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Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Quality of Care Concerns and Leaders' Responses at the Amarillo VA Health Care System in Texas

HEALTHCARE INSPECTION | REPORT #21-02491-129 | APRIL 14, 2022

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations related to hypertension treatment and post-stroke care delivered by a primary care provider (subject provider), nursing staff communication and documentation, and adequacy of telephone communication processes at the Amarillo VA Healthcare System (system) in Texas. The purpose of this review was to evaluate the merit of the allegations and assess system leaders' responses to clinical concerns involving the subject provider.

The OIG was unable to determine whether delays in treatment for hypertension and headaches caused the patient's stroke. The OIG did not find evidence to support that the subject provider or other patient aligned care team (PACT) clinic staff members did not provide timely treatment of the patient's chronic hypertension and headaches in the weeks leading up to the patient's stroke. However, when the patient presented to the clinic with stroke-like symptoms in early 2021, the subject provider and clinic nurse failed to properly assess these signs and symptoms and ensure the patient received urgent medical attention. The delay in evaluation and treatment may have resulted in a more difficult and complex recovery for the patient. The system leaders improperly delayed completing an institutional disclosure related to the patient's stroke. The former Chief of Staff (COS) and the Chief Quality Officer both provided the OIG with explanations for the delay that did not align with Veterans Health Administration (VHA) policy on institutional disclosure.

The OIG confirmed that the subject provider did not request cardiology and neurology consults after the patient experienced a stroke.[1] However, the OIG did not substantiate the implication that the lack of these consults was problematic. The OIG did not find recommendations in the American Heart Association and American Stroke Association (AHA/ASA) guidelines for routine cardiology or neurology consultations during inpatient or outpatient post-stroke care.

The OIG did not substantiate that a licensed vocational nurse (LVN) diagnosed the cause of the patient's headaches. The OIG found that the LVN's use of "sounds like…" was a validation of the patient's vision-related concerns rather than a diagnosis, and the suggestion to contact the Eye Clinic for assessment of vision changes was offered as an option given the patient's request for an eye exam. The patient was instructed to come to the clinic the following day for evaluation by the subject provider, which was responsive to the patient's request and would support the diagnostic process.

The OIG was unable to determine whether the PACT nurses were dismissive and condescending in their communications with the patient and spouse as these terms are subjective and cannot be validated. Nevertheless, the patient reported *feeling* that the LVN and some PACT nursing staff

[1] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and left arrow keys together.

communicated in this manner. Therefore, system leaders have an opportunity to reiterate with the PACT nursing staff VHA's expectation of respectful communication.

The OIG did not substantiate the allegation of needing to use secure messaging to communicate concerns because no one answered the PACT telephone. The system followed VHA guidance for ensuring telephone service was available to all patients through a Call Center where qualified staff offer health care recommendations, schedule appointments, and provide a response to patient care needs. Direct clinic extensions were not routinely provided to patients.

During the inspection, the OIG identified multiple leadership failures related to assessment and follow-through of the subject provider's ongoing quality of care deficits.

- The subject provider's ongoing professional practice evaluations repeatedly reflected failure to complete notes and follow up on test results timely. Despite this, several different chiefs of ambulatory care did not place the subject provider on time-limited focused professional practice evaluations (FPPEs) to address those concerns as they arose. The OIG was unable to discern the reason for this inaction.
- After a new (fourth) tort claim related to the subject provider came to light in November 2020, the former COS did not require a focused clinical care review (FCCR) or other investigation to determine whether other quality of care concerns existed. The former COS asserted that the Chief of Ambulatory Care did conduct clinical reviews; however, the OIG found that the Chief of Ambulatory Care reviewed only three patient cases and that no retrospective review of additional cases involving critical view alerts or other quality indicators was completed.[2]
- The former COS and Medical Executive Committee (MEC) failed to ensure that the FPPE for Cause evaluated the correct quality of care elements across a reasonable number of patients. The former COS told the OIG of having "confidence" in the FPPE for Cause.[3]
- The FPPE for Cause was delayed more than 60 days as the Chief of Ambulatory Care, who was new to the facility and role, had never completed an FPPE for Cause, was not aware of the process, and was provided limited support.
- After summarily suspending the subject provider's privileges in late spring 2021, the system did not conduct a timely FCCR or other review. When privileges are summarily suspended, VHA requires a comprehensive review of the reason for summary suspension within 30 calendar days of the suspension. The cases were not sent to external reviewers

[2] The Chief of Ambulatory Care reviewed three of six cases provided by the risk manager that were identified through a tort claim or other quality process.

[3] The OIG determined deliberations of the Medical Executive Committee should not be publicly disclosed in the report.

until two months later. As of January 2022, more than four months after the FCCR results were available, a privileging action based on the results has not been finalized.

The OIG determined that the compounding effect of these failures allowed the subject provider to continue practicing substandard medicine, and that as a result, patients experienced adverse outcomes. As of early 2022, the subject provider's privileges had not officially been revoked by the System Director. Both the Chief Quality Officer and System Director acknowledged that the process involved in revocation of privileges has taken longer than they expected. The subject provider has been functioning in an administrative capacity, without direct patient care duties since late spring 2021.

The OIG made one recommendation to the Veterans Integrated Service Network Director to assess the system leaders' actions in this case related to professional practice evaluations, an FCCR and institutional disclosure, as well as to take action related to staff training and other identified deficits, as indicated.

The OIG made five recommendations to the System Director related to: ensuring that Emergency Department staff follow established protocols regarding abnormal vital signs; evaluating the registered nurse's failure to ensure the patient received urgent medical attention after presenting with stroke-like symptoms; reiterating with staff VHA's expectations of respectful communications with patients and their families; completing a retrospective review of critical view alerts and other quality of care elements of the subject provider; and ensuring that PACT staff follow communication protocols and electronic health record documentation requirements.

Comments

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

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Contents

Abbreviations

EHR	electronic health record
FCCR	focused clinical care review
FPPE	focused professional practice evaluation
LVN	licensed vocational nurse
MEC	Medical Executive Committee
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
PACT	patient aligned care team
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations related to hypertension treatment and post-stroke care delivered by a primary care provider (subject provider), nursing staff communication and documentation, and telephone communication processes at the Amarillo VA Healthcare System (system) in Texas. The purpose of this review was to evaluate the merit of the allegations and to assess system leaders' responses to clinical concerns involving the subject provider.

Background

The system operates the Thomas E. Creek VA Medical Center in Amarillo and four community-based outpatient clinics located in Lubbock, Childress, and Dalhart, Texas; and Clovis, New Mexico. The system is classified as a Level 2 medium complexity facility, which provides acute general medical and surgical services, outpatient and specialty care services, and mental health and long-term care services. The system is part of Veterans Integrated Service Network (VISN) 17.[1]

Hypertension

Blood pressure is the pressure of blood on the walls of blood vessels. A blood pressure reading has two numbers: systolic (the first or top number) and diastolic (the second or bottom number).[2] In general, blood pressure of 120/80 or lower is considered normal. Hypertension, or high blood pressure, is defined as systolic pressure at or above 130 or diastolic pressure at or above 90. The cause of hypertension is not always known and if not treated, hypertension can harm the blood vessels, which carry blood to all the different parts of the body. Hypertension "can result in strokes, heart attacks, kidney disease, and heart failure." Treatment for hypertension includes lifestyle changes such as weight loss, improved diet, smoking cessation, increased physical activity, and blood pressure-lowering (anti-hypertensive) medication. For blood pressure that exceeds the goal, the VA, Department of Defense (VA/DoD) clinical practice guidelines recommend follow-up with a physician within four weeks of an acute hypertensive episode especially if it is related to a temporary illness or injury, adjustment of the patient's initial

[1] VHA Office of Productivity, Efficiency and Staffing, "Facility Complexity Level Model Fact Sheet," December 15, 2017. The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, and educational and research missions. Complexity levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered the most complex and level 3 facilities are the least complex.

[2] Mayo Clinic "Blood pressure chart: What your reading means," accessed August 16, 2021, https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/in-depth/blood-pressure/art-20050982?p=1. Systolic blood pressure, the top number, measures how much pressure blood exerts against the artery walls when the heart beats. Diastolic blood pressure, the bottom number, measures how much pressure blood exerts against the artery walls while the heart is resting between beats.

anti-hypertensive medication or addition of a new medication from a different class, and consideration of co-interventions from other clinical disciplines to improve the management of blood pressure.[3] The frequency of clinical follow-up may increase depending on the medical care plan to achieve optimal blood pressure.

Stroke

A stroke is an emergency situation caused when blood flow to the brain is restricted or stopped. Factors such as high blood pressure, diabetes, lack of exercise, and high blood cholesterol and lipids, can increase a person's risk for having a stroke.[4] Stroke symptoms may happen suddenly and may include weakness or numbness on one side of the body, problems with vision, severe headaches with no known cause, and confusion or loss of consciousness. Prompt assessment and treatment for suspected stroke is crucial as early intervention and treatment can potentially reduce brain damage and other complications. The longer a stroke goes untreated, the greater the potential for temporary or permanent disabilities such as paralysis, difficulty talking, memory loss, and self-care deficits.

The system is a designated Veterans Health Administration (VHA) Supporting Stroke Facility that delivers triage and stabilization to patients presenting with acute stroke before transferring those patients to facilities offering a higher level of stroke care. The system also provides post-stroke medical care, inpatient and outpatient rehabilitation, and follow-up care. [5]

Allegations and Related Concerns

The OIG received allegations on April 21, 2021, regarding a patient's care, and gained additional clarifications during subsequent interviews:

- The subject provider did not provide prompt treatment for poorly controlled hypertension and headaches, which caused the patient to experience a stroke.

[3] *VA/DoD Clinical Practice Guideline for the Diagnosis and Management of Hypertension in the Primary Care Setting*, Version 4.0, March 2020. Providers can use clinical judgment to individualize blood pressure and treatment goals based on a patient's history and preferences as long as they remain within the clinical practice guidelines relative to age and comorbidities. However, an ideal blood pressure goal is generally 120/80 or lower.

[4] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

[5] VHA Directive 1155(1), *Treatment of Acute Ischemic Stroke*, June 2, 2018. Amended November 13, 2018. A VHA Supporting Stroke Facility is a facility that does not have the necessary personnel, infrastructure, expertise, and programs to deliver consistent care of patients presenting with an acute ischemic stroke, based on staffing, diagnostic services, or numbers/types of beds. VHA Supporting Stroke Facilities must have detailed and current transfer agreements for in-hospital stroke and protocols for emergency medical services diversion in place to triage or transfer acute stroke patients to a designated Comprehensive Stroke Center, Limited Hours Stroke Facility, or Primary Stroke Center.

- The subject provider failed to order follow-up cardiology and neurology referrals after the patient experienced a stroke.
- A licensed vocational nurse (LVN) "diagnosed" the cause of the patient's headaches.
- Nursing staff were condescending and dismissive in their interactions with the patient and spouse.
- The patient had to use secure messaging (to communicate with healthcare providers) because no one answered the patient aligned care team (PACT) clinic telephone.

In accordance with general OIG practices, the team also evaluated system leaders' responses to concerns involving the subject provider's clinical practice.

Scope and Methodology

The OIG initiated the inspection on May 20, 2021, and conducted interviews from June 10 to October 1, 2021.

The OIG team interviewed the patient and spouse to better understand the issues and subject provider-related concerns. The team also interviewed the System Director, former Chief of Staff (COS), Associate Director for Patient Care Services, Deputy COS, Chief of Ambulatory Care, Chief Quality Officer, providers directly involved in the patient's care as outlined in this report, and other staff knowledgeable about the issues under review. Leaders and staff from VHA's Office of Medical Staff Affairs and the Office of General Counsel were also interviewed.

The OIG team reviewed relevant VHA and system policies and procedures, staff training and competency records, and credentialing and privileging-related documents. The OIG also reviewed relevant aspects of the patient's electronic health record (EHR), including secure messaging, from August 2016 through September 2021 and the patient's non-VA medical records from early 2021.[6]

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.

[6] The team requested and reviewed non-VHA patient records obtained by subpoena.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1101, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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.

Case Summary

The patient is in their late 40s with a history of hypertension, mixed hyperlipidemia, chronic pain, obesity, gout, and obstructive sleep apnea, who established primary care at the system in 2016. From late summer 2016 through early winter 2017, the patient's blood pressure readings over six visits ranged from a low of 130/79 to a high of 174/112. In late summer 2017, the patient was started on amlodipine 10 milligrams (mg) daily for hypertension management.[7] The patient was also taking medication for chronic pain in both knees and low back, gout, acid reflux, allergies, and anxiety. From early 2018 through late 2020, the patient's blood pressure readings ranged from 132/90 to 165/117 as measured during 13 visits. In addition, the patient's lipid levels continued to be high, and the subject provider encouraged healthy lifestyle choices such as diet and exercise to manage the hyperlipidemia.[8]

In late 2020, the patient sent a series of secure messages to the PACT clinic related to a pain medication refill. In these messages, the patient reported having headaches, which had been present for more than a week. The patient confirmed having migraines and reported being sensitive to light. The patient wrote, "My vision seems to be affected by this constant headache" and requested an appointment with the subject provider "to include an eye exam." In response, the LVN wrote, "As far as your headaches, it sounds like they all stem from your vision. We cannot make those appointments. You can call optical and schedule that." The LVN also advised the patient to come to the walk-in clinic between 8:00 a.m. and 3:00 p.m. the next day, and then sent a reminder message that a laboratory test would be needed prior to the medication refill.

The subject provider was not available the next morning and another PACT LVN called and encouraged the patient to come to the clinic that afternoon when the subject provider would be

[7] Amlodipine is a medication called a calcium channel blocker, which lowers blood pressure by relaxing blood vessels to improve blood flow.

[8] A lipid panel, or complete cholesterol test, is a test to measure the amount of cholesterol and triglycerides in a patient's blood. The test can determine the risk of fatty deposit buildup that can lead to narrowed or blocked arteries throughout the body. General laboratory guidelines for optimal or desirable lipid-level results reflect a total cholesterol below 200 mg/dL, low-density lipoprotein cholesterol below 100 mg/dL and triglycerides below 150 mg/dL.

present. During this call, the patient expressed displeasure at the previous LVN "diagnosing" [the patient]. The patient did not come to the clinic that day.

In early 2021, the patient completed laboratory testing, which again showed elevated lipid levels with a total cholesterol of 251 milligrams per deciliter (mg/dL), a low-density lipoprotein (LDL) of 173 mg/dL, and triglycerides of 190 mg/dL. That same day, the subject provider conducted a telephone visit with the patient and documented that the patient reported working long hours and 21 straight days in late 2020 due to other personnel being sick with COVID-19. The subject provider also wrote, "In general, [the patient] has felt fine but [the patient] did have increasing migraine headaches and generalized achiness during the time that [the patient] was required to work longer hours." The patient agreed to start cholesterol-lowering medications, which were ordered and mailed to the patient. The plan was for the patient to return to clinic in six months for an in-person visit and contact the clinic should problems arise in the meantime.

The next day, the patient presented to the Emergency Department complaining of a finger injury. In triage, the patient's blood pressure was noted to be 165/119. The Emergency Department provider documented the patient's review of systems was negative for headache, change in vision, cardiac abnormalities, and focal weakness. The patient was discharged home with instructions to elevate and ice the area of injury, take ibuprofen as needed for pain, and follow up with the subject provider in two to three days. There was no further documentation related to the elevated blood pressure.

Ten days later, at 10:25 a.m., the patient sent a secure message to the PACT, writing, "I am experiencing some noted side effects of my [blood pressure] medication. I believe I need to be reassessed to adjust my dosage." The patient reported having three blood pressure "trend note" photos that would be sent through secure messaging, and although the messages appeared to contain photo attachments, this information was not found in the EHR. At 11:18 a.m., an LVN documented in a secure message to the patient, "If these symptoms are present today you may need to be seen in the ER [Emergency Department]" as several of the symptoms were stroke-related. Around noon, the patient presented to the clinic as a walk-in where the registered nurse documented that the patient was complaining of elevated blood pressure, headaches, tingling in the hands and lips, and uncontrolled leaning to the right. The registered nurse further documented that the patient thought the blood pressure was getting too low, and the patient reported having "halved" the current medication dose. As measured in the clinic, the patient's blood pressure readings were 165/115, 174/112, and 173/118.[9] In the Plan of Care section of the unscheduled visit note, the registered nurse documented "Referred to provider for review," and noted that "After reviewing the [signs and symptoms] of [the patient's] current condition," the

[9] The OIG was told that blood pressure data has to be manually entered into the EHR, which may explain why the blood pressure readings were all documented at 12:34 p.m. The OIG had no way to determine the exact time that each blood pressure was taken, or the order of the results, as automatic blood pressure machines do not store the data.

subject provider discontinued the amlodipine and prescribed a different anti-hypertensive medication (a combination of losartan and hydrochlorothiazide). The patient was to return to clinic, with a completed blood pressure log, in two weeks. There was no corresponding note by the subject provider documenting an examination.

Early the following day, the patient presented to a non-VA hospital's emergency department with a blood pressure of 188/99 and complaints of dizziness, blurry vision, and headache for two weeks. The patient was diagnosed with a stroke and admitted to the non-VA hospital around 4:00 a.m.

Two days later, the patient was discharged from the non-VA hospital with instructions to follow up with primary care and outpatient rehabilitation. The patient contacted a system social worker requesting physical therapy and home medical equipment. Physical therapy was initially ordered two times per week for four weeks to address impairments in gait and dynamic stability. Approximately four weeks later, the patient was enrolled in home telehealth for hypertension monitoring. At the time of the OIG inspection, the patient continued to progress in rehabilitation therapy and be followed by home telehealth.

Approximately six months later, a completed neurology consultation reflected that the patient had a possible left [brain stem] lesion and "post-stroke dysesthesia" for which gabapentin was prescribed. The plan included additional neck and brain imaging with a follow-up phone visit in four months.[10]

[10] Gabapentin is a medication called an anticonvulsant, which can be prescribed to relieve pain for some nervous system conditions.

Inspection Results

1. Treatment Timeliness and Compliance with Protocols

The OIG was unable to determine whether delays in treatment for hypertension and headaches caused the patient's stroke. Effective treatment for hypertension often involves anti-hypertensive medication as well as lifestyle adjustments including diet and exercise. In this case, the OIG did not have adequate information to assess the patient's compliance with medication and lifestyle guidance. However, the OIG found that Emergency Department staff failed to follow system protocol to recheck the patient's blood pressure after a high reading during a visit in early 2021. Further, 10 days after the Emergency Department visit, when the patient presented to the clinic with stroke-like symptoms, the subject provider and clinic nurse failed to properly assess these signs and symptoms and ensure the patient received urgent medical attention.

Response to Hypertension and Headache

The OIG did not find evidence to support that the subject provider or other PACT members did not provide timely treatment of the patient's chronic hypertension and headaches in the weeks leading up to the patient's stroke. The complaint specifically referenced the patient's secure message to the PACT in late 2020 requesting a medication refill and a clinic appointment. The patient did report having a headache and vision problems. While the LVN documented telling the patient to come to walk-in clinic the following day and documented the patient's acknowledgment of this plan, the patient did not do so.[11] Based on EHR review, it did not appear to the OIG that the patient reported hypertension-related concerns to the PACT team until [the patient] presented with stroke-like symptoms 10 days after the Emergency Department visit.

The OIG did have concerns about the subject provider's apparent lack of effort to more aggressively control the patient's blood pressure historically. The patient had been taking an anti-hypertensive medication for several years, and blood pressures documented in late summer and early fall 2020 were 151/82 and 153/97, respectively. The OIG noted that for patients in the 30-60 age group, therapeutic guidance suggests blood pressure goals of less than 130/90. Because the patient's blood pressure was consistently above this goal, evidenced-based literature supports treatment options including adding or changing medications and having a pharmacist, nurse, or dietitian provide close blood pressure monitoring and follow up to regulate dosing, or requesting specialty consultation, such as cardiology, as indicated for refractory hypertension. The OIG did not find evidence that the subject provider utilized these options.

During a telephone visit with the subject provider in early 2021, the patient reported having experienced increased headaches during a period when the patient had an intense work schedule

[11] Upon interview with the OIG, the patient was unable to recall this instruction.

the previous month. The patient did not complain of active or ongoing headaches during the phone visit. The subject provider responded to the patient's request for prescription refills, started the patient on a new cholesterol-lowering medication, and reinforced the patient's efforts related to diet, exercise, and stress management. Although the plan was for the patient to follow up in clinic in six months, the OIG found that when new medications were added, an earlier evaluation to determine the effectiveness of the medication, such as an appointment or blood work, would have been the standard of practice as reflected in evidence-based guidelines.

The OIG also found that Emergency Department staff did not follow system protocol requiring that vital signs be rechecked if abnormal, and the responsible provider be notified, prior to the patient's transfer or discharge.[12] The patient's blood pressure in the Emergency Department was 165/119; however, this critically high value was not acknowledged in the EHR, nor was there documentation that the patient's blood pressure was rechecked. Further, instructions issued to the patient at discharge from the Emergency Department addressed the finger injury but not the hypertension. The Emergency Department nurse explained to the OIG the correct procedure for rechecking elevated blood pressures; however, the nurse could not explain why there was no documented evidence that the patient's blood pressure was rechecked.

While the OIG could not determine with certainty whether the patient's outcome would have been better had Emergency Department providers followed protocol relative to high blood pressure readings, the OIG concluded that following protocol and intervening, as indicated, *may* have improved the patient's chances of avoiding the stroke.

Response to Acute Stroke Symptoms

The OIG found that the subject provider and PACT nurse did not follow evidence-based clinical guidelines when the patient presented to the clinic with stroke-like symptoms. The OIG determined that the medical management avenue the subject provider selected—to address the stroke-like symptoms through medication changes in the patient's home setting—was unsafe.

When the patient arrived at the PACT walk-in clinic complaining of hallmark signs and symptoms of stroke, the assessing nurse wrote that the patient "halved" their current medication. Three blood pressure readings, completed during clinic triage and documented in the EHR, were 165/115, 174/112, and 173/118. The patient's constellation of symptoms such as headache and neurologic deficits while in the clinic provided the evidence that the uncontrolled hypertension was causing injury to the brain. Although treatment of a hypertensive emergency relies on preventing and ending the blood pressure's progression upward in an emergency setting, the patient's critically high blood pressure was not addressed. The OIG determined that the patient should have immediately been taken to the system's Emergency Department for urgent

[12] Amarillo VA Health Care System Standard Operating Procedure 118-ED-SOP-01-18, *Emergency Department (ED) Vital Signs Standard Operating Procedures (SOP)*, September 14, 2018.

evaluation and appropriate interventions and monitoring as indicated. The expectation was to urgently stabilize the blood pressure in a monitored environment so that a stroke could be prevented.

Instead of sending the patient to the Emergency Department, the nursing note reflected that the subject provider and nurse discussed the patient's condition, and the subject provider changed the patient's anti-hypertensive medication with a plan for the patient to return to clinic in two weeks. The OIG did not find documented evidence in the EHR that the subject provider completed a progress note for this encounter or saw the patient in person; assessed the patient's neurological and motor functions to determine the extent of the deficits; or asked the patient about the onset of the stroke-like symptoms or when the patient started "self-dosing." In addition to the aforementioned failures, the subject provider's decision to discontinue the patient's amlodipine and start a new medication, losartan, without evaluation and a plan for close monitoring and follow-up, was clinically unsafe.

The OIG concluded that the subject provider's treatment approach to the patient's presentation with hallmark signs and symptoms of a stroke constituted a disregard for basic medical practice and professional responsibility. The earlier that appropriate treatment is initiated after a stroke, the better the outcome. In this case, the nearly 16-hour delay in evaluation and treatment of stroke-like symptoms may have resulted in a more difficult and complex recovery for the patient.

Institutional Disclosure

The OIG determined that the system leaders improperly delayed completing an institutional disclosure related to the patient's stroke.

An institutional disclosure is a formal process in which system leaders, clinicians, and other appropriate individuals "inform the patient or the patient's personal representative that an adverse event occurred during the patient's care that resulted in or is reasonably expected to result in death or serious injury." "Institutional disclosure must be initiated as soon as reasonably possible and generally within 72 hours." However,

> This timeframe does not apply to adverse events that are only recognized after the associated episode of care, for example, through investigation of a sentinel event, a routine quality review, or a look-back. Under such circumstances, if the adverse event has resulted in or is reasonably expected to result in death or serious injury, institutional disclosure is required, but disclosure may be delayed allowing for a thorough investigation of the facts provided.[13]

In this case, the system leaders learned of the patient's stroke on May 28, 2021, through the OIG. The system leaders did not conduct an institutional disclosure based on its interpretation of the

[13] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

directive. An institutional disclosure was subsequently completed on September 16 acknowledging the stroke and providing the patient with information about the process and right to file an administrative tort claim.[14]

On September 17, the system's Chief Quality Officer told the OIG of understanding that an institutional disclosure was to advise the patient or family that the system leaders' actions may have resulted in the patient's adverse outcome. The Chief Quality Officer said that the initial rationale for not completing the institutional disclosure was that because the patient filed the complaint, the patient was "well aware that we… messed up." The former COS told the OIG on September 21 of not pursuing an institutional disclosure because the Risk Manager said they had to be done within three days of the system leaders becoming aware of the event. The Risk Manager told the OIG that the goal was to complete institutional disclosures within three days, but that they were often done after that. The OIG found that the Chief Quality Officer and former COS' answers did not align with VHA policy and were highly troubling given that these two staff members represented the system's quality and clinical leadership.[15]

2. Coordination of Post-Stroke Care

The OIG confirmed the complainant's allegation that the subject provider did not request cardiology and neurology consults after the patient experienced a stroke. However, the OIG did not substantiate the implication that the lack of these consults was problematic. The OIG did not find recommendations in the American Heart Association and American Stroke Association (AHA/ASA) guidelines for routine cardiology or neurology consultations during inpatient or outpatient post-stroke care. Rather, the AHA/ASA guidelines focus on rehabilitation to maximize patient functioning.[16]

The patient was admitted to a non-VA hospital in early 2021 for management of a stroke. The non-VA attending physician did not request cardiology or neurology consults when the patient was hospitalized, nor did the non-VA attending physician recommend those consults be completed once the patient was discharged. The non-VA attending physician requested physical, occupational, and speech therapy consults, and while the non-VA treatment team recommended the patient undergo inpatient rehabilitation, the patient requested outpatient rehabilitation through the VA. The OIG interpreted the non-VA provider's actions to mean that, while cardiology and neurology consults were not clinically indicated at the time of treatment and discharge from the non-VA facility, rehabilitation consults were clinically indicated.

[14] VHA Directive 1004.08.

[15] The former COS left the system in July 2021, becoming COS at another VHA healthcare facility in a different VISN in late August. At the time of this report, the Chief Quality Officer continued in that role at the system.

[16] Carolee J. Winstein, et al., "Guidelines for Adult Stroke Rehabilitation and Recovery," *Stroke* 47 (June 2016): e98-e169. https://www.ahajournals.org/doi/full/10.1161/STR.0000000000000098.

The patient was discharged from the non-VA hospital after a two day hospital stay. Within a week of the discharge, the subject provider entered a consult for rehabilitation services and the patient was evaluated by a physical therapist. An occupational therapy evaluation was also scheduled; however, the patient's spouse subsequently cancelled all future rehabilitative services appointments. Rehabilitation services are central to a patient's functional recovery following an acute stroke.

Although a neurology consult was not initially indicated after the patient's stroke, a nurse practitioner requested a neurology consult approximately five months later as some of the patient's symptoms persisted. The patient was seen by a neurologist seven months after the stroke with a follow-up plan for additional imaging tests.

3. Nursing Staff Communication and Documentation

The OIG did not substantiate the allegation that the LVN diagnosed the cause of the patient's headaches. The diagnostic process involves the "collaboration of patients and their families; diagnosticians, such as physicians…; and healthcare professionals who support the diagnostic process, such as nurses…" As part of the diagnostic process, nurses communicate with patients about their history, listen to their reasons for a visit, document the patients' symptoms, and convey the information to other clinicians.[17]

The OIG identified several deficits in the way the LVN responded to the patient's concerns and documented the exchange and actions in late 2020; however, after interviewing the LVN, the OIG determined that the LVN's use of "sounds like…" was a validation of the patient's vision-related concerns rather than a diagnosis, and the suggestion to contact the Eye Clinic for assessment of vision changes was offered as an option given the patient's request for an eye exam. The LVN advised that the patient could come to the clinic "as [a] walk in" the following day for evaluation by the subject provider, which was responsive to the patient's request and would support the diagnostic process. The LVN told the OIG that the PACT clinic had limited appointment availability due to the COVID-19 pandemic, and the reason for suggesting an Eye Clinic appointment was because the patient could be seen more quickly. The LVN acknowledged that this explanation and other conversations with the patient should have been documented in the EHR. While the LVN told the OIG of reporting the patient's concerns to the registered nurse, the registered nurse told the OIG of having no recall of this report. The EHR did not contain documentation reflecting that the patient's condition was communicated to the subject provider or the registered nurse, either that afternoon or subsequently. Nevertheless, the patient had been advised to come to the PACT's walk-in clinic the following day to be seen by the subject

[17] Erin P. Balogh, Bryan T. Miller, and John R. Ball. Improving Diagnosis in Health Care. National Academies of Sciences, Engineering, and Medicine, 2015. Chapter 4: "Diagnostic Team Members and Tasks: Improving Patient Engagement and Health Care Professional Education and Training in Diagnosis." Nurses report and document changes in the patient's condition and communicates pertinent observations to the care team.

provider. A discussion between the LVN and the subject provider or registered nurse could have resulted in a recommendation for the patient to seek urgent treatment if symptoms persisted. [18]

The OIG was unable to determine whether PACT nurses were dismissive and condescending in their communications with the patient and the patient's spouse. The allegations specifically related to the LVN "diagnosing" the patient's headaches and other discussions with PACT nurses about medications. The OIG found that the terms dismissive and condescending are subjective and therefore cannot be objectively validated.[19] Nevertheless, the patient reported *feeling* that the LVN and some PACT nursing staff communicated in this manner. This perception presents system leaders with an opportunity to reiterate with the PACT nursing staff VHA's expectation of respectful communication.[20]

In an effort to look at this concern another way, the OIG reviewed the series of messages between the LVN and the patient, and interviewed relevant nursing staff, leaders, and the patient advocate, but did not identify concerns about the nature and quality of communications between PACT nursing staff and patients. In addition, the OIG reviewed Patient Advocate Tracking System reports from late 2020 through mid-2021 and did not find complaints from this or other patients concerning the LVN or other PACT nurses' communication.[21]

4. Telephone Communication Processes

The OIG did not substantiate the complainant's allegation of needing to use secure messaging to communicate concerns because no one answered the PACT telephone. The system followed VHA guidance for ensuring telephone service for clinical care needs was available to all patients.

VHA requires that patients have access to healthcare guidance and information via telephone services using trained staff. [22] VHA advises facilities that in order to promote safe patient care, it is important that patients use the Call Center where qualified staff offer appropriate healthcare recommendations, schedule appointments, and provide a timely response to patient care needs. [23]

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[18] VHA Handbook 1101.10(1) *Patient Aligned Care Team (PACT) Handbook,* February 5, 2014. Amended on May 26, 2017.

[19] Lauri Nummenmaa, Riitta Hari, Jari K. Hietanen, and Enrico Glerean. 2018 "Maps of subjective feelings." *Proceedings of the National Academy of Sciences of the United States of America*, Vol. 115, no. 37 (September 11):1. https://www.pnas.org/content/pnas/115/37/9198.full.pdf.

[20] VHA Handbook 1101.10(1).

[21] VHA Directive 1003.04, *VHA Patient Advocacy*, February 07, 2018. The Patient Advocate Tracking System is an electronic system used by the Patient Advocate to enter and track patient compliments, complaints, and programmatic data.

[22] VHA Directive 2007-033, *Telephone Service for Clinical Care*, October 11, 2007.

[23] VHA offers access to safe, timely, and clinically sound health care advice through coordinated telephone service coverage 24 hours a day, 7 days a week (24/7). Telephone service is available through a call center with clinical staff who provide health care advice and information, patient education, and assistance with pharmacy issues and other concerns.

According to several system employees, direct clinic extensions were not routinely provided to patients.

Although the OIG understands that patients may prefer to speak directly to their PACT team and not utilize the Call Center, the OIG concluded that the system offered appropriate avenues for patients to ask questions and communicate clinical concerns using the Call Center, secure messaging, and telehealth. The OIG's review of the patient's EHR revealed that from late 2020 through mid-2021, the patient used secure messaging, telephone, and telehealth to communicate with PACT staff members.

5. System Leaders' Responses to the Subject Provider's Clinical Deficits

The OIG determined that system leaders' responses to clinical concerns were inadequate to ensure that the subject provider's patients received safe, quality care. VHA has several mechanisms to evaluate providers' clinical performance.

- Peer review, conducted for quality management purposes, is an evaluation of the care delivered by individual providers within a selected episode of care and is critical to the identification of learning opportunities for clinical practice improvement.[24] These peer reviews are confidential and protected by 38 U.S.C. § 5705.
- Management review is any review that is conducted for purposes other than confidential quality assurance. [25] Management reviews are not protected under 38 U.S.C § 5705, and include the following four types:
    - Ongoing professional practice evaluation (OPPE), which is the routine and ongoing monitoring of privileged practitioners and allows the facility to identify professional practice trends that impact the quality of care and patient safety.[26]
    - Focused professional practice evaluation (FPPE), which is an oversight process employed by a facility when a provider does not have documented evidence of competent performance of the privileges requested. FPPE is a time-limited period during which the medical staff leadership evaluates and determines the provider's professional performance. The FPPE typically occurs at the time of a provider's initial appointment to the medical staff; however, it may be used when a question arises regarding a currently privileged practitioner's ability to provide safe, high-quality patient care.[27]

[24] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

[25] VHA Directive 1190.

[26] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. VHA Directive 1190.

[27] VHA Handbook 1100.19 and VHA Directive 1190.

- FPPE for Cause, which is a customized opportunity for a provider to demonstrate improvement or requisite knowledge and skill; usually initiated after a concern has been identified from other clinical oversight reviews.[28]
- Focused clinical care review (FCCR), which is a retrospective review of a provider's practice for which there is an identified concern or issue.[29]

Subject Provider's Performance History

The subject provider was initially appointed to the medical staff and was granted privileges to practice at the system in October 2008. For the next 12 years, the subject provider was rated highly satisfactory or better during annual proficiency reviews, successfully completed routine OPPEs, and received several monetary awards. On multiple occasions between 2015 and 2020, however, the reviewing supervisor commented on the relevant appraisal that the subject provider was not documenting clinical work or completing encounters in a timely manner. In fact, the OPPE for the period October 1, 2019, through March 31, 2020, reflected that the subject provider would "need continuous monitoring and pushing on completion of notes, which [the subject provider] has NOT done successfully for most if not all of [the subject provider's] time here."

In 2016–2017, two tort claims related to the subject provider's clinical care were settled. From 2018 through May 2020, three additional cases involving deficits in the subject provider's clinical care were identified through system processes. The subject provider's care deficits included failure to order and follow up on radiology examinations and findings and failure to properly prescribe antibiotic medications.

The subject provider's privileges were renewed for another two years, with OPPEs every six months to track patient notification letters of laboratory and radiology results, as well as timeliness of documentation and encounter completion.

In November 2020, two months after the subject provider was re-privileged, the system's Risk Manager was alerted to another tort claim involving the subject provider's alleged failure to adequately monitor a patient's lung nodule. The Risk Manager provided the Chief Quality Officer with a brief summary of six concerning cases. The Chief Quality Officer then contacted VHA's Director of Medical Staff Affairs for guidance and potential courses of action. The Chief Quality Officer followed up this discussion with an email to the System Director, former COS, and the Deputy COS. The email, sent on a Friday, reflected "significant" concerns about whether the subject provider was providing safe patient care and included several pointed questions; specifically, whether the subject provider could provide safe care on Monday. The email went on

[28] VHA Handbook 1100.19.

[29] "Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance," VHA Medical Staff Affairs Quality Safety, Value.

to clarify that a summary suspension of privileges was "pushing the pause button while the facility looks a little deeper to see what… is [or] is not going on." Summary suspension of privileges occurs "when the failure to take such action may result in an imminent danger to the health of any individual."[30]

In December 2020, the subject provider was placed on an FPPE for Cause based on concerns reflected in several tort claims, as well as concerns that the subject provider did not review and address view alerts timely. The former COS told the OIG that the decision for FPPE for Cause was predicated, in part, on the concern that suspending the subject provider from practice during a time when the system was short on providers while also responding to COVID-19-related challenges would create additional burdens on patient care delivery. The Chief of Ambulatory Care told the OIG that the subject provider had been temporarily assigned to the inpatient ward from approximately November 2020 to January 2021 to assist with COVID-19 patients. Further, the System Director stated that this assignment was less concerning because of the continuous review "…by multiple people" so that an "aberrant result" was less likely to be missed.

On May 28, 2021, system leaders were informed by the OIG of concerns that the subject provider did not treat the patient's hypertension and headaches in a timely manner, which may have resulted in a stroke as discussed in this report. In late spring, the System Director summarily suspended the subject provider's privileges, citing "aspects of [the subject provider's] clinical practice [that did] not meet the accepted standards of practice and potentially constitute an imminent threat to patient welfare." [31]

OIG Concerns—Oversight and Performance Monitoring

The OIG identified multiple leadership failures related to assessment and follow-through of the subject provider's ongoing quality of care deficits. The OIG determined that the compounding effect of these failures allowed the subject provider to continue practicing substandard medicine, and that as a result, patients experienced adverse clinical outcomes[32].

- The subject provider's appraisals and OPPEs completed by multiple chiefs of ambulatory care repeatedly reflected the subject provider's failure to complete notes and encounters and follow up on test results in a timely manner. Despite this, the subject provider was

[30] VHA Handbook 1100.19.

[31] The FPPE for Cause was completed in late spring, and while the aggregated data showed improvement in closing the view alerts and encounters, however the FPPE for Cause was deemed unsuccessful as a patient suffered an adverse outcome (stroke) in early 2021.

[32] VHA Handbook 1050.01. Adverse events are "untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical facility, outpatient clinic, or other VHA facility." Within the context of this report, the OIG considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher-level care.

not placed on time-limited FPPEs to address those concerns as they arose. The OIG was unable to discern the reason for this inaction.

- After the fourth tort claim related to the subject provider came to light in November 2020, the former COS did not require an FCCR or other investigation to determine whether other quality of care concerns existed. According to VHA's Director of Medical Staff Affairs, a retrospective FCCR of 100 percent of the provider's critical view alerts should have been conducted to inform the most appropriate path forward. While the former COS asserted that the Chief of Ambulatory Care did conduct clinical reviews, the OIG found that the Chief of Ambulatory Care reviewed only three of the six patient cases provided by the Risk Manager. The Chief of Ambulatory Care did not retrospectively review any additional cases involving critical view alerts or other quality indicators.
- When provided with evidence that the subject provider's clinical practice potentially constituted a threat to patient welfare, such as a missed cancer diagnosis and untimely communication of critical test results, the subject provider was placed on an FPPE for Cause rather than summary suspension of privileges.[33] The former COS and the Medical Executive Committee (MEC) failed to ensure that the FPPE for Cause evaluated pertinent quality of care elements across a reasonable number of patients such that decisions about success or failure of the FPPE for Cause would be based on sufficient and relevant data.[34] Specifically, the FPPE for Cause was insufficient on multiple levels:
    - The focus was on documentation issues and reducing the number of open view alerts; it did not address the entirety of the quality of care issues identified in the tort claims and peer reviews.
    - The evaluation was delayed until March 2021, reportedly because the new Chief of Ambulatory Care, who was responsible for monitoring the subject provider, did not know how to proceed. The Chief of Ambulatory Care told the OIG of starting in that role in late November 2020 and of having never completed an FPPE for Cause in any previous roles. The Chief of Ambulatory Care told the OIG of being referred by the OPPE/FPPE Coordinator to another physician who had developed an FPPE for Cause before and of working with that physician to "figure it out." The OPPE/FPPE Coordinator told the OIG of discussing a process issue with the

[33] The former COS told the OIG that the decision for FPPE for Cause was predicated, in part, on the concern that suspending the subject provider from practice during a time when the system was short on providers while also responding to COVID-19-related challenges would create additional burdens on patient care delivery. The subject provider was temporarily assigned to the inpatient ward to assist with COVID-19 patients, an assignment that leaders asserted allowed for more oversight.

[34] The standard form for OPPEs and FPPEs was used and specified additional metrics for evaluation. However, the form did not specify the size and selection of the review population or appropriate elements to include in the review.

Chief of Ambulatory Care but said that service chiefs determine the review elements.[35]

- The review only included seven randomly selected cases over the entirety of the FPPE for Cause from March 1, 2021, through June 7, 2021, and those reviews did not include assessment of whether individual patients associated with unaddressed view alerts received quality care and appropriate follow-up. Rather, aggregated data on the number of view alerts and timeliness of response was presented to the MEC.

When asked whether the FPPE for Cause reviewed all the necessary quality of care elements to evaluate the subject provider's ability to deliver quality and safe care, the former COS told the OIG of being "100-percent confident" that the FPPE for Cause provided the information needed to revoke the subject provider's privileges. This confidence was despite clear support that previous reviews and evaluations failed to include serious clinical allegations and multiple unaddressed view alerts, and an unsatisfactory delay in conducting review and oversight. The OIG found the former COS' answer failed to satisfactorily address leadership's inadequate quality review process or provide an adequate rationale to ensure prompt oversight given evidence that the subject provider's delivery of care potentially created an imminent risk to patients.

OIG Concerns—Delayed FCCR After Summary Suspension

The OIG determined that the system leaders did not conduct a timely FCCR or other review after summarily suspending the subject provider's privileges in late spring 2021. The OIG found that responsible staff and leaders did not appear to be knowledgeable about the requirements and expectations surrounding this activity.

When privileges are summarily suspended, "the comprehensive review of the reason for summary suspension should be accomplished within 30 calendar days of the suspension," and when this cannot be accomplished in 30 days, "the circumstances should be documented with an expectation of when the comprehensive review will be completed."

The System Director's summary suspension letter to the subject provider stated, "This suspension is in effecting [sic] pending a Focused Clinical Care Review of these allegations." Two weeks later, the subject provider responded to the suspension letter and was subsequently granted additional time to collect evidence in support of (the subject provider's) defense. Over the next two months, the facility extended the subject provider's summary suspension.

[35] The process issue was related to the timing of the subject provider's signature on the FPPE for Cause form, which delayed implementation of the FPPE for Cause.

- In an email on June 16, the former COS emailed the Office of General Counsel (OGC) with information about the case, FPPE for Cause, and tort claims. The email ended with "… thank you for sending [this] information to an external reviewer."
- On June 23, the former COS emailed the System Director and an OGC attorney, writing "We also sent [the subject provider's] records to an external reviewer and [an OGC attorney] is helping us with this process."
- In late summer, the summary suspension letter stated, "The investigation has not yet concluded, and we are making every effort to finalize the review as expeditiously as possible."

The OIG found no evidence that an investigation by system leaders was underway on August 12 and noted that the cases and instructions to the external reviewers were not sent by the system until August 30.

Based on document review and interviews, the OIG determined that although the former COS represented the OGC was sending cases for external review, OGC is typically not responsible for sending out clinical or management reviews. This is the responsibility of system leaders. Two OGC attorneys told the OIG that their office only got involved in the disciplinary aspects related to provider performance and conduct; clinical or management reviews are coordinated by system leaders system. One OGC attorney told the OIG that the former COS was advised of this in mid-June during a virtual meeting, but this advisement did not appear to prompt the former COS to pursue an alternative means to secure external reviewers for the FCCR.

The Chief Quality Officer told the OIG that the former COS had been communicating with OGC but did not include [quality office staff] on those communications. As a result, the quality office staff did not know what had been said or decided. Given the significant issues surrounding the provider's performance, the OIG would have expected other leaders, like the System Director and Chief Quality Officer, to aggressively pursue status updates. Based on interviews with the former COS and Chief Quality Officer, the OIG determined that the interpersonal relationship between these leaders was strained and negatively impacted the quality and effectiveness of their communications.

FCCR Results and Delayed Privileging Action

On August 30, the FPPE/OPPE Coordinator sent instructions on completing the FCCR to three VHA providers employed at other facilities, requesting they conduct a management review. In addition to two "control" cases provided to the reviewers for the purpose of establishing inter-rater reliability, the reviewers were each charged with assessing eight different patients randomly selected by the FPPE/OPPE Coordinator. Therefore, the total review population included the 2 control cases and the 24 individually assigned cases, for a total of 26 cases. The reviewers were asked to review and respond to the following three questions:

1. Were there appropriate diagnostic/laboratory tests ordered given the clinical evidence/notes found?
2. Were there appropriate and timely treatment decisions based on the clinical presentation?
3. Was the standard of care met? If not, please explain.

Reviewers found that in 9 of the 26 cases (35 percent), the subject provider did not meet some element of the standard of care. Reviewers cited concerns with management of abnormal test results, imaging studies, and specialty consults. In one case, a computed tomography scan for a neck mass, which revealed "Neoplasm and infection are possible considerations," was not reviewed and acted on. The patient was diagnosed with cancer two months later. The FCCR found that "aspects of [the subject provider's] clinical practice [did not] meet the accepted standards of practice and potentially constitute[d] an imminent threat to patient welfare."

As of January 2022, more than four months after the FCCR results were available, a privileging action based on the results has not been finalized. Both the Chief Quality Officer and System Director acknowledged that the privileging process has taken longer than they expected. Additionally, the system leaders have not reported concerns about the providers' s practice to the National Practitioner Data Bank or the Texas State Licensing Board as required by VHA.[36]

Conclusion

The OIG was unable to determine whether delays in treatment for hypertension and headaches caused the patient's stroke. The OIG did not find evidence to support that the subject provider or other PACT staff members did not provide timely treatment of the patient's chronic hypertension and headaches in the weeks leading up to the patient's stroke. However, the OIG found that Emergency Department staff failed to follow system protocol to recheck the patient's blood pressure after a high reading in early 2021. Further, when the patient presented to the clinic 10 days later with stroke-like symptoms, the subject provider and clinic nurse failed to properly assess these signs and symptoms and ensure the patient received urgent medical attention consistent with evidence-based practice. The OIG concluded that the subject provider's treatment approach to the patient's condition constituted a disregard for basic medical practice and professional responsibility. In this case, the nearly 16-hour delay in evaluation and treatment may have resulted in a more difficult and complex recovery for the patient. The OIG determined

[36] VHA Handbook 1100.17, *National Practitioner Data Bank (NPDB) Reports*, December 28, 2009. "Final Actions related to professional competence or conduct that adversely affect clinical privileges of a physician or dentist for a period longer than 30 calendar days must be reported to the NPDB and a copy of this report must be sent to the SLB in the state in which the facility is located and the SLB in all states where the practitioner holds licenses." Upon interview, the OIG noted that the system's Acting Credentialing and Privileging Coordinator appeared to be unsure of the process to report providers to the NPDB and SLBs.

that system leaders improperly delayed completing an institutional disclosure until almost four months after learning about the patient's stroke.

The OIG confirmed that the subject provider did not request cardiology and neurology consults after the patient experienced a stroke. However, the OIG did not substantiate the implication that the lack of these consults was problematic. The OIG did not find recommendations in the AHA/ASA guidelines for routine cardiology or neurology consultations during inpatient or outpatient post-stroke care. Approximately seven months after the stroke, the patient was seen by a neurologist when some stroke symptoms persisted.

The OIG did not substantiate the allegation that the LVN "diagnosed" the cause of the patient's headaches. The OIG identified several deficits in the way the LVN responded to the patient's concerns and documented the exchange and actions in late 2020; however, the OIG determined that the LVN's use of "sounds like…" was a validation of the patient's vision-related concerns rather than a diagnosis, and the suggestion to contact the Eye Clinic for assessment of vision changes was offered as an option given the patient's request for an eye exam. The patient was instructed to come to the clinic the following day for evaluation by the subject provider, which was responsive to the patient's request and would support the diagnostic process.

The OIG was unable to determine whether the PACT nurses were dismissive and condescending in their communications with the patient and spouse as alleged by the complainant, as these terms are subjective and cannot be validated. Nevertheless, the patient reported *feeling* that the LVN and some PACT nursing staff communicated in this manner. Therefore, system leaders have an opportunity to reiterate with the PACT nursing staff VHA's expectation of respectful communication.

The OIG did not substantiate the complainant's allegation of needing to use secure messaging to communicate concerns because no one answered the PACT telephone. The system followed VHA guidance for ensuring telephone service was available to all patients through a Call Center where qualified staff offer appropriate health care recommendations, schedule appointments, and provide a timely response to patient care needs. Direct clinic extensions were not routinely provided to patients.

During the inspection, the OIG identified multiple leadership failures related to assessment and follow-through of the subject provider's ongoing quality of care deficits. The OIG found that

- the subject provider's OPPEs repeatedly reflected failure to complete notes and follow up on test results timely. Despite this, the subject provider was not placed on time-limited FPPEs to address those concerns as they arose;
- during late 2020, the facility placed the subject provider on an FPPE for Cause (rather than summary suspension) even though an FCCR or other investigation was not conducted to determine whether other quality of care concerns existed;

- the FPPE for Cause was not only delayed more than 60 days due to an administrative knowledge deficit but was also insufficient to evaluate the adequacy of the subject provider's clinical care; and
- the system leaders did not conduct a timely FCCR or other review after summarily suspending the subject provider's privileges in late spring.

The OIG determined that the compounding effect of these failures allowed the subject provider to continue practicing substandard medicine, and that as a result, patients experienced adverse outcomes.

Recommendations 1–6

1.The Amarillo VA Healthcare System Director ensures Emergency Department staff follow established protocols for clinical assessment, frequency, and intervention regarding abnormal vital signs, and monitors for compliance. [37]

2. The Amarillo VA Healthcare System Director completes an evaluation of the registered nurse's failure to ensure the patient received urgent medical attention after presenting to the clinic with stroke-like symptoms and takes appropriate action as indicated.

3.The Amarillo VA Healthcare System Director reiterates expectations that patient aligned care team staff engage in respectful communications with patients and their families, and monitors patient advocate data as well as patient satisfaction survey data for evidence of compliance.

4. The Amarillo VA Healthcare System Director completes a retrospective review of critical view alerts and other quality of care elements of the subject provider for the two years immediately preceding the subject provider's summary suspension, takes clinical and administrative actions in accordance with Veterans Health Administration guidelines, and monitors for compliance.[38]

5. The Amarillo VA Healthcare System Director ensures patient aligned care team staff follow communication protocols and electronic health record documentation requirements, and monitors for compliance.

6. The Veterans Integrated Service Network Director evaluates the system leaders' actions in this case related to ongoing professional practice evaluation and focused professional practice evaluation for cause processes, focused clinical care review, and institutional disclosure; takes action related to staff training and other identified deficits, as needed; and monitors for compliance.

[37] All recommendations in this report addressed to VA leaders are directed to the individual in that position—whether in an acting or permanent capacity.

[38] Quality of care elements could be informed by the findings of the 26 Focused Clinical Care Evaluations completed in September 2021.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: March 15, 2022

From: Director, VA Heart of Texas Health Care Network (VISN17)

Subj: Healthcare Inspection—Quality of Care Concerns and Leaders' Responses at the Amarillo VA Health Care System in Texas

To: Office of the Under Secretary for Health (10)

Thank you for the opportunity to respond to the Draft Report: Quality of Care Concerns and Leaders' Responses at the Amarillo VA Health Care System in Texas. VA remains committed to honoring our Nation's Veterans by ensuring a safe environment to deliver exceptional health care. I agree with the responses from the Amarillo Leadership team and have provided a response to the VISN recommendation.

(*Original signed by*:)

Wendell Jones, MD, MHA
VISN 17 Network Director

VISN Director Response

Recommendation 6

The Veterans Integrated Service Network Director evaluates the system leaders' actions in this case related to ongoing professional practice evaluation and focused professional practice evaluation for cause processes, focused clinical care review, and institutional disclosure; takes action related to staff training and other identified deficits, as needed; and monitors for compliance.

Concur.

Target date for completion: August 2022

VISN Director Comments

Corrective Action Plan:

VISN 17 Credentialing Privileging Officer and Deputy QMO [Quality Management Officer] will provide oversight for the actions listed above. C&P [Credentialing and Privileging] Officer will meet monthly with the facility C&P Manager to evaluate and track status of these monitors; OPPE; FPPE for Cause and Focused Clinical Care review. Each monitor will be reviewed monthly with the facility C&P Manager. Any issues will be addressed appropriately. Progress of the monitors will reported through VISN QSV Committee monthly. FPPE for Cause and FFCR will be entered in VHA NPDB/SLB tracker.

Appendix B: System Director Memorandum

Department of Veterans Affairs Memorandum

Date: March 14, 2022

From: Director, Amarillo VA Health Care System (504)

Subj: Healthcare Inspection—Quality of Care Concerns and Leaders' Responses at the Amarillo VA Health Care System in Texas

To: Director, VA Heart of Texas Health Care Network (10N17)

1. We appreciate the opportunity to work with the Office of Inspector General as we continuously strive to improve patient safety and quality of care.
2. Please see the attached responses.
3. For any follow-up questions, please contact the Chief Quality Officer or the VISN Quality Management Officer.

(*Original signed by*:)

Rodney S. Gonzalez, MD
Medical Center Director

System Director Response

Recommendation 1

The Amarillo VA Healthcare System Director ensures Emergency Department staff follow established protocols for clinical assessment, frequency, and intervention regarding abnormal vital signs, and monitors for compliance. [39]

Concur.

Target date for completion: September 30, 2022

Director Comments

The Chief of Staff will ensure that all Emergency Department (ED) providers are educated on established protocols for clinical assessment, and the expectations for frequency, and intervention regarding abnormal vital signs. The Quality and Patient Safety (QPS) service will monitor ED provider's compliance with expectations, and if expectations are not met, feedback will be provided. A monitor will be created to assess compliance with addressing abnormal vital signs for 30 patients per month until 90% compliance has been sustained for 6 consecutive months. Data will be reported through Governance to ensure appropriate leadership oversight and action.

Recommendation 2

The Amarillo VA Healthcare System Director completes an evaluation of the registered nurse's failure to ensure the patient received urgent medical attention after presenting to the clinic with stroke-like symptoms in early 2021, and takes appropriate action as indicated.

Concur.

Target date for completion: June 30, 2022

Director Comments

The Associate Director, Patient Care Services will ensure a formal review will be conducted of the nurse's failure to ensure the patient received urgent medical attention after presenting to the clinic with stroke-like symptoms in early 2021. Findings from this review will be addressed, as appropriate. Additionally, any learning opportunities identified will be shared broadly with patient aligned care team (PACT) RNs. QPS will follow this process to completion and will

[39] All recommendations in this report addressed to VA leaders are directed to the individual in that position—whether in an acting or permanent capacity.

report on progress through the governance structure to ensure appropriate leadership oversight and action.

Recommendation 3

The Amarillo VA Healthcare System Director reiterates expectations that patient aligned care team staff engage in respectful communications with patients and their families, and monitors patient advocate data as well as patient satisfaction survey data for evidence of compliance.

Concur.

Target date for completion: September 30, 2022

Director Comments

The Medical Center Director will ensure training and expectations of customer service are shared with the patient aligned care team staff. Patient advocate and satisfaction survey data will be monitored for trends. Additionally, an informal, end-of-visit survey will be given to patients at the end of their appointments to determine their perception of being treated respectfully. This data will also be monitored for trends and internal benchmarking and real-time service recovery. All data will be monitored by QPS until satisfaction data is at or greater than national average for six consecutive months. Data will be reported through Governance to ensure appropriate leadership oversight and action.

Recommendation 4

The Amarillo VA Healthcare System Director completes a retrospective review of critical view alerts and other quality of care elements of the subject provider for the two years immediately preceding the subject provider's summary suspension, takes clinical and administrative actions in accordance with Veterans Health Administration guidelines, and monitors for compliance.[40]

Concur.

Target date for completion: September 30, 2022

Director Comments

The Chief of Staff will ensure that retrospective view alerts are identified. It has been determined that the most pertinent view alerts to review will be abnormal imaging. Two years of view alerts will be identified, filtered to the abnormal imaging, and reviewed for quality-of-care concerns by a provider (peer), assigned by the Chief of Staff. Any concerns or issues identified will be

[40] Quality of care elements could be informed by the findings of the 26 Focused Clinical Care Evaluations completed in September 2021.

referred, as appropriate. These reviews will be tracked by QPS monthly to ensure timely completion of the review until 100% of the alerts have been reviewed. Data will be reported through Governance to ensure appropriate leadership oversight and action.

Recommendation 5

The Amarillo VA Healthcare System Director ensures patient aligned care team staff follow communication protocols and electronic health record documentation requirements, and monitors for compliance.

Concur.

Target date for completion: September 30, 2022

Director Comments

The Chief of Staff will ensure goals of communication and electronic health record documentation are shared with patient aligned care team staff. Targets will be established by the Medical Executive Board for the number of view alerts and open notes allowed. As the expectations are made clear, the number of unsigned notes and view alerts will be monitored by QPS for compliance with established thresholds until 90% of staff are compliant with the goals for six consecutive months. Data will be reported through Governance to ensure appropriate leadership oversight and action.

Additional comments:

The Amarillo AVAHCS has identified some of the root issues contributing to the findings in this report included inconsistent OPPE process and PACT teamlets not optimizing individual roles and responsibilities. In an effort to address the issues beyond this specific recommendation, the Amarillo VAHCS has already taken steps to address some of the broader issues identified in this report. Actions include more robust OPPE processes and oversight, as well as inviting a third-party VA subject matter expert to assist in establishing proper PACT functioning. We anticipate that these measures will further promote improved patient safety and quality of care.

Glossary

To go back, press "alt" and "left arrow" keys.

cardiology. The study of the heart and its action and diseases.[41]

cholesterol. A steroid alcohol that is present in animal cells throughout the body.[42]

chronic pain. Ongoing or recurrent pain lasting beyond acute illness or injury or more than three to six months.[43]

dysesthesia. A loss in the sense of touch.[44]

gout. A disease that causes painful swelling of the joints, especially in the toes.[45]

hyperlipidemia. The presence of excess fat or lipids in the blood.[46]

hypertensive emergency. A blood pressure reading is 180/120 or greater combined with any other associated symptoms such as chest pain, shortness of breath, back pain, numbness or weakness, change in vision, or difficulty speaking.[47]

low-density lipoprotein. A lipoprotein of blood plasma that is composed of a moderate proportion of protein with little triglyceride and a high proportion of cholesterol and that is associated with increased probability of developing atherosclerosis. Also called bad cholesterol.[48]

neurology. A branch of medicine concerned especially with the structure, function, and diseases of the nervous system.[49]

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[41] *Merriam-Webster.com Dictionary*, "cardiology," accessed September 8, 2021, https://www.merriam-webster.com/dictionary/cardiology.

[42] *Merriam-Webster.com Dictionary*, "cholesterol," accessed September 8, 2021, https://www.merriam-webster.com/dictionary/cholesterol.

[43] American Chronic Pain Association, "chronic pain," accessed September 8, 2021, https://www.theacpa.org/conditions/chronic-pain/.

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[45] *Merriam-Webster.com Dictionary*, "gout," accessed September 8, 2021, https://www.merriam-webster.com/dictionary/gout.

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[47] "Hypertensive Crisis: When You Should Call 911 for High Blood Pressure," American Heart Association, accessed September 20, 2021, https://www.heart.org/en/health-topics/high-blood-pressure/understanding-blood-pressure-readings/hypertensive-crisis-when-you-should-call-911-for-high-blood-pressure.

[48] *Merriam-Webster.com Dictionary*, "LDL," accessed September 8, 2021, https://www.merriam-webster.com/dictionary/LDL.

[49] *Merriam-Webster.com Dictionary*, "neurology," accessed September 8, 2021, https://www.merriam-webster.com/dictionary/neurology.

obstructive sleep apnea. Brief periods of recurring interruption of breathing during sleep due to obstruction of the upper airway or malformed pharyngeal tissues that occurs chiefly in overweight middle-aged and elderly individuals.[50]

occupational therapy. Therapy based on engagement in meaningful activities of daily life (such as self-care skills, education, work, or social interaction), especially to enable or encourage participation in such activities despite impairments or limitations in physical or mental functioning.[51]

physical therapy. Therapy for the preservation, enhancement, or restoration of movement and physical function impaired or threatened by disability, injury, or disease that utilizes therapeutic exercise, physical modalities (such as massage and electrotherapy), assistive devices, and patient education and training.[52]

rehabilitation. The physical restoration of a sick or disabled person by therapeutic measures and reeducation to participation in the activities of a normal life within the limitations of the person's physical disability.[53]

speech therapy. Therapeutic treatment of impairments and disorders of speech, voice, language, communication, and swallowing.[54]

triglycerides. Type of fat found in blood which may contribute to hardening of the arteries, increasing the risk of stroke, heart attack and heart disease.[55]

walk-in. Providing medical services to patients without an appointment.[56]

[50] *Merriam-Webster.com Dictionary*, "obstructive sleep apnea," accessed September 8, 2021, https://www.merriam-webster.com/medical/obstructive%20sleep%20apnea.

[51] *Merriam-Webster.com Dictionary*, "occupational therapy," accessed September 8, 2021, https://www.merriam-webster.com/dictionary/occupational%20therapy.

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[53] *Merriam-Webster.com Dictionary*, "rehabilitation," accessed September 8, 2021, https://www.merriam-webster.com/dictionary/rehabilitation.

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[55] Mayo Clinic, "triglycerides," accessed October 25, 2021, https://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/triglycerides/art-20048186.

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