DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Delay in Diagnosis and Subsequent Suicide at a Veterans Integrated Service Network 15 Medical Facility

HEALTHCARE INSPECTION | REPORT #19-00022-153 | JUNE 26, 2019

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate an allegation related to a delay in diagnosis of a patient's cancer at a Veterans Integrated Service Network (VISN) 15 medical facility (facility).[1] The patient subsequently died by suicide.[2]

The OIG substantiated a delay in the patient's diagnosis. The patient, who had been regularly receiving care at the facility for over 20 years, complained of dizziness and chronic sinusitis in summer 2016. The patient's assigned primary care provider ordered two imaging studies that were completed after the assigned provider left employment at the facility. Another provider, who was not assigned to the patient, reviewed the results and ordered a follow-up test that showed abnormalities suggestive of a malignancy. The patient was not fully evaluated for the abnormalities that were identified in 2016 until spring 2018. A preliminary diagnosis of cancer, made in summer 2018, was confirmed by biopsy five days later. Shortly after an evaluation to decide treatment options, the patient died by suicide. The OIG identified multiple deficiencies in the coordination of the patient's care between and among the involved primary and specialty care providers, and in the communication of abnormal test results to the patient that contributed to the delayed diagnosis.

The OIG determined that the patient was assigned multiple primary care providers during the time frame at issue, and the facility failed to provide a seamless transition when changes in providers occurred. One failure in the coordination of the patient's care occurred when data in the computerized program used to assign patients to providers, the Patient Centered Management Module, was not updated for almost three months. Automated test result notifications that depended on correct assignments would not have occurred and, in this patient's case, likely contributed to a failure in patient notification of abnormal test results. Other deficiencies in coordination of care included a failure in the designation of surrogates (the naming of a specific individual in a similar role who can cover for the absent staff member) and receipt of automated electronic notifications (view alerts) when imaging study abnormalities were noted.

The OIG was unable to determine or track the surrogate(s) responsible for notifying the patient about the abnormal test results in 2016. The primary care provider who ordered the follow-up test did not take action in relation to the abnormal test results. The patient's electronic health record did not contain evidence that this provider designated a surrogate who might have received the results in the provider's absence. Interviewees were unable to explain the surrogacy process to OIG inspectors, including who was responsible for designating surrogates. When a

[1] The name of the facility is not being disclosed to protect the privacy rights of the subject of the report pursuant to 38 U.S.C. §7332, Confidentiality of Certain Medical Records, January 3, 2012.

[2] The circumstances surrounding the patient's suicide will be reviewed in a separate report.

provider designates a surrogate, the surrogate will receive view alerts for the patients. The OIG was unable to fully evaluate the receipt of view alerts due to a purging of notifications for the time frame at issue.

The OIG determined that apart from system deficiencies related to coordination of care, providers did not consistently take timely action if/when view alerts or other communications were received; communicate crucial outstanding patient care information to other providers; and/or review the patient's history during assessments.

Providers who order tests are responsible for communicating test results to the patient in a timely fashion and taking action as necessary to address abnormal results. The OIG did not find evidence that the patient received timely notification of the abnormal summer 2016 computed tomography imaging study results or was informed of the need to undergo a surgical evaluation in 2017. Despite requests from the patient via secure messages related to obtaining test results and numerous opportunities to provide information to the patient during face-to-face visits, staff did not document in the electronic health record that they had informed the patient of the summer 2016 abnormal computed tomography scan of the neck results, the need for a surgical evaluation in 2017, or the clinical significance of the abnormal results before early spring 2018.

As part of its quality management process, the facility began a review of the patient's course of events at the time of the suicide. Facility managers completed peer reviews of relevant providers and a required Behavioral Health Autopsy report; they submitted an issue brief to VISN 15.[3] The facility did not initiate a fact-finding review or an administrative investigative board. The OIG did not find documentation of a clinical or institutional disclosure in the patient's electronic health record. The OIG was told that the facility had not conducted an institutional disclosure because an internal review was not yet completed. As of February 5, 2019, an internal review had been submitted to the Facility Director but was not yet signed.[4]

The internal review that the facility conducted was characterized as a Healthcare Failure Mode and Effect Analysis (HFMEA), which is typically a prospective review, not a retrospective review. Per Veterans Health Administration (VHA) policy, a root cause analysis, which is a retrospective review, must be conducted to evaluate certain events. For example, a root cause analysis must be done for events that, after weighing the severity of harm incurred and the anticipated probability of recurrence of the incident, rate high on a 1–3 scale.[5] When interviewed, the Patient Safety Manager indicated that an HFMEA was done because of the complexity of the events, and the multiple services and facility processes involved. It was

[3] The Behavioral Health Autopsy is a report created by VA staff after a veteran has completed suicide. The Behavioral Health Autopsy Program has a goal of better understanding the context of veterans' lives prior to their suicide through analysis of their medical records and interviews with their families and mental health providers.

[4] The internal review was signed on February 15, 2019.

[5] VHA Handbook, 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

determined that the time frame for completing a root cause analysis (45 days) was too short to evaluate the multiple processes involved in the patient's care. Conducting an HFMEA allowed a longer review period. A VISN 15 manager also informed the OIG that the facility considered the review to be administrative in nature. While the facility characterized the review as an HFMEA, the OIG noted that the review for this patient was retrospective in nature and made recommendations to remedy identified deficiencies. To avoid confusion between the prospective nature of HFMEA and the retrospective nature of a root cause analysis, the OIG recommended that the facility follow VHA guidance related to conducting a root cause analysis for future adverse events.

The OIG made one recommendation to the Executive in Charge related to the planning and implementation of the new electronic health record, and ten recommendations to the Facility Director related to a review of the patient's clinical care, Patient Centered Management Module and provider assignments, designation of surrogates, view alerts, secure messaging communication, patient notification of test results, disclosures of adverse clinical events, and quality management activities related to root cause analysis.[6]

Comments

The Executive in Charge, VISN 15, and Facility Directors concurred with the OIG's recommendations and submitted acceptable action plans. (See appendixes B, C, and D, pages 28–36 for the comments.) The OIG considers all recommendations open and will follow up on the planned actions until they are completed.

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[6] The recommendation for the Under Secretary for Health was submitted to the Executive in Charge who has the authority to perform the functions and duties of the Under Secretary for Health.

Contents

Abbreviations

Choice	Veterans Choice Program
CPRS	computerized patient record system
CT	computed tomography
EHR	electronic health record
ENT	Ear, Nose, and Throat
HFMEA	Healthcare Failure Mode and Effect Analysis
OIG	Office of Inspector General
PACT	patient aligned care team
PCMM	Patient Centered Management Module
PCP	primary care provider
RCA	root cause analysis
SAC	Safety Assessment Code
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate an allegation related to a delay in diagnosis of a patient's cancer at a Veterans Integrated Service Network (VISN) 15 medical facility (facility).[7] The patient subsequently died by suicide.

Background

Coordination of Care

Patient Aligned Care Teams

Veterans Health Administration (VHA) initiated a team-based approach to primary care in 1994 with the goal of providing accessible, timely, and coordinated patient care. In 2009, this approach was officially adopted under the rubric, Patient Aligned Care Team (PACT). VHA further delineated its policy and established procedures for implementation of PACTs to improve coordination and access to care in 2014.[8]

A PACT teamlet consists of a provider, a registered nurse, a licensed practical nurse/vocational nurse/health technician, and a clerk; the teamlet is assigned one entire panel of patients.[9] It is VHA's expectation that team members "meet often to talk with [v]eterans and each other, about the patient's healthcare goals and the progress toward achieving them." The PACT coordinates all aspects of the veteran's health care and collaborates with other care teams as needed to accomplish the veteran's healthcare goals.[10]

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[7] The name of the facility is not being disclosed to protect the privacy rights of the subject of the report pursuant to 38 U.S.C. §7332, Confidentiality of Certain Medical Records, January 3, 2012.

[8] VHA Handbook 1101.10(1), *VHA Patient Aligned Care Team (PACT) Handbook,* February 5, 2014, amended May 26. 2017; Care coordination is the administrative process that aids the patient in accessing healthcare resources in the VA and the community to address their goals and healthcare needs. This can include referrals to other healthcare providers as well as the ordering of tests, imaging studies, or supplies.

[9] VHA Handbook 1101.02. *Primary Care Management Module (PCMM),* April 21, 2009. A panel is the group of veterans assigned to a specific primary care provider or team. This handbook was rescinded and replaced by VHA Directive 1406, *Patient Centered Management Module (PCMM) For Primary Care,* June 20, 2017 which does not specifically include a definition of panel but includes discussion of panel size: "[f]or all PACTs, panel size is the total number of pending and active PCMM PACT assignments."

[10] VHA, Office of Patient Care Services, "Coordinated Care-PACT," September 15, 2016. https://www.patientcare.va.gov/primarycare/pact/coordination.asp. (The website was accessed on January 11, 2019.)

Patient Centered Management Module

VHA implemented a software program in 2009 that was used to assign patients to a care team, generally PACTs, and to track the data for national reporting and performance measurement.[11] In June 2017, VHA enhanced the capabilities of the software and issued Patient Centered Management Module (PCMM) guidelines and business rules with the goal of ensuring reliable and consistent data entry.[12]

PCMM coordinators at each facility are charged with maintaining the currency of the PCMM database information including assignments within the team and assignments of patients to a provider (provider of record).[13] When configured correctly, PCMM enables the use of electronic alerts that notify PACTs when a patient's testing, imaging, and consults are available for review.[14]

Automatic Electronic Alerts

VHA's electronic health record (EHR) system includes the option of automatic electronic alerts (view alerts) that notify facility staff of actionable clinical information such as completion of test results and the status of consults.[15] Facilities may designate certain view alerts as mandatory that providers cannot disable (turn off).[16] For example, facilities may designate view alerts associated with significantly abnormal test results as mandatory.[17] Health informatics staff, such as clinical applications coordinators, set the pre-determined parameters for view alerts.[18]

When providers are scheduled to be out of the office and not available to receive and respond to view alerts for a pre-determined length of time, a staff member of similar professional

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[11] VHA Handbook 1101.02, *Primary Care Management Module (PCMM),* April 21, 2009. Rescinded by VHA Directive 1406, dated June 20, 2017.

[12] VHA Directive 1406, *Patient Centered Management Module (PCMM) For Primary Care*, June 20, 2017. The name of the module was changed in 2017. For this report, the OIG uses the acronym PCMM for both the 2009 and 2017 management modules for ease of readability.

[13] For this report, the OIG uses different terms to describe providers depending on the context of the activity under review: (1) Provider of record is a provider assigned to a patient in PCMM; the provider of record will receive automatic electronic alerts for that patient depending on how the PCMM and the EHR alert packages are configured; (2) Requesting and receiving providers are terms used within the context of clinical consults; and (3) Ordering provider is the term used within the context of the ordering of a test or imaging study; VHA Handbook 1101.02; VHA Directive 1406.

[14] VHA Technical Manual, Computerized Patient Record System (CPRS) V. 1.0. November 2018; VHA Handbook 1101.10(1).

[15] VHA Technical Manual, Computerized Patient Record System (CPRS) V. 1.0. November 2018.

[16] Shear, J, Mercer, Richard, Thaker, K. et al. *Communication of Test Results Toolkit.* April 2012, Links updated 2015.

[17] VHA Technical Manual, Computerized Patient Record System (CPRS) V. 1.0. November 2018.

[18] VHA Technical Manual, Computerized Patient Record System (CPRS) V. 1.0. November 2018.

background (surrogate) must be designated to address the absent provider's view alerts.[19] According to the 2017 PCMM directive, surrogates for PACT staff can be entered in the PCMM. The directive further requires that a service-level official be designated by facility leaders to be responsible for "[i]dentifying teamlet PCMM surrogates to enable the identification of PACT staff members who are responsible for covering the PACT teamlet when staff member absences occur."[20]

Surrogates may also be designated in the EHR by staff or clinical applications coordinators; all view alerts that would be routed to the original staff member will be forwarded to the surrogate for the indicated period of time.[21] At the facility, providers who order imaging studies must document appropriate contact information when an initial order is placed to include "assigning a surrogate to receive abnormal test result notification when they are not available to review results in a timely manner."[22]

Allegation with Related Concerns

The OIG received an allegation in 2018 related to a delay in diagnosis of a patient's squamous cell carcinoma of the neck that involved the base of the tongue. During a preliminary review of the patient's care, the OIG's Office of Healthcare Inspections identified concerns related to the patient's coordination of care, communication of test results, and the facility's response after leaders learned about the course of events that preceded the patient's suicide.

[19] VHA Directive 1406, *Patient Centered Management Module (PCMM) For Primary Care*, June 20, 2017.

[20] VHA Directive 1406. The 2009 directive does not address surrogates.

[21] VHA Technical Manual, Computerized Patient Record System (CPRS) V. 1.0. November 2018.

[22] Facility Policy.

Scope and Methodology

The OIG initiated the inspection on October 2018 and conducted a site visit November 5–9, 2018. The inspection time frame was January 2016 through June 2018. The events under review included care at the facility with references to visits to a second VISN 15 facility. The circumstances surrounding the patient's suicide will be reviewed in a separate report.

The OIG team interviewed staff via telephone and/or in person including the Facility Director (Director), Chief of Staff, Chief of Ambulatory Care, Chief of Radiology, Chief of Surgery, Chief Quality Officer, Risk Manager, Patient Safety Manager, PCMM Coordinator, a clinical applications coordinator, radiation oncologist, facility administrative staff, as well as facility providers and staff knowledgeable of radiology, oncology, and primary care clinical operations.

Team members noted two limitations to the inspection. The first limitation was the unavailability of several PCPs who provided care to the patient during the time frame at issue. The primary care provider (PCP) who ordered the summer 2016 computed tomography (CT) scan of the neck resigned from the VA prior to the OIG initiating the inspection. Two other PCPs left the facility prior to the inspection. The second limitation was the automatic purging of all view alerts (automatic electronic notifications) from the facility's computer system for the time frame at issue that did not allow a full evaluation of the view alert process and/or receipt of the notifications.[23]

The OIG team reviewed relevant VHA and facility directives, policies and procedures, EHRs, and relevant committee meeting minutes.

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

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

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

[23] As determined by the Office of Information and Technology, the purging of view alerts occurred on a daily basis and view alerts older than 185 days were deleted.

Patient Case Summary

The patient, who was in their 60s, had a history of hypertension, hyperlipidemia, macular degeneration, and post-traumatic stress disorder.[24] The patient did not smoke, use illegal drugs, or abuse alcohol. The patient had been regularly receiving care at the facility for over 20 years.

In early 2016, a facility provider (PCP 1) referred the patient through the Veterans Choice Program (Choice) to an Ear, Nose, and Throat specialist (ENT) for complaints of dizziness and nausea.[25] No masses of the head or neck were noted on physical exam.

The patient saw a different provider (PCP 2) in early summer 2016, with complaints of dizziness and chronic sinusitis. PCP 2 ordered an ultrasound of the carotid arteries and a maxillofacial CT scan.[26] The two imaging studies were completed approximately two weeks later. The radiologist noted bilateral neck masses per the ultrasound that were "probably lymphadenopathy," coded the results as abnormal, and recommended a CT scan of the neck.[27] The maxillofacial CT scan showed a deviated nasal septum, minimal right mastoid effusion, and no evidence of sinus infection.[28]

Six days later, the patient sent a secure message to the PACT asking about the imaging studies results (see appendix A for more information related to secure messaging). PCP 3 ordered a CT scan of the neck. A PACT registered nurse documented that the patient was called, "the plan" was relayed, and the patient verbalized understanding and agreement with the plan.

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[24] The OIG uses the singular form of they (their/them) to protect the patient's privacy. *Hypertension* is a long-term condition of high blood pressure that occurs when the force of blood pushing against the walls of the blood vessels is consistently too high, which can lead to heart disease or other complications. *Hyperlipidemia* is a term for several acquired or genetic disorders that increase the amount of lipids (fats, triglycerides, and cholesterol) in the blood. An increase in lipids can lead to a higher risk of stroke or heart attack. *Macular degeneration* is an incurable eye disease caused by the deterioration of the part of the eye that sends pictures of images from the eye to the brain. As defined by the VA National Center for Posttraumatic Stress Disorder, "posttraumatic stress disorder is a mental health problem that some people develop after experiencing or witnessing a life-threatening event, like combat, a natural disaster, a car accident, or sexual assault."

[25] Choice was established by the Veterans Access, Choice, and Accountability Act of 2014. Under this program, VHA contracts with third-party administrators to coordinate purchased care from community-based care providers. A consult and pre-authorization for care in the community are required for services rendered through Choice.

[26] Carotid arteries are the blood vessels that carry blood from the heart to the brain; a maxillofacial CT scan is a diagnostic test that produces multiple images or pictures of the face, the jaw, and the sinuses.

[27] According to the National Cancer Institute, lymph nodes, part of the body's immune system, filter substances that travel through the lymphatic fluid; the nodes contain lymphocytes (white blood cells) that help the body fight infection and disease."

[28] Lymphadenopathy is the swelling of lymph nodes or glands; The nasal passages are separated by a thin wall (septum) that may be displaced or deviated to one side making one nasal passage smaller than the other. A mastoid effusion is a collection of fluid in a bony area of the skull located behind the ear. https://www.merriam-webster.com/dictionary/mastoid; https://www.merriam-webster.com/dictionary/effusion. The maxillofacial CT scan was coded by the radiologist as minor abnormality.

The patient underwent the CT scan of the neck 12 days later. The radiologist noted multiple neck masses consistent with abnormal lymph nodes and reported that the findings likely represented a malignancy that involved the base of the tongue. The radiologist coded the study results as abnormal. Six days after the scan, the patient requested the results of the CT scan by a secure message. A PACT licensed practical nurse responded to the patient, stating that the message would be forwarded to the provider. Although a provider, PCP 4, acknowledged receipt of the nurse's message the next day, the EHR does not contain documentation that PCP 4 communicated the CT scan of the neck results to the patient.

Approximately one month later, the patient presented to the emergency department complaining of sinus problems. Antibiotics were prescribed. No tests or imaging studies were ordered.

In early 2017, the patient saw another provider, PCP 5, who noted enlarged anterior cervical lymph nodes per physical exam. PCP 5 also noted the results of the summer 2016 abnormal CT scan of the neck and the lack of follow-up related to the abnormal imaging study. PCP 5 entered an e-consult to the Hematology/Oncology service explaining PCP 5's temporary status (leaving the facility in a week) and willingness to "push through any preliminary studies to be done prior to initial appointment." (See appendix A for more information related to consults.) The EHR does not contain documentation that PCP 5 notified the patient of the abnormal CT scan of the neck results.

The following month, the e-consult was completed by a hematologist who recommended a surgery consult for a biopsy.[29]

Although PCP 5 planned to leave the facility in early 2017, PCP 5 was still at the facility when the hematologist completed the consult and noted the recommendation for a surgical consult. PCP 5 entered a request for a surgical consult later the same day. However, the request did not specifically indicate the reason for the surgical consult. Three days later, the surgery service added comments to the consult in the patient's EHR asking if the consult was a request for a lymph node biopsy. Additional comments were entered the next week ("please see notes and advise"). When no response to the comments was received from the ordering provider, the consult was discontinued by the surgical service approximately one week later.[30]

In spring 2017, the patient was seen by PCP 6 who noted "posterior pharynx drainage" and a supple neck with "right lymph [node] enlarged." The EHR does not contain documentation of a review of the CT scan of the neck or the two subsequent consults. PCP 6 advised the patient to return to the clinic in one year.

[29] A hematologist is a medical doctor who specializes in blood disorders that include diseases of the lymphatic system; Although the clinically indicated date was for the same day, the consult urgency status was "routine."

[30] The surgical service staff's comment included information that fine needle aspirations were performed at the second VISN 15 medical facility, that the consult was discontinued, and advised the requesting provider to re-consult the surgical service if necessary.

In late summer 2017, the patient sent a secure message with complaints of increased symptoms and requested an ENT consult after an emergency department visit and multiple courses of antibiotics for sinusitis. PCP 7 ordered an ENT consult that was canceled by the ENT service pending a repeat maxillofacial CT scan. Sinus x-rays were completed on three days later.

The next day, the patient sent a secure message requesting the results of the summer 2016 maxillofacial CT scan. The patient's PACT registered nurse responded with the results of the CT scan results and the 2017 sinus x-rays results. The repeat maxillofacial CT scan, ordered by PCP 7, was done about two weeks later and showed no significant change from the summer 2016 maxillofacial CT scan. PCP 7 did not reactivate the consult to ENT.

In early 2018, after the patient had a series of falls,[31] PCP 8 evaluated the patient after ordering and reviewing x-rays and a CT of the knee. PCP 8 entered an orthopedic consult that was completed five days later. The EHR does not contain documentation that PCP 8 reviewed CT scans unrelated to the orthopedic complaints.

In early spring 2018, the patient presented to the emergency department after noting a mass under the chin. The patient complained to the triage nurse of difficulty swallowing for "past weeks." The emergency department provider ordered a CT scan of the neck. The radiologist noted the previously reported enlarged lymph nodes from the summer 2016 CT scan of the neck and a new abnormality at the base of the tongue. The emergency department provider referred the patient to general surgery for a lymph node biopsy.

A facility general surgeon evaluated the patient two weeks later and submitted a consult to the second VISN 15 facility's ENT service for a lymph node biopsy. Various consults and communications occurred over the next several weeks:

- In spring 2018, the second VISN 15 facility ENT service discontinued the surgeon's consult with a note stating a lack of access and inability to accommodate the consult and suggested Choice referral.
- A Choice consult that had been entered and was discontinued as the patient did "… not meet criteria." A new consult was placed for the patient to be seen by a VHA ENT provider at a third VISN 15 facility.
- A non-VA ENT provider evaluated the patient, noted right neck lymphadenopathy, and saw no obvious masses via fiberoptic laryngoscopy.[32] The provider planned to follow up on the previous images.
- The patient secure messaged the PACT about a visit to a non-VA provider who had diagnosed acid reflux and asked that the VA pay for the medication.

[31] Per the EHR, the patient's falls were not associated with reports of lightheadedness or being dizzy.

[32] A fiberoptic laryngoscopy is an examination of the back of the throat by a physician with a flexible scope.

- A week later, the patient secure messaged the PACT: "I just asked [the third VISN 15 facility] if i [*sic*] paid a [non-VA provider to do the biopsy] could i get reimbursed through the VA, and she said no…i feel if something serious is wrong, i will be dead before the VA does anything. Is there any way you can speed up the biopsy at the [second VISN 15 facility] for me? This lengthly [*sic*] ordeal has been a great weight on my mind! Thanks for any help you can give me."
- The third VISN 15 facility ENT provider evaluated the patient, noted a mass on the tongue, and referred the patient for a biopsy.
- The second VISN 15 facility ENT provider evaluated the patient and conducted a fine needle aspiration biopsy.[33] The preliminary diagnosis was squamous cell carcinoma of the tongue with node involvement.[34]
- In summer 2018, the patient underwent a direct laryngoscopy with biopsy that confirmed the squamous cell carcinoma diagnosis.

The patient was referred to the second VISN 15 facility radiation therapy services and was evaluated approximately a week later. The radiation oncology clinic registered nurse documented the patient did not have suicidal or homicidal ideation. The radiation oncologist evaluated the patient and made treatment plan recommendations. The patient completed suicide on the grounds of the facility later that day.

[33] A fine needle aspiration is an ultrasound-guided biopsy that uses sound waves to help locate a nodule or abnormality and remove fluid or a tissue sample for examination under a microscope.

[34] Merck Manual. *Squamous Cell Carcinoma.* Squamous cell carcinoma, which arises from the squamous cells in the skin's outermost layer, is the second most common form of skin cancer. In order to distinguish squamous cell carcinoma from other skin cancers, a biopsy is done to make a diagnosis. When tumors are small and not spread to other areas, treatment is usually curative. https://www.merckmanuals.com/home/skin-disorders/skin-cancers/squamous-cell-carcinoma. (The website was accessed on February 3, 2019.)

Inspection Results

The OIG substantiated a delay in the diagnosis of the patient's squamous cell carcinoma of the tongue and neck. Factors that contributed to the delay included a lack of coordination of care for the patient and a failure to communicate test results (see appendix A for more information related to the communication of test results). The OIG also evaluated the facility's quality management response in reviewing the events that led to the patient's suicide.

1. Coordination of Care

The OIG determined that over the span of almost 20 months, the facility failed to provide a seamless transition for the patient's care when changes in PCPs occurred; and individual providers failed to follow up or share information with other providers related to the patient's abnormal test results.[35] In 2018, another 71 days elapsed between the time the patient was notified of a need for a biopsy during an emergency department visit and care was coordinated for the patient to undergo a fine needle aspiration needed for diagnosis.[36]

2016 Abnormal Imaging Study Results

At the facility, a provider who orders a laboratory test or imaging study receives a view alert when results of the test or study are available and the results are abnormal.[37] During an interview, the OIG was told that once opened, the view alert is automatically deleted and cannot be re-reviewed by the provider. The view alert includes a categorization of normal versus abnormal results, known at the facility as a "code." While providers may elect to "turn off" some view alerts, facility providers are not able to disable the receipt of view alerts associated with abnormal test results, one of the facility's mandatory view alerts.

In early summer 2016, the patient's then-assigned PCP (PCP 2) ordered imaging studies (carotid ultrasound and maxillofacial CT scan) but resigned from the facility before the tests were completed. About a week after the tests were done, when the patient contacted the assigned PACT team for the results, PCP 3, who was in the clinic that day, reviewed the results and noted that a different CT scan was needed to further evaluate the ultrasound results that had been coded as abnormal.[38] PCP 3 ordered a CT scan of the neck. The patient was notified of the need for a CT scan of the neck. The radiologist issued results that day and noted multiple abnormal neck masses that likely represented a malignancy. The radiologist coded the summer 2016 report as

[35] Action was not initiated relative to the patient's summer 2016 abnormal second CT scan until spring 2018.

[36] The patient was notified of a need for a biopsy spring 2018 and underwent an initial diagnostic test in early summer 2018.

[37] VHA Technical Manual, Computerized Patient Record System (CPRS) V. 1.0. November 2018.

[38] PCP 3 was no longer employed at the facility and was subsequently not interviewed.

abnormal which would have generated a view alert to the provider of record and the ordering provider.[39]

Although PCP 2 left the facility in early summer 2016, PCMM listed the provider of record as PCP 2 until fall 2016. Therefore, the provider of record was not available to receive the abnormal summer 2016 CT scan of the neck view alert. While the facility did not provide specific information about this patient's PCMM 2016 assignment, the PCMM coordinator told the OIG that facility practice was to leave patients assigned to previous providers until a new provider was available. Different providers "covered" the position in the interim. The facility's policy that discusses the designation of surrogates for receiving view alerts related to abnormal imaging studies does not address surrogates for providers who leave the facility.[40] Had the patient been reassigned to another provider in PCMM in a timely fashion, a newly assigned provider of record may have been available in summer 2016 to receive the abnormal results and taken action.

As the ordering provider, PCP 3, who was responsible for notifying the patient of the abnormal test results and follow-up, should have received a view alert when the summer 2016 imaging study results were available. The patient's EHR contains no evidence that PCP 3 took action related to the abnormal CT scan of the neck results. According to facility clinic leave documentation, it appears that PCP 3 was available on the date the view alert would have been sent; however, the facility was unable to track whether PCP 3 received and/or opened this view alert because all view alerts for the relevant time frame were purged from the system per routine deletion procedures in 2017.[41]

Approximately a week after the summer 2016 CT scan, the patient asked through a secure message, "[a]re there any significant results to the CT scan of my neck and head that was done a little over a week ago?" The next day, the licensed practical nurse responded to the patient that the patient's message would be forwarded to the PCP for review and the patient would be contacted with the results. The licensed practical nurse then entered a note in the EHR asking the PCP to contact the patient with test results, and PCP 4 acknowledged receipt of the note.[42] However, the EHR contains no evidence that PCP 4 took action related to the abnormal results.[43]

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[39] VHA Technical Manual, Computerized Patient Record System (CPRS) V. 1.0. November 2018.

[40] A surrogate is a specific individual in a similar role that is assigned to cover for the corresponding PACT staff-member during short-term or unplanned absences. VHA Directive 1406, *Patient Centered Management Module (PCMM) For Primary Care,* June 20, 2017.

[41] When interviewed, facility staff were unable to identify whether PCP 3 had been officially designated as a surrogate for PCP 2 who had left the facility or whether PCP 3 had designated a surrogate for himself for the time frame at issue. PCP 3 had left the VA before the OIG initiated this inspection. Per the OIG team's review of the clinic's schedule for summer 2016, it appears that PCP 3 was present in the clinic during the time frame at issue and would have been able to access the view alert at issue had the PCP received one.

[42] PCP 4 was no longer employed at the facility and was not interviewed.

[43] The failure to communicate the abnormal test results is discussed in Issue 2.

In early fall 2016, PCP 4 was reassigned to the patient in PCMM. Although assigned to the patient for several months, the EHR indicates that PCP 4 had no direct contact with the patient. The OIG was informed that view alerts sent to the previous provider of record would not be automatically re-routed to a newly assigned provider.

2017 Hematology/Oncology and Surgical Consults

In early 2017, the patient was seen by a contracted locum tenens physician (PCP 5).[44] PCP 5 planned on leaving the facility in approximately a week's time. Upon review of the patient's EHR, PCP 5 noticed that the abnormal 2016 CT scan of the neck results had not been addressed. PCP 5 attempted to expedite the patient's care with a hematology/oncology e-consult. While PCP 5 informed the OIG that, as the usual course of business, the 2016 abnormal imaging studies would have been discussed with the patient, PCP 5 did not document a discussion of the results with the subject patient.

For 30 days, no action was taken on PCP 5's submitted hematology/oncology e-consult. A hematologist completed the consult the next month with a recommendation to refer the patient to surgery for a biopsy. PCP 5's time at the facility was extended, the EHR noted the hematologist's recommendation for a biopsy, and PCP 5 entered a surgical consult that day. PCP 5 reported to the OIG in an interview that the surrogate would have received all view alerts, and this may have included view alerts related to the surgical consult but was uncertain if this occurred.[45]

According to one of the facility's clinical applications coordinators, the ordering provider, but not the provider of record in PCMM, automatically receives a view alert when comments are added to a consult by the receiving provider and/or when the consult is discontinued. The requesting provider may also configure and manually add the name of other providers to receive an alert. According to an interview, the Chief of Ambulatory Care was unaware of PCP 5's submission of a consult on the PCP's last day at the facility.

However, had view alerts been configured for PCP 5 to receive notifications of changes made to the consult request by the receiving provider, PCP 5 would not have been available or able to receive them, and would not have had access to the patient's EHR after that date. OIG inspectors found no documented evidence that a provider responded to the surgical consult view alerts.

Between the discontinued early spring 2017 surgical consult and the 2018 emergency department visit when a second surgical consult was ordered, the patient was evaluated for orthopedic

[44] A locum tenens physician is a healthcare provider who is temporary or short-term.

[45] PCP 5 indicated speaking with the patient's next assigned PCP (PCP 6), but the conversation was not documented; it is therefore unknown if information about this patient was discussed during that contact. When interviewed, PCP 6 confirmed being familiar with PCP 5.

complaints and underwent left knee surgery at a non-VA medical facility, was seen on three occasions in the emergency department, and had multiple PACT team contacts.[46] Other than PCP 5 in early 2017, the patient's medical care providers failed to discover or take action related to the summer 2016 abnormal test results, the discontinued surgical consult, and/or the requests by the patient to obtain the summer 2016 CT scan results until spring 2018.

Between late fall 2015 and early summer 2018, the patient was assigned and reassigned in PCMM to eight providers. On at least one occasion, as noted previously in this report, the assignment in PCMM did not accurately reflect the provider of record for almost three months.[47]

In 2018, another 71 days elapsed between the time the patient underwent a second CT scan of the neck that showed additional abnormalities and the patient was notified during an emergency department visit of a needed biopsy. The patient then underwent a fine needle aspiration biopsy. During that time, the patient was evaluated by a facility staff surgeon and referred to the second VISN 15 facility ENT service. Due to access issues, the patient was referred to Choice for non-VA care. Due to a failure to meet the criteria for Choice, the patient was referred to the third VISN 15 facility ENT. When the patient was seen by the third VISN 15 facility ENT service in late spring 2017, the patient was referred back to the second VISN 15 facility ENT who performed a fine needle biopsy in early summer 2018.

The OIG was unable to identify a standardized process for orienting new-to-VA and/or newly hired PCPs to the outstanding needs of their assigned patients that would avoid gaps in care. One interviewee stated PCP orientation was minimal, training related to the computer system was negligible, and previously assigned providers were generally not available for hand-off communications. Additionally, the interviewee stated the intense workload allowed little time with each patient.

Although the Chief of Ambulatory Care informed the OIG that PCPs were aware of the surrogacy system in 2016, the OIG was unable to identify or track the process for this patient in either document reviews or in interviews with available providers. Similarly, the OIG was unable to track the surrogate process for the early 2017 surgical consult.

The OIG concluded that inaccurate data entry in the PCMM system used for directing view alerts to the ordering provider and/or the provider of record, and deficiencies in the surrogate process contributed to a failure of coordinated care for this patient. The OIG was unable to fully evaluate the receipt of view alerts due to a purging of notifications for the time frame at issue.

[46] The patient was also seen multiple times by mental health providers; however, mental health providers would not normally review a patient's EHR for non-mental health-related conditions. The OIG inspectors did not find evidence of discussion of a mental health condition related to the unreported test results in the EHR that might have triggered a mental health provider to review non-mental health-related records.

[47] The eight assignments involved a total of six providers. The patient was reassigned to the same provider on two occasions.

Alternatively, providers did not take timely action if/when view alerts or other communications were received; failed to designate surrogates or communicate crucial outstanding patient care information to other providers; and failed to review the patient's history during assessments.

The OIG was unable to determine the impact of the 71-day lapse, between notification of the need for a biopsy and the fine needle aspiration, on the patient's medical care. When interviewed, the radiation oncologist who evaluated the patient in early summer 2018 opined that the squamous cell carcinoma appeared to still be localized and the prognosis was 50–60 percent curative at the time of this assessment; in mid-summer 2016, the prognosis may have been 70–80 percent curative.

2. Communication of Test Results

The OIG did not find evidence in the patient's EHR of timely notification of the abnormal summer 2016 CT imaging study results or that the patient was informed of the need to undergo a surgical evaluation in 2017. Despite requests from the patient via secure messages related to obtaining test results and numerous opportunities for patient notification, staff did not document in the EHR that they had informed the patient of the summer 2016 abnormal CT scan of the neck results, the need for a surgical evaluation in 2017, or the clinical significance of the abnormal results before early spring 2018.

Facility Responsibilities

In 2015, VHA policy delineated responsibilities related to the patient notification of test results to medical facility leaders that included the need for "the delegation of clear responsibility and accountability related to test result follow-up; especially when multiple providers are involved in the care of the patient."[48] Guidance in successfully accomplishing this goal included tips on how medical facilities could set up view alerts, designate surrogates, and the need to train providers to be proficient with managing view alerts and patient notifications.[49] VHA policy also states

> Patient notifications and subsequent clinical actions must be documented in CPRS [computerized patient record system] by the ordering provider(s) or designee(s) in response to critical, urgent, and clinically significant test results that require therapeutic intervention or action. If results are discussed within a patient visit, this should be documented within the visit progress note. The extent of documentation may vary

[48] VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.

[49] VHA Directive 1088. Patient notification methods include notification by letter, secure messaging, or face-face visit.

depending on the context of the test result and resultant action plan or therapeutic intervention.[50]

The facility's 2016 policy regarding communication of critical and abnormal results required ordering providers to take appropriate action for results of any orders that were placed, including assignment of a surrogate "when they are not available to review results in a timely manner."[51] Per the facility Chief of Ambulatory Care, providers were aware of the need to designate a surrogate in 2016; however, staff noted their confusion as to the specifics of how and when.

Provider Responsibilities

VHA policy indicated that individual providers who ordered the tests were responsible for all results unless providers made clear, mutually agreeable arrangements with a surrogate provider.[52] This responsibility included patient notification of test results.

During interviews, OIG inspectors determined that facility providers were not clear about how to, or who should, designate a surrogate, which view alerts were mandatory, and other pertinent information related to providers' responsibility to ensure the patient received proper notification of test results.

2016 Evaluations or Contacts without Documented Patient Notification

PCP 3 ordered the summer 2016 CT scan of the patient's neck that was reported abnormal. The OIG inspectors found no evidence of arrangements for a designee by PCP 3 who would be responsible for informing the patient of abnormal test results. Further, although PCP 3 was not assigned to the patient, PCP 3 had primary responsibility to notify the patient of the test results. Additionally, the OIG team found no evidence that PCP 3 sent the patient a notification letter or discussed the results. The patient was not seen or examined by PCP 3 while PCP 3 was employed at the facility. Therefore, PCP 3 did not have the opportunity to inform the patient of the test results during a face-to-face clinic visit. OIG inspectors found no evidence that PCP 3 ordered further tests or consulted with other physicians to evaluate the abnormal test results.

When the patient requested results of the CT scan of the neck in summer 2016, through a secure message, a PACT licensed practical nurse responded that a provider would be notified of the request and would contact the patient with the results. PCP 4, who was eventually assigned to the patient in PCMM in fall 2016, acknowledged receipt of the PACT licensed practical nurse's message the same day. The OIG found no evidence that PCP 4 sent the patient a notification

[50] VHA Directive 1088.

[51] Facility Policy.

[52] VHA Directive 1088.

letter, spoke with the patient about the results, or took action to further evaluate the abnormal test results. PCP 4 was eventually assigned to the patient but had no direct contact with the patient before the patient was reassigned to another PCP; therefore, PCP 4 had no opportunity to inform the patient of the abnormal test results during a clinic visit.

In late summer 2016, the patient was seen in the facility emergency department with complaints of sinus problems. The emergency department provider ordered an antibiotic but did not order laboratory tests or imaging studies in the EHR on this day.

2017 Evaluations or Contacts without Documented Patient Notification

During the early 2017 clinic visit with PCP 5, PCP 5 noticed neck lymphadenopathy and the lack of follow-up on the abnormal CT scan of the neck. PCP 5 took action by submitting consults to two specialty services.[53] While PCP 5 informed the OIG that as a practice, the results of the abnormal test would have been discussed with the patient, PCP 5 did not document a discussion of the results with the patient. Without documentation of this discussion and the patient's lack of secure messages regarding this discussion, the OIG could not conclude that the patient was aware of the abnormal results or their possible clinical significance. The OIG also concluded that the patient was likely unaware of PCP 5's two efforts to contact specialty teams in early 2017; the first 2017 consult was an e-consult that did not require contact with the patient; and the patient did not question the PACT as on other occasions about abnormal test results or request additional follow-up until four months later when the patient wanted to be evaluated for sinusitis.

Other opportunities for patient notification of abnormal test results and follow-up occurred in spring and summer 2017. The provider who was assigned to the patient in spring (PCP 6) evaluated the patient during a routine annual exam and noted an enlarged lymph node on the right side of the neck that was otherwise supple. PCP 6 noted some drainage in the back of the patient's throat with mild redness in the area and ordered an antibiotic. According to an interview, PCP 6 did not conduct a comprehensive review of the patient's EHR and was unaware of the summer 2016 abnormal CT scan of the neck results and the consults that PCP 5 had submitted in early 2017.

In summer 2017, the patient was seen in the emergency department for complaints of sinusitis. The emergency department provider ordered another round of antibiotics. Approximately two weeks later, another PCP (PCP 7), who had been assigned to the patient since the visit to PCP 6 in spring 2017, evaluated the patient, did not notice any neck masses, and ordered antibiotics.[54]

[53] The hematology/oncology consult was an e-consult and did not require contact with the patient. The oncologist recommended a surgical evaluation. PCP 5 submitted a surgery consult but it was closed when PCP 5, whose last day was the day the surgical consult was submitted, did not respond to questions about the patient's history.

[54] PCP 7 was no longer employed at the facility and was not interviewed.

In late summer, PCP 7 ordered sinus x-rays and then a maxillofacial CT scan. Before the maxillofacial CT scan was done, the patient requested the results from the 2016 maxillofacial scan in a secure message. A PACT nurse responded: "Results of CT: Impression: No evidence of sinusitis. Deviated nasal septum. Minimal right mastoid effusion."

Between summer 2016 (first abnormal CT scan of the neck) and spring 2018 (second abnormal CT scan of the neck), multiple facility providers evaluated the patient for various reasons. The patient was seen by mental health, ophthalmology, and orthopedic providers. The OIG team did not identify documented complaints that would have triggered a provider to review previously ordered tests and test results.

3. Facility Response

As part of its quality management process, the facility began a review of the patient's course of events at the time of the suicide in 2018. Facility managers alerted VISN 15 staff via an issue brief, requested peer reviews of all relevant providers, and completed the required Behavioral Health Autopsy report (see appendix A for more information related to a Behavioral Health Autopsy report). The OIG did not find documentation of a clinical or institutional disclosure in the patient's EHR related to a delay in the notification of the summer 2016 abnormal test results or diagnosis of squamous cell carcinoma to the patient or family members (see appendix A for more information related to an institutional disclosure). The facility did not initiate a fact-finding review or an administrative investigative board; an Healthcare Failure Mode and Effect Analysis (HFMEA) was initiated rather than a root cause analysis (RCA) (see appendix A for more information related to HFMEAs and RCAs).

Disclosures

Clinical Disclosure

Per VHA policy, "as a general rule, documentation of a clinical disclosure is required when harm is more than minor."[55] (See appendix A for more information about clinical disclosures.)

PCP 5, who evaluated the patient in early 2017, informed OIG inspectors that while PCP 5 did not document disclosing the delay of abnormal test results to the patient, it would have been usual practice to convey such information to patients.

The emergency department provider who evaluated the patient in early spring 2018 did not document disclosing the delay in notification of abnormal test results to the patient. When

[55] VHA Handbook 1004.08; VHA Directive 1004.08 contains the same or similar language related to documentation of clinical disclosures.

interviewed, the provider did not remember what was told to the patient but emphasized that follow-up was important and to call if no one called the patient.

OIG inspectors found no documentation of a clinical disclosure to family members regarding the patient's delay in diagnosis when the family was informed of the patient's suicide in 2018.

The lack of patient notification and follow-up on the 2016 abnormal test results were more than minor lapses in care. Therefore, if the providers disclosed such events to the patient or the family as part of the clinical disclosure process, documentation of the disclosure was required. The OIG found no evidence of documentation of a clinical disclosure in the EHR.

Institutional Disclosure

Per VHA policy, "an institutional disclosure must be performed regardless of when the event is discovered." While "disclosure *may* be delayed to allow for a thorough investigation of the facts provided," the expectation is that the institutional disclosure be initiated "as soon as reasonably possible."[56] Per facility policy

> In some cases, it may be apparent that an adverse event has occurred, but its cause is not clear. In those situations, the Veteran and/or the Veteran's personal representative needs to be told what has occurred and what is known about the problem. They need to be informed as to whether the problem is being investigated and if additional information will be provided to them once a review is completed.[57]

When interviewed in late 2018, facility staff members informed OIG inspectors that an institutional disclosure had not been done because it was not known yet what had happened. Facility managers determined that an HFMEA should be completed before an institutional disclosure took place. However, according to facility policy, in situations when information is unknown about an adverse event, facility managers had a responsibility to inform the patient's personal representative about what was known, that the problem was being investigated, and that additional information would be available once the review was completed.

HFMEA

Per VHA policy, an RCA must be conducted to evaluate Safety Assessment Code (SAC) 3 events (see appendix A for more information related to SAC scoring). The Patient Safety Manager rated this patient's death to be a SAC 3 (see appendix A for more information related to patient safety).[58] When interviewed, the Patient Safety Manager indicated that based on the

[56] VHA Handbook 1004.08; VHA Directive 1004.08 contains the same or similar information related to institutional disclosures.

[57] Facility Policy.

[58] VHA Handbook 1050.01.

complexity of the events, the multiple services and facility processes involved, and after consultation with facility leaders, the decision was made to conduct an HFMEA rather than an RCA despite the SAC 3 score.[59] The Patient Safety Manager considered the time frame for completing an RCA (45 days) to be too short to evaluate the multiple processes involved in the patient's care. Conducting an HFMEA allowed a longer review period.[60] A VISN 15 manager also informed the OIG that the facility considered the review to be administrative in nature. While the facility characterized the review as an HFMEA, the OIG noted that the HFMEA for this patient was retrospective in nature and made recommendations to remedy identified deficiencies. To avoid confusion between the prospective nature of HFMEA and the retrospective nature of an RCA, the OIG recommended that the facility follow VHA guidance related to conducting an RCA for certain future adverse events.

[59] When requested by the OIG, neither the facility nor the VA National Center for Patient Safety were able to provide documentation concerning a consult regarding use of an HFMEA versus an RCA.

[60] The Patient Safety Manager informed the OIG that the event was not being investigated, but the facility opted to perform a retrospective review of areas for improvement to prevent future occurrences.

Conclusion

The OIG substantiated a delay in the diagnosis of the patient's squamous cell carcinoma of the tongue and neck related to multiple deficiencies in the coordination of care and communication of abnormal test results. The first identified opportunity for diagnosis was summer 2016, when the patient underwent a CT scan of the neck that showed lymph node abnormalities. The patient was not notified of the results for many months despite a request sent via secure messaging specifically asking about the results.

The patient was evaluated by five different PCPs over the two years before the suicide and assigned to eight different providers in PCMM between fall 2015 and summer 2018. A failure to update data in PCMM at the time the imaging studies were ordered in summer 2016 may have contributed to poor coordination of the patient's care, failure of view alerts to be directed to the assigned provider, and lack of patient notification of test results.

Individual providers failed to designate surrogates, did not take timely action if/when view alerts or other communications were received, did not communicate crucial outstanding patient care information to other providers, and failed to review the patient's history during assessments.

Similarly, providers failed to communicate test results to the patient. The patient had two CT scans (a maxillofacial scan categorized as a minor abnormality and a neck scan with a possible malignancy). While the patient eventually received results of the maxillofacial scan in spring 2017, the EHR contains no documentation that the patient received the results of the CT scan of the neck until spring 2018, when a neck scan was repeated.

Facility managers did not conduct a fact-finding or other administrative review. Disclosure to the patient or patient's representative had not taken place as of February 11, 2019.

The OIG is concerned that as part of their quality management process, facility leaders elected to conduct an HFMEA rather than an RCA. The OIG noted that the HFMEA, although generally used for prospective reviews, was retrospective in nature for this patient and the reviewers made recommendations to remedy identified deficiencies. To avoid confusion regarding the decision of which review to perform in the future, the OIG recommended that the facility follow VHA guidance related to adverse events that require an RCA review.

Recommendations 1–11

1. The Under Secretary for Health ensures that the planning and implementation of the new electronic medical record includes, (a) a fail-safe system that allows communication and tracking of test results to multiple clinical staff members who coordinate patient notification, appropriate follow-up testing and clinical management, and (b) the ability to monitor actions taken by the responsible provider(s).

2. The Veterans Integrated Service Network 15 Medical Facility Director initiates an administrative review of the clinical care the patient received and takes action as appropriate based on the results.

3. The Veterans Integrated Service Network 15 Medical Facility Director ensures that Patient Centered Management Module provider and patient assignments are timely, and data are validated as required by Veterans Health Administration policy.

4. The Veterans Integrated Service Network 15 Medical Facility Director issues guidance that establishes a clearly-defined process for the designation of surrogates to include abnormal test results and consults.

5. The Veterans Integrated Service Network 15 Medical Facility Director confirms that once issued, providers are trained on the process for designation of surrogates and monitor compliance.

6. The Veterans Integrated Service Network 15 Medical Facility Director reviews current view alert parameters, evaluates providers' knowledge and management of view alerts, and takes action, as necessary, to ensure and monitor compliance.

7. The Veterans Integrated Service Network 15 Medical Facility Director evaluates communication among Patient Aligned Care Team members, including the sharing of, the timeliness of, and the response to patient secure messages, and takes action based on the evaluation.

8. The Veterans Integrated Service Network 15 Medical Facility Director reviews processes within Primary Care related to patient notification of test results and takes action to ensure test results are communicated to patients as required by Veterans Health Administration policy.

9. The Veterans Integrated Service Network 15 Medical Facility Director reviews Veterans Health Administration and the Veterans Integrated Service Network 15 Medical Facility policies concerning disclosure of adverse events to patients and/or their representatives and ensures that staff are aware of discussions and documentation required to comply with these policies.

10. The Veterans Integrated Service Network 15 Medical Facility Director reviews the events in the patient's care and conducts additional actions related to the disclosure of adverse events to

the patient's representative as warranted by Veterans Health Administration and Veterans Integrated Service Network 15 Medical Facility.

11. The Veterans Integrated Service Network 15 Medical Facility Director reviews quality management practices and ensures compliance with Veterans Health Administration guidance related to root cause analysis when future adverse events are identified and takes action as necessary.

Appendix A: Additional Background

Behavioral Health Autopsy Program

In November 2012, VHA implemented the Behavioral Health Autopsy Program requiring suicide prevention coordinators to complete an EHR review and analysis within 30 days of their awareness of a veteran's death by suicide.[61] Suicide prevention coordinators conduct the analysis using an EHR template that includes relevant historical events and medical history and then submit the collected information to VHA's national Mental Health Services Suicide Prevention Program.[62] VHA does not require VISN and facility leaders to review the information prior to submission; however, facility leaders may require staff to submit it for their review prior to transmitting the information. Behavioral Health Autopsies are protected information and are used for quality improvement purposes.

Clinical and Institutional Disclosures

VHA policy states that adverse events are "occurrences of harm or potential harm directly associated with care or services provided within the jurisdiction of the Veterans Healthcare System."[63] VHA policy further requires

> …clinical disclosure of adverse events is a process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the patient's care.[64]

VHA policy also states that institutional disclosure

> …is a formal process by which facility leader(s) together with clinicians and others, as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is

[61] VA Deputy Under Secretary for Health for Operations and Management, Memorandum - *Behavioral Autopsy Program Implementation,* December 11, 2012.

[62] VA Deputy Under Secretary for Health for Operations and Management, Memorandum - *Behavioral Autopsy Program Implementation*, December 11, 2012.

[63] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012, corrected copy October 12, 2012. This handbook was rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events*, October 31, 2018. The 2018 directive contains the same or similar language regarding clinical disclosure.

[64] VHA Handbook 1004.08, VHA Directive 1004.08 contains the same or similar language as the handbook regarding clinical disclosure.

> reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse.[65]

Additionally, institutional disclosure may follow a clinical disclosure and contribute to a series of conversations that occurs between the facility and the patient as information is gathered from investigations or other reviews.[66] In situations where the cause of the adverse event is unclear, the patient or the patient's representative should be told what is known at the time and that additional information will be provided once investigations or reviews are complete.[67]

Communication of Test Results and Patient Notification

In October 2015, VHA issued Directive 1088 that required medical facility directors to develop a written policy related to communication of test results to providers and patients. The directive states that

> …all test results requiring action must be communicated by the ordering provider, or designee, to patients no later than 7 calendar days from the date on which the results are available. For test results that require no action, results must be communicated by the ordering provider, or designee, to patients no later than 14 calendar days from the date on which the results are available. Depending on the clinical context, certain test results may require review and communication in shorter time frames.[68]

The PACT PCP may delegate other PACT members to inform patients of test results but the PCP is responsible for "appropriate clinical actions" and follow-up.[69] PACT staff may communicate test results in person during a face-to-face visit, by phone, in writing, or via a secure message. The PCP or designated staff must document the communications in the patient's EHR, including notification from the laboratory to ordering provider, and note any patient concerns.[70] Documentation must include clinical actions taken in response to critical, urgent, and clinically significant abnormal diagnostic results.

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[65] VHA Handbook 1004.08; VHA Directive 1004.08 contains the same or similar language as the handbook regarding institutional disclosure.

[66] VHA Handbook 1004.08.

[67] VHA Handbook 1004.08.

[68] VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.

[69] VHA Directive 1088; Appropriate clinical action and follow up in the context of this report are interpreted to mean: notify the patient of the abnormal test results, verify their understanding of the significance of the finding, refer them to the correct specialist, assist with getting a timely appointment with the specialist; monitor the course of treatment, and/or refer to other specialists as needed.

[70] VHA Directive 1088.

Consult

Accomplishing the veteran's healthcare goals often requires coordination of care with providers outside of primary care, called specialty care.[71] When a veteran requires the services of a specialty care provider, the PACT provider (requesting provider) submits a consult request through the EHR system. The specialty care service receiving the consult request (receiving provider) is responsible for taking appropriate actions.[72] The requesting and receiving providers may communicate via questions and comments entered in the EHR consult request.[73] After addressing the purpose for the consult request, which generally includes scheduling the patient for an appointment and completing a face-to-face evaluation, the receiving provider must follow the approved process after care is rendered to complete the consult. The requesting provider can access the consult document in the EHR and view the information supplied by the specialty care staff.[74]

Providers may request an e-consult that allows the receiving provider to respond to the request without a face-to-fact visit with the patient. An e-consult may be submitted when the requesting provider is seeking an opinion or when necessary prerequisite tests or treatments have not yet been completed. Providers are encouraged to use e-consults "to the extent possible because they often allow the consult question to be answered more quickly."[75] When an e-consult is submitted, the requesting provider includes a time frame for when the e-consult should be completed.[76]

Healthcare Failure Mode and Effect Analysis

VHA staff use the HFMEA evaluation tool to identify system weaknesses and potential failure modes within a healthcare system. HFMEA offers users analytical data that enable a team to proactively identify and address vulnerabilities.[77] Unlike an RCA that is a retrospective analysis,

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[71] "Specialty care is the provision of specialist or sub-specialist advice and treatment. Specialty care provides veterans with clinical advice, diagnosis, and treatment related to the special training and expertise of the provider."

[72] VHA Directive 1232(1), *Consult Processes and Procedures*, August 24, 2016, amended September 23, 2016. Actions include requesting additional testing prior to scheduling the patient for an appointment or adding comments to clarify the request. Adding comments may trigger an alert to the requesting provider depending on the consult notification setup.

[73] VHA Directive 1232(1).

[74] VHA Directive 1232(1).

[75] VHA Directive 1232 (1).

[76] VHA Directive 1232(1); Acting Deputy Under Secretary for Health for Operations and Management, *Update to Workload Specifications for the Electronic Consult (E-Consult) Program,* January 10, 2014. The two acceptable time frames (urgency status) are routine and stat (immediate). For routine consults, the requesting provider enters a date (clinically indicated date) that they would expect the e-consult to be completed. If the requesting provider needs an immediate response, the requestor must contact the receiving provider to discuss the patient's situation.

[77] Joseph DeRosier, PE, CSP, Using Health Care Failure Mode and Effect Analysis™, May 2002.

an HFMEA is an analysis of a single topic or system within the organization before an event occurs. An HFMEA also differs from an RCA in its single topic focus of evaluation, reporting requirements and senior-level oversight, and emphasis on process over chronological flow of events.[78] As the HFMEA process is used to identify risks to prevent future patient harm, information in HFMEA reports is not generally protected under 38 USC § 5705.[79] However, if there are data or documents held confidential or privileged under 38 USC § 5705 that have been incorporated into the HFMEA report, then that specific information will be deemed protected data.

Patient Safety

The goal of the VHA Patient Safety Program is to prevent harm to patients and take appropriate steps to form a "culture of safety."[80] VHA requires compliance with The Joint Commission standards including that "leaders create and maintain a culture of safety and quality throughout the hospital."[81] According to the Agency for Healthcare Research and Quality, the key components of a "culture of safety" are to prevent or reduce errors and improve overall healthcare quality through

- Acknowledgement of the high-risk nature of healthcare activities and the determination to achieve consistently safe operations,
- A blame-free environment,
- Encouragement of collaboration across disciplines to seek solutions to patient safety problems, and
- Organizational commitment of resources to address safety concerns.[82]

[78] Using Health Care Failure Mode and Effect Analysis™, May 2002.

[79] 38 USC § 5705 is a law that provides protections to documents created by the VA as part of a "medical quality-assurance program" and restricts access to those documents to only certain individuals and agencies.

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

[81] The Joint Commission Standard LD.03.01.01. https://e-dition.jcrinc.com. (The website was accessed on July 6, 2018); VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Program*, May 9, 2017.

[82] U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, Patient Safety Primer, *Culture of Safety*, June 2017. https://psnet.ahrq.gov/primers/primer/5/culture-of-safety. (The website was accessed on July 3, 2018).

A safety culture approach seeks to identify and address systems issues that lead individuals to engage in unsafe behaviors, while maintaining individual accountability. The traditional culture of individual blame impairs the advancement to a safety culture.[83]

Root Cause Analysis

An RCA is a focused review that seeks to understand why a patient safety event occurred, and to identify system improvements to prevent a recurrence of the same issues. RCAs are conducted for quality improvement purposes and considered confidential. RCA results must be communicated to the VISN and the National Center for Patient Safety for tracking and trending purposes.[84]

VHA defines adverse events that may require an RCA as "untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within a VHA facility."[85] Sentinel events are the most serious types of adverse events defined as unexpected occurrences involving death, serious physical or psychological injury, requiring immediate investigation and response, for example an RCA.[86]

Safety Assessment Code

VHA requires patient safety managers to evaluate every reported patient safety event and assign a Safety Assessment Code (SAC) score using a matrix that weighs the severity of harm incurred by the patient and the anticipated probability of recurrence of the incident. SAC ratings range from 1 (lowest magnitude) to 3. The SAC rating dictates whether additional investigation or action is required relating to the patient safety event. For example, an CA) must be conducted for any incident that is rated as SAC 3.[87]

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[83] U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, Patient Safety Primer, Patient Safety Network *Culture of Safety*.

[84] VHA Handbook, 1050.01; The National Center of Patient Safety is a national office aligned under VHA's Office of Quality, Safety, and Value that works to promote a culture of safety in VA medical facilities. https://www.patientsafety.va.gov/. (This website was accessed on February 3, 2019.)

[85] Iatrogenic means inadvertent or unintentional illnesses, infections, or injuries that often occur as a result from being in a hospital. https://www.merriam-webster.com/dictionary/iatrogenic. (The website was accessed January 31, 2019); VHA Handbook, 1050.01.

[86] VHA Handbook 1050.01.

[87] VHA Handbook, 1050.01.

Secure Messaging

VHA launched an internet-based portal, My Health*e*Vet[88] in 2003 that allows veterans to access their personal health information online.[89] The portal offers an email-type service, Secure Messaging, for veterans to communicate electronically with their healthcare teams.[90] Veterans are encouraged to use Secure Messaging to make non-urgent inquiries about their personal health, provide updates on their health conditions, request medication renewals or referrals to specialists, and make administrative inquiries. On the rare occasion that a veteran sends a secure message related to an urgent or emergent matter, the PACT member responding to the secure message should not reply via Secure Messaging but use other more emergent communication to the veteran.[91] For non-urgent, non-emergency messages, care teams should respond within three federal business days.

Secure messages that are clinically pertinent require a provider's (or qualified non-physician healthcare professional) review and "clinical decision making is performed at some level with the care plan being communicated to the patient electronically."[92] When a PACT member is not available to respond to a secure message, users have the ability to designate a surrogate to act in their stead.

[88] My Health*e*Vet is an internet-based portal which allows veterans to access their Personal Health Record, link to resources, and communicate with VHA providers. https://www.myhealth.va.gov/. (The website was accessed on January 23, 2019.)

[89] Mazmanian, Adam. My HealtheVet Turns 15. https://fcw.com/articles/2018/12/17/va-myhealthevet-turns-fifteen.aspx. (The website was accessed on February 2, 2019.)

[90] VA Secure Messaging. https://www.va.gov/health-care/secure-messaging/. (The website was accessed on February 2, 2019.)

[91] My Health*e*Vet. Secure Messaging Examples, Documentation and Information. May 2016.

[92] My Health*e*Vet. Secure Messaging Examples.

Appendix B: Executive in Charge Comments

Department of Veterans Affairs Memorandum

Date: May 17, 2019

From: Executive in Charge, Office of the Under Secretary for Health (10)[93]

Subj: OIG Draft Report, Delay in Diagnosis and Subsequent Suicide at a Veterans Integrated Service Network 15 Medical Facility

To: Assistant Inspector General for Healthcare Inspections (54)
Director, GAO/OIG Accountability Liaison (GOAL) Office (VHA 10EG GOAL Action)

1. Thank you for the opportunity to review the Office of the Inspector General (OIG) draft report on Delay in Diagnosis and Subsequent Suicide at a Veterans Integrated Service Network 15 Facility. I concur with the recommendation 1 and provide the attached action plan.
2. If you have any questions, please email Karen Rasmussen, M.D., Director, GAO OIG Accountability Liaison at VHA10EGGOALACTION@va.gov.

(*Original signed by*:)
Richard A. Stone, M.D.

[93] The recommendation for the Under Secretary for Health was submitted to the Executive in Charge who has the authority to perform the functions and duties of the Under Secretary for Health.

Comments to OIG's Report

Recommendation 1

The Under Secretary for Health ensures that the planning and implementation of the new electronic medical record includes (a) a fail-safe system that allows communication and tracking of test results to multiple clinical staff members who coordinate patient notification, appropriate follow-up testing and clinical management, and (b) the ability to monitor actions taken by the responsible provider(s).

Concur in principle.

Target date for completion: November 2019

Executive in Charge Comments

VA's Office of Electronic Health Records Management collaborating with VHA clinical councils will ensure that the planning and implementation of the new electronic medical record includes workflow configurations of existing Cerner capabilities with respect to communications of test results between responsible clinical staff members and patients. We will aim for the safest system available, however, the standard of "fail-safe" is not achievable in any system that depends on human-to-human contact – such as test result communications. Tracking and monitoring functions will be included in the planning to the extent existing workflows and Cerner capabilities can be configured for these functions.

At completion of this action plan, VA will provide documentation of incorporation of workflow configuration for test result communications, monitoring, and tracking in the Cerner development plan.

Status: In process Target Completion Date: November 2019

Appendix C: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: May 8, 2019

From: Director, VA Heartland Network (10N15)

Subj: Healthcare Inspection—Delay in Diagnosis and Subsequent Suicide at a Veterans Integrated Service Network 15 Medical Facility

To: Executive in Charge (10N)

1. Attached is the facility response to the Healthcare Inspection Delay in Diagnosis and Subsequent Suicide at a Veterans Integrated Service Network 15 Facility.
2. I have reviewed and concur with the facility's responses.
3. For additional questions, please feel free to contact Dawna Bader, VISN 15 Acting Management Officer.

(*Original signed by:)*
William P. Patterson, MD, MSS
Network Director
VA Heartland Network (VISN 15)

Appendix D: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: May 8, 2019

From: Director, VISN 15 Medical Facility

Subj: Healthcare Inspection—Delay in Diagnosis and Subsequent Suicide at a VISN 15 Medical Facility

To: Director, VA Heartland Network (10N15)

1. This is a tragic event which has not occurred in a Veterans Integrated Service Network 15 Medical Facility (facility) previously. I am very much saddened for the Veteran and [redacted][94] family. When one of our Veterans is harmed that is one too many.
2. At the facility, we established processes to assure patients are assigned to providers and Patient Aligned Care Teams and receive coordinated primary health care. Teams discuss care needs and follow processes from National Directives and local policies. Staff are trained to communicate with Veterans and engage them in their care. The processes to report adverse events and critical test results are in place. Staff tracks quality metrics to validate that our care meets community quality standards.
3. In June 2018, the facility implemented the Daily Management System (DMS) for operational teams and units. Teams huddle daily with a focus on methods, equipment, staffing, and supplies to address today's work today, assuring that safety is discussed. By using DMS, the facility has been able to make great improvements by engaging and empowering employees, providing a just culture, holding leaders accountable, and continually improving care to Veterans. In 2019, a new governance structure was implemented focusing on facility pillars of care which allows for enhancing our oversight, actions, and accountability.
4. My team and I welcome all feedback and understand that improvement is a continuous process. Our Veteran suffered a tragic outcome because of an unusual and unfortunate pattern of having multiple primary care providers and lack of communication and transition of care in a very short timeframe. This is devastating to me and my entire team. The active work that we are doing in the facility to achieve high reliability will ensure that no other Veteran falls through the cracks, so we can state with conviction that Zero Harm is achieved.
5. Please find attached my concurrences and responses. If additional information is needed please contact my office [redacted].

(*Original signed by*:)
Director, VISN 15 Medical Facility

[94] All instances of redacted information are pursuant to 5 U.S.C. § 552a(b) (2013); 38 U.S.C. § 5701; and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936.

Comments to OIG's Report

Recommendation 2

The Veterans Integrated Service Network 15 Medical Facility Director initiates an administrative review of the clinical care the patient received and takes action as appropriate based on the results.

Concur.

Target date for completion: September 1, 2019

Director Comments

An administrative in-depth review was initiated in December 2018 and completed on February 15, 2019 and approved by the Director. While this was an administrative review, the team used the Healthcare Failure Mode and Effect Analysis (HFMEA) principles to investigate the clinical care of the patient because the HFMEA tool yielded greater detail on the specific events than would a typical root cause analysis (RCA). Facility Leaders immediately began acting upon this information to prevent similar system failures in the future. In the review, 19 recommendations for improvement were made and 14 of them have been either fully implemented or partially implemented. It is anticipated that the remaining recommendations will be completed by September 1, 2019. Leaders continue to monitor all actions, improvements, and outcomes related to this event to ensure their effectiveness and results are reported monthly through the Patient Safety Committee and Quality, Safety, and Value Board.

Recommendation 3

The Veterans Integrated Service Network 15 Medical Facility Director ensures that Patient Centered Management Module provider and patient assignments are timely, and data are validated as required by Veterans Health Administration policy.

Concur.

Target date for completion: July 1, 2019

Director Comments

Leaders reviewed the current processes and policy related to Patient Centered Management Module (PCMM) assignment and implemented changes whereby patients are reassigned as soon as the admin team is made aware when providers are absent for an extended time or separated from facility employment. Additionally, the facility Standard Operating Procedure (SOP) for PCMM [redacted] has been updated to reflect current practice and comply with VHA directive. Providers received initial training on this process, and Primary Care Services Chiefs and the

Group Practice Manager (GPM) received additional training on PCMM to re-emphasize the importance of accurate PCMM assignment. PCMM data will be reviewed and validated on a monthly basis and reported through the [redacted] Committee to Medical Executive Board (MEB).

Recommendation 4

The Veterans Integrated Service Network 15 Medical Facility Director issues guidance that establishes a clearly-defined process for the designation of surrogates to include abnormal test results and consults.

Concur.

Target date for completion: September 1, 2019

Director Comments

Facility leaders ensure that providers receive training on assignment of surrogates during their absence consistent with SOP [redacted]. Clinical Application Coordinators and supervisors train providers at staff meetings, orientation, at [redacted] and through email on the requirement to identify, communicate and take action on the assignment of surrogates when absent for longer than 3 days and upon separation of employment. They also receive training on provider requirements for management of abnormal results and consults by the surrogate which are part of SOP [redacted].

The facility is currently using a SharePoint request system to designate surrogates. To strengthen and enhance surrogate tracking at a central location, the facility is incorporating the surrogate request into the [redacted] Light Electronic Action Framework (LEAF) System. This enhancement will allow clinical services to identify a surrogate at the same time they are entering clinic cancelation requests.

Recommendation 5

The Veterans Integrated Service Network 15 Medical Facility Director confirms that once issued, providers are trained on the process for designation of surrogates and monitor compliance.

Concur.

Target date for completion: September 1, 2019

Director Comments

Training of providers on assignment of surrogates already occurs at staff meetings, during orientation, at [redacted] and through email. While training is already being provided, Clinical

Service Chiefs are in the process of providing additional training and instruction as an extra measure to ensure all providers are competent in this task. Compliance with re-training providers and monitoring compliance with assigning surrogates will be monitored monthly by Clinical Service Chiefs and reported to leaders through the Quality, Safety, and Value Board.

Recommendation 6

The Veterans Integrated Service Network 15 Medical Facility Director reviews current view alert parameters, evaluates providers' knowledge and management of view alerts, and takes action, as necessary, to ensure and monitor compliance.

Concur.

Target date for completion: August 1, 2019

Director Comments

Facility leaders have confirmed that all mandatory view alerts are in place. In 2017, the *View Alerts Optimization Program* was published and providers across VISN 15, including the facility, were trained on sorting and adjusting view alerts, as well as, tips on managing alerts. While training was already provided, facility providers are being instructed and retrained locally at staff meetings, orientation, [redacted] and by email regarding mandatory view alerts and management of other optional alerts that enable them to effectively manage their patient panel. Clinical Service Chiefs are overseeing completion of provider training and monitoring compliance by reviewing aged alerts greater than 30 days. Results from this monitoring is reported monthly to the Chief of Staff and Quality, Safety, and Value Board.

Recommendation 7

The Veterans Integrated Service Network 15 Medical Facility 15 Director evaluates communication among Patient Aligned Care Team members, including the sharing of, the timeliness of, and the response to patient secure messages, and takes action based on the evaluation.

Concur.

Target date for completion: July 1, 2019

Director Comments

Secure messages are expected to be responded to within 3 business days. An escalation message to additional PACT team members is sent when timeframes are not met. Monthly reports are run and shared with providers as secure messages exceed response time requirements. The Secure Messaging Program Specialist (SMPS) is developing a local policy to strengthen this process and staff will be retrained on the secure messaging follow-up process and policy after it is approved.

Results of responding to Secure Messages will be monitored on a monthly basis by the SMPS for actions taken and reported up to Nurse Executive Board and to the Performance Excellence Executive Council.

Recommendation 8

The Veterans Integrated Service Network 15 Medical Facility Director reviews processes within Primary Care related to patient notification of test results and takes action to ensure test results are communicated to patients as required by Veterans Health Administration policy.

Concur.

Target date for completion: August 1, 2019

Director Comments

Facility [redacted] policies for patient notification of tests results have been revised to comply with VHA Directives. Providers have been instructed at staff meetings, orientation, at [redacted] and through emails regarding their responsibility to notify patients of test results within the required time frame. Ongoing training and just in time training occurs for new providers and existing providers when outcome data indicate further training is needed. Monitoring occurs through the External Peer Review Program (EPRP) and reported monthly to the Quality, Safety, and Value Board. Service Level On-going Professional Practice Evaluation (OPPE) which include data on notification of test results are also monitored and reported to the Professional Standards Board (PSB) at time of reprivileging and to MEB monthly.

Recommendation 9

The Veterans Integrated Service Network 15 Medical Facility Director reviews Veterans Health Administration and the Veterans Integrated Service Network 15 Medical Facility policies concerning disclosure of adverse events to patients and/or their representatives and ensures that staff are aware of discussions and documentation required to comply with these policies.

Concur.

Target date for completion: Completed April 16, 2019

Director Comments

Leaders reviewed the local policy [redacted] and it is up-to-date. Additionally, all key leaders reviewed VHA Directive on Disclosure of Adverse events by April 12, 2019 and participated in an educational forum covering this topic on April 16, 2019. During the educational forum, discussion was held on clinical and institutional disclosure processes, and case studies were presented to illustrate when a clinical or institutional disclosure was warranted, or both. Training on how to initiate clinical and institutional disclosures also occurred in the forum, including

required documentation in CPRS. Finally, Service Chiefs were tasked with reminding providers about the need to disclose adverse events to their patients as part of routine delivery of care.

Recommendation 10

The Veterans Integrated Service Network 15 Medical Facility Director reviews the events in the patient's care and conducts additional actions related to the disclosure of adverse events to the patient's representative as warranted by Veterans Health Administration and Veterans Integrated Service Network 15 Medical Facility policies.

Concur.

Target date for completion: Completed May 9, 2019

Director Comments

Facility leaders reviewed the patient's care in the electronic medical record and an Institutional Disclosure meeting was held with the Veteran's representative on May 9, 2019. Upon completion of the disclosure, a progress note was entered into the Veteran's CPRS record utilizing the required Institutional Disclosure progress note template.

OIG Comment: The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 11

The Veterans Integrated Service Network 15 Medical Facility Director reviews quality management practices and ensures compliance with Veterans Health Administration guidance related to root cause analysis when future adverse events are identified and takes action as necessary.

Concur.

Target date for completion: July 1, 2019

Director Comments

The Patient Safety Manager in collaboration with VISN 15 Patient Safety Officer will review the facility's quality management practices regarding the use of Root Cause Analyses (RCA) and implement corrective actions, as needed, to ensure compliance with the VA National Center for Patient Safety Handbook.

OIG Contact and Staff Acknowledgments

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