness standards and resolved efficiently taking into account individual health care needs.”³⁶

2013 Sleep Studies

For 2013, we identified 2,237 in-house sleep study consult requests. We found that 1,926 of 2,237 sleep study consult requests (86.1 percent) were associated with a scheduling delay. We determined that with 724 of the 1,926 sleep study consult

³⁵ VHA Directive 2008-056, *VHA Consult Policy*, September 16, 2008, was in effect at the time of the events discussed in this report; it was rescinded and replaced with VHA Directive 1232(1), *Consult Process and Procedures*, August 24, 2016, amended September 23, 2016.

³⁶ Ibid.

requests (37.6 percent) associated with a scheduling delay, patients experienced a hospitalization and/or death after the provider requested the consult. We reviewed the EHRs of these 724 patients and determined that no patients experienced an adverse clinical outcome as a result of the delays.

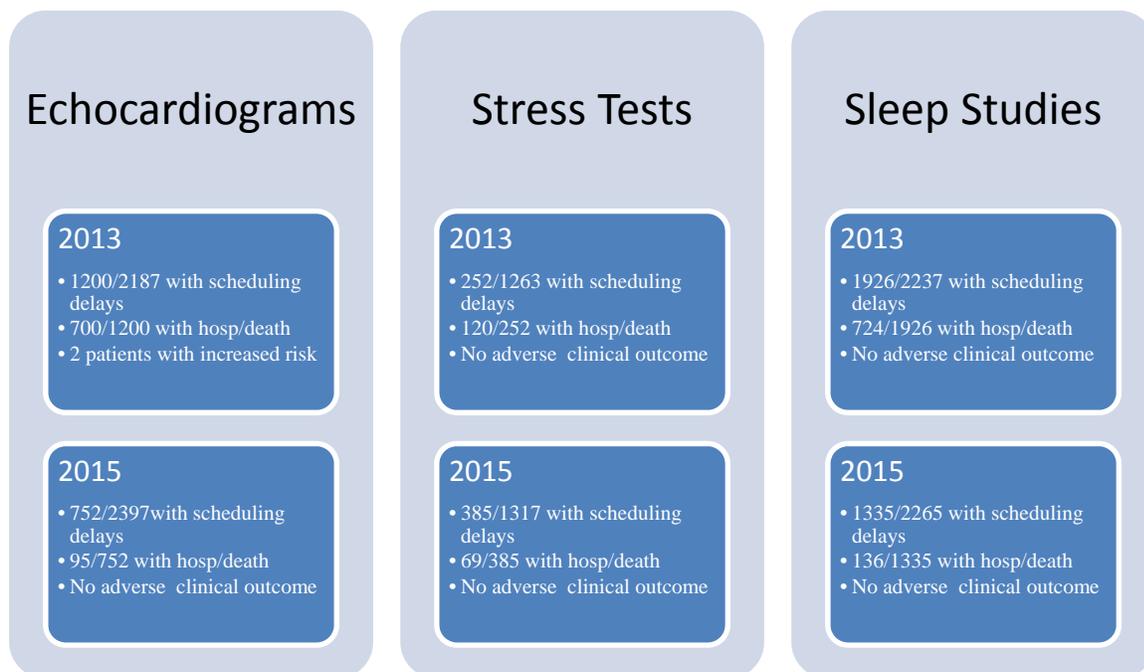
2015 Sleep Studies

For 2015, we identified 2,265 in-house sleep study consult requests. We found that 1,335 of 2,265 in-house sleep study consult requests (58.9 percent) were associated with a delay in scheduling. We determined that for 136 of 1,335 in-house sleep study consult requests (10.2 percent) associated with scheduling delays, patients experienced a hospitalization and/or death after the provider requested the consult. We reviewed the EHRs of these 136 patients and determined that no patients experienced an adverse clinical outcome as a result of the delays.

Analysis of Sleep Studies

We noted a 27.2 percent decrease in scheduling delays for in-house sleep study consult requests and a 27.4 percent decrease in the number of delayed sleep study consults associated with a patient hospitalization and/or death when comparing 2013 and 2015 consult scheduling and patient data specific to hospitalizations and/or death. We did not identify patients whose scheduling delays were associated with an adverse clinical outcome.

Figure 1: Summary of OIG Analysis of 2013 and 2015 Echocardiograms, Stress Tests, and Sleep Studies with Delayed Scheduling



Source: OIG Analysis

Issue 2: Discontinuing and Resubmitting Echocardiogram Consults

We substantiated that a small number of echocardiogram consults were discontinued within 30 days then later resubmitted as a new consult without explanatory documentation. We could not determine that echocardiogram consults were discontinued within 30 days and resubmitted to appear timely.³⁷ According to VHA Directive 2008-056, “all requests for clinical consultations are clinically completed with results consistent with VHA timeliness standards and resolved efficiently taking into account individual health care needs.”³⁸ We reviewed 2013 and 2015 echocardiogram consult requests.

In 2013, we identified 2,187 echocardiogram consult requests and found 220 of these were discontinued within 30 days and resubmitted as new consults. We found 4 of the 220 consults were discontinued and resubmitted without documentation and the remaining 216 consults were discontinued and resubmitted with supporting documentation.

In 2015, we identified 2,397 echocardiogram consult requests and found 217 of these were discontinued within 30 days and resubmitted as new consults. We found 4 of the 217 consult requests were discontinued and resubmitted without documentation and the remaining 213 consults were discontinued and resubmitted with supporting documentation.

Issue 3: Non-VA Care for Echocardiograms and Stress Tests

We did not substantiate that facility managers refused to approve non-VA echocardiograms and stress tests as a cost savings decision. We reviewed 2013 and 2015 non-VA echocardiogram and stress test consult requests to determine if facility managers refused to approve non-VA care. (See Figure 2.)

In 2013, we identified 118 non-VA echocardiogram consult requests. We found 111 of 118 non-VA echocardiogram consults (94.1 percent) were approved, 2 of 118 non-VA echocardiogram consults (1.7 percent) were not approved, and 5 of 118 non-VA echocardiogram consults (4.2 percent) were discontinued or cancelled prior to approval for non-VA care.

In 2015, we identified 38 non-VA echocardiogram consult requests. We found 30 of 38 non-VA echocardiogram consults (78.9 percent) were approved, 2 of 38 non-VA echocardiogram consults (5.3 percent) were not approved, and 6 of 38 non-VA

³⁷ *VHA Consult/Request Tracking User Manual*, Version 3.0, originally released December 1997, last revision February 2016. The Consult Request Tracking System allows for “Discontinued Orders,” “Order Cancellation,” and “Order Discontinued,” pages 183-184.

³⁸ VHA Directive 2008-056, *VHA Consult Policy*, September 16, 2008, was in effect during the time of the events discussed in this report; it was rescinded and replaced with VHA Directive 1232(1), *Consult Process and Procedures*, August 24, 2016, amended September 23, 2016. The current Directive contains similar language regarding VHA consult management policy: “to ensure timely and clinically appropriate care to all Veterans by standardizing and managing consultation processes.”

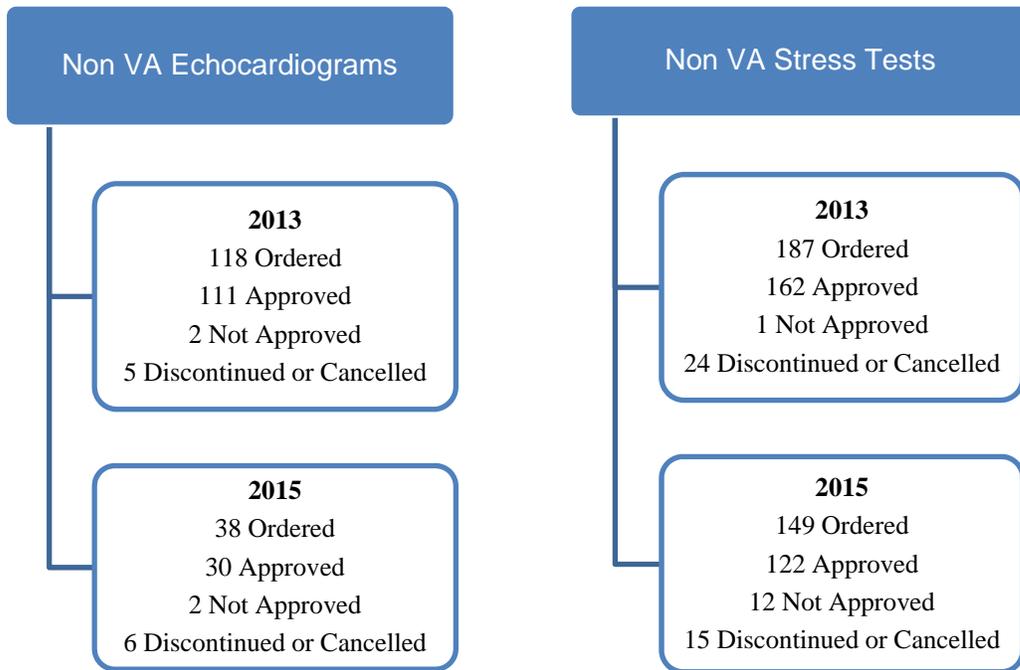
echocardiogram consults (15.8 percent) were discontinued or cancelled prior to approval for non-VA care.

In 2013, we identified 187 non-VA stress test consult requests. We found 162 of 187 non-VA stress test consults (86.6 percent) were approved, 1 of the 187 (0.5 percent) non-VA stress test consults were not approved, and 24 non-VA stress test consults (12.8 percent) were discontinued or cancelled prior to approval for non-VA care.

In 2015, we identified 149 non-VA stress test consult requests. We found 122 of 149 non-VA stress test consults (81.9 percent) were approved, 12 of 149 non-VA stress test consults (8.1 percent) were not approved, and 15 of 149 non-VA stress test consults (10 percent) were discontinued or cancelled prior to approval for non-VA care.

In our review of non-VA echocardiogram and stress test consult requests, we did not find evidence that facility managers refused to approve non-VA echocardiograms and stress tests as a cost savings decision.

Figure 2: Summary of OIG Analysis of 2013 and 2015 Non-VA Echocardiogram and Stress Test Approval Status



Source: VA OIG Analysis

Issue 4: Other Quality of Care Concerns

Cardiac Catheterization Reports

We substantiated that a cardiologist did not sign cardiac catheterization reports timely; however, we did not substantiate that untimely signing of cardiac catheterization reports resulted in delayed care for three identified patients. According to facility's Bylaws and

Rules of the Medical Center Staff, completion and filing of reports or diagnostic and therapeutic procedures must be accomplished within 24 hours.³⁹

We reviewed the EHRs of the three identified patients. We found that a cardiologist did not sign one patient's cardiac catheterization report until 4 months after the procedure and two patients' cardiac catheterization reports were not signed until 6 months after the procedure. With respect to the three identified patients, documentation in the EHRs of each patient showed that managing providers were aware of the results of the catheterization procedures, and made immediate management decisions based on those results. While we did find that the catheterization reports were not signed within the required 24-hour period, we found no evidence that this caused a delay in care. In general, however, access to a report is important for the non-acute care teams managing these patients in different settings, such as a patient's primary care provider. Such access allows these providers to review, reinforce, and monitor recommended medication, dietary, and lifestyle modifications made by the cardiologists based on findings from the catheterization.

Event Monitoring

We did not substantiate that a cardiologist did not timely review an event monitor tracing strip which resulted in a patient undergoing an invasive surgical procedure. According to documentation in the EHR, transmission of the tracing strip in question was not successful, the technician could not locate the tracing strip, and the tracing strip was not available for the cardiologist to review. We found that a cardiologist did not respond to a view alert related to the tracing strip in a timely fashion, but determined the delay in responding to the view alert was not a contributing factor in the patient undergoing an invasive surgical procedure. Subsequent multiple event monitor transmissions did not show abnormalities. Because the external event monitor was not successful in identifying abnormalities corresponding to the patient's report of symptoms, an internal loop recorder was implanted.

In 2012, an event monitor was mailed to the patient. One month later, the patient had a syncopal episode and attempted to transmit a tracing strip. The next week, the patient telephoned a Cardiology clinic provider and reported the syncopal episode and transmission.

The clinic provider entered a note documenting the patient's telephone call indicating that he/she would alert technicians and a cardiologist to check if telemetry strips were available for review. One of the technicians also entered a note on the day of the patient's telephone call indicating that the patient had returned the event monitor by mail and there were no transmissions. The cardiologist did not timely acknowledge receipt as required by VHA policy: "CPRS users must respond promptly (as defined by facility

³⁹ William S. Middleton VA Hospital, *Bylaws and Rules of the Medical Staff*, adopted by the Medical Staff, William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin, February 27, 2012.

policy) to View Alerts, which notify them of documents requiring authentication.”⁴⁰ Physicians and other caregivers must monitor and take appropriate action on their computerized prompts for signature, currently known as “View-Alerts.”⁴¹

Although the cardiologist did not acknowledge receipt of the view alert until early 2013, we found documentation that the patient received another event monitor (monitor #2) one month after returning monitor #1. Despite multiple event monitor transmissions and contact with cardiology staff, over the next several weeks, tracing strips from monitor #2 did not show abnormalities that corresponded to the patient’s report of symptoms. A cardiologist recommended an implantable loop recorder in an effort to diagnose the underlying abnormality responsible for the patient’s symptoms. Approximately 8 weeks after receiving monitor #2, the patient underwent an invasive procedure for the implantation of a loop recorder as multiple previous external event monitors had not identified heart rate and rhythm issues responsible for the patient’s symptoms.⁴² The patient was followed closely by cardiology staff over the next 3 years without identification of an etiology for intermittent symptoms. During a clinic visit in 2016, the patient asked cardiology clinic staff about removal of the loop recorder. As of early 2017, plans for removal of the loop recorder with the patient continued.

90-Day Supply of Clopidogrel

We did not substantiate that pharmacy staff refused to give veterans a 90-day supply of clopidogrel, gave only a 30-day supply, and the lack of a 90-day supply contributed to missed doses.

We reviewed a Memorandum dated March 22, 2007, from the facility’s Chief of Staff and Chief of Pharmacy Service to facility providers regarding restrictions and a new ordering method for clopidogrel. The use of the drug clopidogrel was being restricted due to patient safety concerns, including prolonged use without an evidence-based indication and economics. According to the Memorandum, the VISN’s leadership staff and the facility’s Pharmacy and Therapeutics Committee members approved the *Clopidogrel (Plavix®) Criteria for Use in Veteran Patients* established by the VHA Pharmacy Benefits Management Services and the Medical Advisory Panel.⁴³ On

⁴⁰ VHA Handbook 1907.01, *Health Information Management and Health Records*, August 25, 2006 was in effect at the time of the events discussed in this report; it was rescinded and replaced September 2012 by VHA Handbook 1907.01, *Health Information Management and Health Records*, dated July 22, 2014. The Handbooks contain the same language regarding View Alerts.

⁴¹ Ibid. Notifications are electronic messages that provide information or which prompt staff to act on a clinical event. Clinical events, such as unsigned or un-cosigned documents, critical prompt staff to act on a clinical event. Clinical events, such as unsigned or un-cosigned documents, critical laboratory value, or a change in orders, trigger a notification to be sent to all recipients identified by the corresponding package (Laboratory, CPRS, Radiology, etc.). **NOTE:** In CPRS, notifications are located on the bottom of the Patient Selection screen. In VistA, notifications are located with a prompt “View Alerts” when the user logs onto the system.

⁴² *Implantable “Loop Recorder”- A New Diagnostic Tool for Syncope of Unknown Cause*, US National Library of Medicine National Institutes of Health. <https://www.ncbi.nlm.nih.gov/pubmed/16623256>. Accessed March 22, 2017.

⁴³ *Clopidogrel (Plavix®) Criteria for Use in Veteran Patients*, VHA Pharmacy Benefits Management Services and the Medical Advisory Panel. <http://www.pbm.va.gov/apps/VANationalFormulary/>. Accessed March 1, 2017.

April 9, 2007, facility pharmacy managers initiated a new ordering process for clopidogrel in accordance with these criteria:

- Clopidogrel will be removed from the outpatient medication tab in CPRS.
- The only way to order clopidogrel for outpatients is through a “Clopidogrel Medication Utilization Evaluation [(MUE)]⁴⁴ progress note.”
- The MUE will ask the provider the following questions:
 - date of event
 - indication
 - remaining months of therapy
- If the indication and duration of therapy are consistent with National Criteria, the provider will be able to order clopidogrel immediately.
- Inpatient clopidogrel orders will be unaffected by this process until discharge.
- Existing prescriptions for clopidogrel are being reviewed by clinical personnel.

We reviewed the EHRs of six patients who were identified as having missed dosages due to receiving a 30-day supply of clopidogrel. We identified that a provider had completed and submitted an MUE progress note for all six patients. The MUE note included indication and duration of therapy. We found three of the six patients received a 30-day supply of clopidogrel and three patients received a 90-day supply of clopidogrel as requested by a provider. We did not find evidence that a 30-day supply of clopidogrel contributed to missed dosages for the three patients who received a 30-day supply of clopidogrel.

Conclusions

We substantiated delays in scheduling in-house echocardiograms for patients. We reviewed 2013 and 2015 in-house echocardiogram consult requests and identified two patients whose scheduling delays increased their risk for sudden cardiac death while waiting for an echocardiogram. After several months delay, both patients underwent echocardiograms followed by surgical procedures to treat their life-threatening conditions. The physician reviewer found the two identified patients had an increased risk for sudden cardiac death related to a delay in scheduling an echocardiogram.

We substantiated delays in scheduling in-house stress tests for patients. However, we did not find documentation of an adverse clinical outcome related to delays in scheduling patients for a stress test.

⁴⁴ According to the Society of Health System Pharmacists, a MUE is a performance improvement method that can focus on evaluating and improving medication-use processes. *Am J Health-Syst Pharm.* 1996; 53:1953–5. ASHP guidelines on medication-use evaluation. American Society of Health-System Pharmacists. <https://www.ashp.org/DocLibrary/BestPractices/FormGdlMedUseEval.aspx>. Accessed December 2, 2016.

We substantiated delays in scheduling in-house sleep studies for patients. However, we did not find evidence of an adverse clinical outcome related to delays in scheduling patients for a sleep study.

We substantiated that a small number of echocardiogram consults were discontinued within 30 days then later resubmitted as new consults without explanatory documentation. We could not determine that echocardiogram consults were discontinued within 30 days and resubmitted to appear timely.⁴⁵ In 2013, we found 4 of the 220 consults were discontinued and resubmitted without documentation and the remaining 216 consults were discontinued and resubmitted with supporting documentation. In 2015, 4 of 217 consult requests were discontinued and resubmitted without documentation and the remaining 213 consults were discontinued and resubmitted with supporting documentation.

We did not substantiate that facility managers refused to approve non-VA, echocardiograms and stress tests as a cost savings decision. In our review of non-VA echocardiogram and stress test consult requests, we did not find evidence that facility managers refused to approve non-VA echocardiograms and stress tests as a cost savings decision.

We substantiated that a cardiologist did not sign cardiac catheterization reports timely; however, we did not substantiate that untimely signing of cardiac catheterization reports resulted in delayed care for three identified patients. We found that a cardiologist did not sign one patient's cardiac catheterization report until 4 months after the procedure and two patients' cardiac catheterization reports were not signed until 6 months after the procedure. Documentation in the EHRs of each patient showed that managing providers were aware of the results of the catheterization procedures, and made immediate management decisions based on those results.

We did not substantiate that a cardiologist did not timely review an event monitor tracing strip which resulted in a patient undergoing an invasive surgical procedure. We found that a cardiologist did not respond to a view alert related to the tracing strip in a timely fashion, but determined the delay in responding to the view alert was not a contributing factor in the patient undergoing an invasive surgical procedure.

We did not substantiate that pharmacy staff refused to give veterans a 90-day supply of clopidogrel, gave only a 30-day supply, and the lack of a 90-day supply contributed to missed doses. We reviewed the EHRs of six patients who were identified as having missed dosages due to receiving a 30-day supply of clopidogrel. We found three of the six patients received a 30-day supply of clopidogrel and three patients received a 90-day supply of clopidogrel as requested by a provider. We did not find evidence that a 30-day supply of clopidogrel contributed to missed dosages for the three patients who received a 30-day supply of clopidogrel.

⁴⁵ *VHA Consult/Request Tracking User Manual*, Version 3.0, originally released December 1997, last revision February 2016. The Consult Request Tracking System allows for "Discontinued Orders," "Order Cancellation," and "Order Discontinued," pages 183-184.

Recommendations

1. We recommended that the Facility Director ensure that outpatient echocardiography and stress test consult requests are scheduled and completed in accordance with Veterans Health Administration policy.
2. We recommended that the Facility Director ensure that sleep study consult requests are scheduled and completed within the timeframe required by Veterans Health Administration policy.
3. We recommended that the Facility Director ensure that patients' cardiac diagnostic and procedure reports are signed within the timeframe specified by policy to ensure appropriate follow-up and patient care coordination.

Prior OIG Reviews January 1, 2013 through March 31, 2017

Facility Reports

Review of Alleged Waste of Funds at VHA's Madison VA Medical Center

9/30/2016 | 15-00650-423

Combined Assessment Program Review of the William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin

9/30/2015 | 15-00617-539

Review of Community Based Outpatient Clinics and Other Outpatient Clinics of William S. Middleton Memorial Veterans Hospital, Madison, WI

9/28/2015 | 15-00165-529

Audit of Selected VHA Non-Institutional Purchased Home Care Services

9/30/2013 | 11-00330-338

Combined Assessment Program Review of the William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin

4/12/2013 | 13-00431-173

Topic Related Reports

Consult Delays

Healthcare Inspection – Consult Delays and Management Concerns, VA Montana Healthcare System, Fort Harrison, Montana

3/10/2017 | 13-00431-173

Healthcare Inspection – Improper Consult and Appointment Management Practices, False Documentation, and Document Scanning Errors, Charlie Norwood VA Medical Center, Augusta, Georgia

3/10/2017 | 14-02890-168

Healthcare Inspection – Echocardiography Scheduling and Quality of Care Concerns, Edward Hines, Jr. VA Hospital, Hines, Illinois

2/2/2017 | 15-01900-142

Healthcare Inspection: Alleged Improper Management of Dermatology Requests Fayetteville VA Medical Center Fayetteville, North Carolina

5/3/2016 | 14-02890-286

Healthcare Inspection – Pulmonary Medicine Clinic Appointment Cancellations, William Jennings Bryan Dorn VA Medical Center, Columbia, South Carolina

1/6/2016 | 15-00992-71

Healthcare Inspection - Deficient Consult Management, Contractor, and Administrative Practices, Central Alabama VA Health Care System, Montgomery, Alabama

7/29/2015 | 14-04530-452

Healthcare Inspection – Quality of Care Concerns in a Diagnostic Evaluation, Jesse Brown VA Medical Center, Chicago, Illinois

9/29/2015 | 14-02952-498

Healthcare Inspection – Alleged Consult Processing Delay Resulting in Patient Death, VA Eastern Colorado Health Care System, Denver, Colorado

7/7/2015 | 14-04049-379

Healthcare Inspection – Quality of Care and Access to Care Concerns, Jack C. Montgomery VA Medical Center, Muskogee, Oklahoma

6/16/2015 | 14-04573-378

Healthcare Inspection: Alleged Consult Management Issues and Improper Conduct, W.G. (Bill) Hefner VA Medical Center, Salisbury, North Carolina

2/18/2015 | 14-04194-118

Healthcare Inspection – Alleged Delay in Gastroenterology Care, Durham VA Medical Center, Durham, North Carolina

11/6/2014 | 14-03298-20

Healthcare Inspection: Improper Closure of Non-VA Care Consults, Carl Vinson VA Medical Center, Dublin, Georgia

8/12/2014 | 14-03010-251

Healthcare Inspection: Audiology Staffing, Consult Management, and Access to Care, Sheridan VA Healthcare System, Sheridan, Wyoming

11/5/2013 | 13-03670-13

Staffing

Healthcare Inspection – Follow-Up of Scheduling, Staffing, and Quality of Care Concerns at the Alaska VA Healthcare System, Anchorage, Alaska

3/9/2017 | 15-05249-162

Healthcare Inspection – Nurse Staffing and Patient Safety Reporting Concerns, VA Roseburg Healthcare System, Roseburg, Oregon

10/12/2016 | 15-00506-420

Review of an Alleged Radiology Exam Backlog at the W.G. (Bill) Hefner VAMC in Salisbury, NC

10/4/2016 | 14-02890-425

OIG Determination of VHA Occupational Staffing Shortages

9/28/2016 | 16-00351-453

Healthcare Inspection – Emergency Department, Mental Health Service, and Suicide Prevention Training Concerns, Mann-Grandstaff VA Medical Center, Spokane, Washington

9/14/2016 | 15-03713-288

Healthcare Inspection – Reported Primary Care Staffing at St. Cloud VA Health Care System, Veterans Integrated Service Network 23, Eagan, Minnesota

8/11/2016 | 15-05490-367

Healthcare Inspection – Staffing and Quality of Care Issues in the Community Living Center, Charlie Norwood VA Medical Center, Augusta, Georgia

3/19/2015 | 14-02437-117

Healthcare Inspection – Staffing and Patient Care Issues, West Palm Beach VA Medical Center, West Palm Beach, Florida

2/12/2015 | 14-01708-123

Healthcare Inspection – Alleged Insufficient Staffing and Consult Management Issues, Carl Vinson VA Medical Center, Dublin, Georgia

1/7/2015 | 14-04702-60

Healthcare Inspection – Podiatry Clinic Staffing Issues and Delays in Care, Central Alabama Veterans Health Care System, Montgomery, Alabama

5/19/2014 | 13-04474-157

Healthcare Inspection – Quality of Care, Management Controls, and Administrative Operations, William Jennings Bryan Dorn VA Medical Center, Columbia, South Carolina

2/6/2014 | 13-00872-71

Healthcare Inspection – Inadequate Staffing and Poor Patient Flow in the Emergency Department, VA Maryland Health Care System, Baltimore, Maryland

9/18/2013 | 12-03887-319

Healthcare Inspection–Appointment Scheduling and Access Patient Call Center, VA San Diego Healthcare System, San Diego, California

1/28/2013 | 12-04108-96

Wait Times

Audit of Veteran Wait Time Data, Choice Access, and Consult Management in VISN 6

3/2/2017 | 16-02618-424

Review of Alleged Wait-Time Manipulation at the Southern Arizona VA Health Care System

11/9/2016 | 14-02890-72

Review of an Alleged Radiology Exam Backlog at the W.G. (Bill) Hefner VAMC in Salisbury, NC

10/4/2016 | 14-02890-425

Healthcare Inspection – Evaluation of Reported Wait Times, VA Greater Los Angeles Healthcare System, Los Angeles, California

6/30/2016 | 16-02197-339

Review of VHA's Alleged Manipulation of Appointment Cancellations at VAMC Houston, TX

6/20/2016 | 15-03073-275

Healthcare Inspection – Alleged Delayed Mental Health Treatment and Other Care Issues, Kansas City VA Medical Center, Kansas City, MO

9/2/2015 | 14-03531-402

Healthcare Inspection – Care of an Urgent Care Clinic Patient, Tomah VA Medical Center, Tomah, Wisconsin

6/18/2015 | 15-02456-396

Healthcare Inspection – Alleged Lack of Timeliness and Quality of Care Concerns at the Memphis VA Medical Center, Memphis, Tennessee

4/16/2015 | 15-00347-154

Healthcare Inspection – Emergency Department Staffing and Patient Safety Issues, VA San Diego Healthcare System, San Diego, California

9/3/2014 | 14-00271-265

Review of Alleged Patient Deaths, Patient Wait Times, and Scheduling Practices at the Phoenix VA Health Care System

8/26/2014 | 14-02603-267

Interim Report: Review of VHA's Patient Wait Times, Scheduling Practices, and Alleged Patient Deaths at the Phoenix Health Care System

5/28/2014 | 14-02603-178

Healthcare Inspection – Alleged Excessive Wait for Emergency Care and Staff Disrespect, VA Southern Nevada Healthcare System, Las Vegas, Nevada
4/30/2014 | 14-01104-134

Healthcare Inspection – Emergency Department Length of Stay and Call Center Wait Times, VA Eastern Colorado Health Care System, Denver, Colorado
12/23/2013 | 13-03862-35

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Additional Scope and Methodology Information

This appendix provides supplemental scope and methodology information for how we evaluated the delays in diagnostic procedure consults ordered and the impact of delays on patients from January 1, 2013, through December 31, 2013, and January 1, 2015, through December 31, 2015.

Table 1. CDW Data Extracted and Analyzed by OIG

CDW Location (database.schema.table)	How Extracted Data Were Used
CDWORK.DIM.STA3N	Obtained station numbers for study population
CDWORK.DIM.LOCATION	Decoded VA station physical location (for reference only)
CDWORK.DIM.REQUESTSERVICE	Distinguished between administrative from clinical consults
CDWORK.DIM.CLINICALTERM	Decoded clinical terminology (for reference only)
CDWORK.DIM.PROVIDERNARRATIVE	Decoded provider narrative (for reference only)
CDWORK.DIM.CPT	Obtained CPT codes and descriptions
CDWORK.DIM.ICD9	Obtained ICD-9-CM codes
CDWORK.DIM.ICD9DESCRIPTION VERSION	Obtained ICD-9-CM descriptions
CDWORK.CON.CONSULT	Obtained all consults for selected stations
CDWORK.CON.CONSULTACTIVITY	Identified consult activities for cancellation or closure without patient encounters

CDWORK.SPATIENT.SCONSULTREASON	Obtained text identifying the reason for the consult
CDWORK.SPATIENT.SPATIENT	Obtained patient identifiable information, including date of death
CDWORK.APPT.APPOINTMENT	Identified appointments created from consults; if applicable
CDWORK.OUTPUT.VISIT	Identified if patient physically visited station during timeframe for an outpatient encounter
CDWORK.OUTPUT.VDIAGNOSIS	Identified if patient had a diagnosis of any type at outpatient encounter
CDWORK.OUTPUT.VPROCEDURE	Obtained full record of patient visit containing adverse event outpatient procedure
CDWORK.INPAT.INPATIENT	Identified if patient had an inpatient stay during timeframe at VA station
CDWORK.INPAT.INPATIENTDISCHARGEDIAGNOSIS	Identified if patient had a discharge diagnosis of any type during inpatient stay
CDWORK.INPAT.INPATIENTFEEDIAGNOSIS	Obtained FEE inpatient records showing hospitalization and obtaining either discharge or admit diagnosis
CDWORK.FBCS.DSS_AUTHSUPPDATA	Provided a link between FEE encounters and ordered consult by authorization
CDWORK.FEE.FEEAUTHORIZATION	Obtained FEE authorizations linked to consults by ID
CDWORK.FEE.FEEINITIALTREATMENT	Obtained FEE visits linking the authorization to the type of treatment
CDWORK.FEE.FEESERVICEPROVIDED	Obtained FEE outpatient records for patients

CDWORK.FEE.FEEINPATINVOICE	Obtained FEE inpatient records showing hospitalization
CDWORK.FEE.FEEINPATINVOICEI CDDIAGNOSIS	Obtained diagnosis for FEE inpatient visits
CDWORK.SSTAFF.SSTAFF	Obtained provider information if required (for reference only)

Source: OIG -53T Data Center

Table 2. Consult Urgencies and Associated Timeframes Used to Identify Delays

Consult Urgency	Expected Timeframe
Routine	Within 30 days
Next available	Within 30 days
Within 1 month	Within 30 days
Within 1 week	Within 7 days
Within 72 hours	Within 3 days
Within 48 hours	Within 2 days
Within 24 hours	Within 1 day
Today	Same day
STAT	Within 6 hours
Emergency	Within 4 hours

Source: OIG and OIG analysis of VA documents:

VHA Directive 2008-056, VHA Consult Policy, September 16, 2008 and VHA Consult Business Rules that have been incorporated into VHA Directive 1232(1), Consult Process and Procedures, August 24, 2016, amended September 23, 2016.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: July 13, 2017

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

Subj: **Healthcare Inspection**—Delays in Scheduling Diagnostic Studies and Other Quality of Care Concerns, William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin

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

1. I have reviewed the draft report and concur with the response to the recommendations provided by Madison VAMC.

(original signed by:)
Renee Oshinski

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: June 22, 2017

From: Director, William S. Middleton Memorial Veterans Hospital (607/00)

Subj: **Healthcare Inspection**— Delays in Scheduling Diagnostic Studies and Other Quality of Care Concerns, William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin

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

1. I concur with the findings and recommendations of the Office of the Inspector General report Delays in Scheduling diagnostic Studies and Other Quality of Care Concerns.
2. The William S. Middleton Memorial Veterans hospital did experience delays in scheduling echocardiograms and stress tests during the review periods of 2013 and 2015. Two patients out of over 11, 600 consults reviewed had a delay in care of potential clinical significance, however neither patient experienced an adverse clinical outcome. Both patients received the medical treatment indicated for their condition.
3. The Williams S. Middleton Memorial Veterans hospital did experience delays in scheduling sleep studies during the review periods of 2013 and 2015. Workload for sleep studies traditionally outpaces capacity, inside and outside the VA. Since 2015, the facility has added an additional sleep technologist, a Nurse Practitioner, and a Medical Director to the sleep program. Clinic time has been increased and E-consults have been implemented. The William S. Middleton Memorial Veterans Hospital refers Veterans who cannot be treated within 30 days to Choice providers in accordance with the guidelines.
4. Attached please find the facility actions and progress in the reviewed areas since the time of this report, and plans for continued compliance. If you have any questions or need further information, please contact Chief, Quality Management at 608-256-1901 ext. 17718.

(original signed by:)

John J. Rohrer

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the Facility Director ensure that outpatient echocardiography and stress test consult requests are scheduled and completed in accordance with Veterans Health Administration policy.

Concur

Target date for completion: Completed; March 2016

Facility response: The William S. Middleton Memorial Veterans Hospital has completed monthly reviews and has been able to schedule all echocardiograms and stress tests within one week of the request since March of 2016.

OIG Comment: Based on information received, we consider this recommendation closed.

Recommendation 2. We recommended that the Facility Director ensure that sleep study consult requests are scheduled and completed within the timeframe required by Veterans Health Administration policy.

Concur

Target date for completion: Completed; July 2016

Facility response: The William S. Middleton Memorial Veterans Hospital is completing and ensuring the scheduling of sleep studies is complete following the guidelines of the VHA Choice Program. Monthly reviews demonstrate that all patients that the facility cannot treat within 30 days are referred to Choice providers.

OIG Comment: Based on information received, we consider this recommendation closed.

Recommendation 3. We recommended that the Facility Director ensure that patients' cardiac diagnostic and procedure reports are signed within the timeframe specified by policy to ensure appropriate follow-up and patient care coordination.

Concur

Target date for completion: October 31, 2017

Facility response: The facility's policy requires that reports are signed within 72 hours. Quality Management staff will monitor monthly data to ensure compliance with the

policy. Data collected will be reported up to the Medical Executive Committee to ensure 90 percent compliance is achieved and sustained.

OIG Contact and Staff Acknowledgments

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