Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 15-00827-68

Healthcare Inspection

Poor Follow-Up Care and Incomplete Assessment of Disability
VA San Diego Healthcare System
San Diego, California

January 5, 2016

Washington, DC 20420

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Executive Summary

At the request of Senator Dianne Feinstein and the VA Secretary, the VA Office of Inspector General (OIG) Office of Healthcare Inspections and Office of Audits and Evaluations conducted an inspection to evaluate the circumstances surrounding the death of a patient at the VA San Diego Healthcare System (system), San Diego, CA. The Office of Healthcare Inspections evaluated the quality of care provided for the patient prior to his suicide. The Office of Audits and Evaluations assessed whether the San Diego VA Regional Office (VARO) Rating Decision accurately decided the patient's compensation claim.

We determined that the quality of care provided for the patient's chronic pain did not adhere to the VA/DoD *Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*. System providers did not order urine drug testing, complete a suicide risk assessment, or obtain an opioid pain care agreement as part of the patient's chronic pain therapy. The patient continued to receive refills of hydrocodone without a face-to-face assessment with a provider for 22 months. A provider also did not follow up on the patient's message indicating that he wished to discontinue hydrocodone and did not offer assistance in tapering off the medication or suggest alternative treatments.

We also determined that the patient was newly diagnosed with traumatic brain injury and post-traumatic headaches during a Compensation and Pension examination in January 2014, but there was no follow-up plan to address these issues.

Although the San Diego VARO decided the patient's claim prematurely without obtaining all relevant service treatment records from the U.S. Department of Defense (DoD), after reviewing these additional records, OIG Office of Audits and Evaluations did not find that the outcome of the patient's compensation claim was incorrect.

We recommended that the Under Secretary for Health ensure that Compensation & Pension examiners document that patients with new diagnoses are counseled on the need for follow-up care and provided assistance in obtaining VA care, and that all clinically relevant communications are documented in the electronic health record. We recommended that the System Director implement processes to ensure that providers adhere to the *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain,* including follow-up assessment at appropriate intervals, when treating patients with chronic opioid therapy, and confer with Regional Counsel for possible disclosure(s) to the surviving family member(s) of the patient. We also recommended that San Diego VA Regional Office Director review a sample of the specific rater's work and determine whether failure to obtain relevant service treatment records is a systemic issue with this rater when making compensation claim decisions.

Comments

Under Secretary for Health, VISN and System Directors

The Under Secretary for Health and the Veterans Integrated Service Network and System Directors concurred with Recommendations 1–4 and provided acceptable action plans. (See Appendixes B–E, pages 14–20 and 22 for the Under Secretary's and Directors' comments.) We will follow up on the planned actions until they are completed.

OIG Response to System Director Comments

In response to Comment #3: The System Director noted that our report relies heavily on the VA/DoD Clinical Practice Guideline without clarifying "as to when a guideline is applicable or the significant differences between a 'guideline for care' and a requirement for care."

The VHA Pain Management Directive stated evidence-based pain management protocols using guidelines should be implemented in all clinical settings. VHA's Pain Management website prominently references the VA/DoD Clinical Practice Guideline.

Further, the VA San Diego Healthcare System Memorandum 11-54, Pain Management, approved by the System Director and Chief of Staff on June 20, 2012, directed providers to order interventions "in accordance with…current clinical practice guidelines" and referenced the VA/DoD Clinical Practice Guideline.

Since the VHA Pain Management Directive and the facility memo signed by the System Director instruct providers to implement and adhere to evidence-based guidelines, with frequent reference to the VA/DoD Clinical Practice Guideline, we used the document to delineate what the optimal care should have been for this patient.

Additionally, in response to Comment #3: The System Director wrote, "One of the references quoted in support of the Guideline (Chou et al. 2015), while important, was published months after the event and could not have been known to the practitioner or the health care system." We used the reference by Chou et al. 2015 to illustrate the pros and cons of opioid use. We did not rely on the article for findings or recommendations.

In response to Comment #4: The System Director noted that in regards to the new patient visit in January 2013, "without applying hindsight, the veteran could not have been said to have a stable or chronic opioid prescription that fell within the purview of the Clinical Practice Guideline."

For clarification, our intent was not to focus on the Jan 2013 visit, but rather to point out that the patient was not evaluated by his PCP for 22 months after this initial appointment. Although the provider continued to prescribe opioid medication, he did not conduct reassessments, a suicide risk assessment, urine drug screen, or an opioid pain care agreement. While the System Director correctly pointed out that the patient

cancelled multiple appointments, the provider had other options to encourage the patient to attend appointments, such as not refilling opioid medications until the patient returned to the clinic for a face to face visit.

VA Regional Office San Diego Director

The VA Regional Office San Diego Director partially concurred with Recommendation 5 and stated station training will be provided to all VARO raters. (See Appendix E, pages 21–23.) The target completion date is June 30, 2015. The Director indicated that training would emphasize the Expanded Admission, Discharge, and Transfer (ADT) in the veteran's electronic health record. However, the Director stated they will need to seek clarification from Compensation Service regarding development procedures for additional records based upon information found in the Expanded ADT.

OIG Response

The VA Regional Office San Diego Director's comments and actions regarding training are responsive to the recommendation. We will review the training and follow up during our next benefits inspection to ensure staff have all relevant documentation when deciding a claim.

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Assistant Inspector General for
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Purpose

At the request of Senator Dianne Feinstein and the VA Secretary, the VA Office of Inspector General (OIG) Office of Healthcare Inspections and Office of Audits and Evaluations conducted an inspection to evaluate the circumstances surrounding the death of a patient at the VA San Diego Healthcare System (system), San Diego, CA. The Office of Healthcare Inspections evaluated the quality of care provided for the patient prior to his suicide. The Office of Audits and Evaluations assessed whether the San Diego VA Regional Office (VARO) Rating Decision accurately decided the patient's compensation claim.

Background

The system is part of Veterans Integrated Service Network (VISN) 22 and serves patients in the California counties of San Diego and Imperial Valley. The system consists of a medical center, located in La Jolla, and six community based outpatient clinics (CBOCs) located in Chula Vista, Escondido, Imperial Valley, Mission Valley, Mission Gorge Annex, and Oceanside. The medical center has 304 authorized beds and provides medical, surgical, mental health, geriatric, spinal cord injury, and advanced rehabilitation services. Mental health services at La Jolla include an inpatient mental health unit and a walk-in clinic for urgent visits. The Oceanside CBOC offers comprehensive outpatient mental health services, including a Behavioral Health Interdisciplinary Program and a Post-Traumatic Stress Disorder (PTSD) program.

References and Guidance

The Veterans Health Administration (VHA) Pain Management Directive, published in October 2009, provides policy and implementation procedures for the improvement of pain management in VA facilities. It calls for the use of published clinical guidelines for pain management protocols.[1]

The *VA/Department of Defense Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain* (VA/DoD Guideline), dated May 2010, recommends a step-wise approach for opioid dose adjustments to maximize pain control while minimizing potential adverse effects.[2] The VA/DoD Guideline applies to all patients prescribed opioids for at least 90 days. Consistent with the VA/DoD Guideline, a recent review concluded that, while multiple harms are associated with long-term opioid therapy, evidence of its effectiveness is limited.[3] To mitigate the likelihood of opioid misuse or adverse outcomes, the VA/DoD Guideline recommends that prescribers of

[1] VHA Directive 2009-053 *Pain Management*, October 28, 2009. This Directive expired October 31, 2014 and has not yet been updated.
[2] *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, Version 2.0, May 2010.
[3] Chou R, Turner JA, Devine EB, et al. *The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention workshop*, Ann Intern Med. 2015; 162:276–286.

long-term opioids assess patients at least every 1–6 months for treatment effectiveness, adverse effects, and adherence to therapy. In addition, prescribers are advised to monitor for evidence of opioid misuse or substance abuse, and consider the use of written opioid pain care agreements (OPCAs) and periodic urine drug testing (UDT). OPCAs generally list expectations for providers and patients, such as following dosing recommendations, random UDT, and having only one prescriber for opioids to prevent multiple prescriptions. (See Appendix A for an example of an OPCA.)

Due to concerns that OPCAs may contain language considered threatening to the patient-physician therapeutic relationship, in May 2014, VHA established policy regarding informed consent for long-term opioid therapy. The policy required VA facilities to develop and publish local policy by November 6, 2014. Prior to initiating long-term opioid therapy, prescribers should complete the informed consent process whereby they discuss the risks, benefits, and alternatives of the treatment with patients.[4] The documentation of an informed consent should take the place of an OPCA.

Suicide Risk Assessment

Studies have shown that chronic pain is associated with an elevated risk of suicidal thoughts, planning, and attempts.[5] One particular study on 260,254 veterans showed that those who reported severe pain were more likely to die by suicide than those who reported less pain.[6] The VA/DoD Guideline recommends a suicide risk assessment at the onset of therapy and regularly thereafter. High suicide risk is a relative contraindication for opioid therapy.

Scope and Methodology

We conducted this review from October 29, 2014, through March 9, 2015. The Office of Healthcare Inspections conducted site visits to the medical center and the Oceanside CBOC, which are approximately 30 miles apart, in December 2014.

Office of Healthcare Inspections staff interviewed the patient's wife, Chief of Pharmacy, Chief of Information Technology, Compensation and Pension (C&P) managers, clinical care providers, and other staff. We listened to the Patient Care Call Center audio recordings. We reviewed the patient's electronic health record (EHR); pharmacy records from November 20, 2012, through November 6, 2014; and email messages

[4] VHA Directive 1005 *Informed Consent For Long-Term Opioid Therapy For Pain,* May 6, 2014.
[5] Ratcliffe GE, Enns MW, Belik SL, Sareen J. *Chronic Pain Conditions and Suicidal Ideation and Suicide Attempts: An Epidemiologic Perspective*, Clin J Pain. 2008; 24: 204–210. Ilgen MA, Zivin K, McCammon RJ, Valenstein M. *Pain and Suicidal Thoughts, Plans, and Attempts in the United States,* Genl Hospl Psychiat. 2008; 30: 521–527.
[6] Ilgen MA, Zivin K, Austin KL, et al. *Severe Pain Predicts Greater Likelihood of Subsequent Suicide,* Suicide Life Treat Behav. 2010; 40 (6): 597–608.

from My Health*e*Vet.[7] We reviewed the VA/DoD Guideline, VHA and local policies, and queried the State of California's Controlled Substance Utilization Review & Evaluation System (CURES).[8] We reviewed the system's internal investigation of the patient's care.

Office of Audits and Evaluations staff interviewed San Diego VARO management and staff and reviewed the patient's disability compensation claim. They also reviewed all associated service treatment records and other pertinent documents, to assess whether the claim was decided accurately in accordance with Veterans Benefits Administration (VBA) policy.

We **substantiated** allegations when the facts and findings supported that the alleged events or actions took place. We **did not substantiate** allegations when the facts showed the allegations were unfounded. We **could not substantiate** allegations when there was no conclusive evidence to either sustain or refute the allegation.

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

[7] My Health*e*Vet is the VA's online personal health record that allows patients to send secure email messages to their providers. They can use the program to request refills of medications, and view their appointments, lab results, clinic notes, medication list, and immunization records.

[8] The California Department of Justice's CURES Program maintains opioid prescription information that is received from California pharmacies. The San Diego VA pharmacy does not provide data to CURES, but facility staff have access to CURES data.

Case Summary

The patient was a man in his mid-thirties who had a history of knee pain beginning in the military. He was diagnosed with traumatic brain injury (TBI), post-traumatic headaches, and hearing loss by the VA C&P examiners. He committed suicide in 2014.

During the course of his military service, the patient was deployed overseas. In pre- and post-deployment health assessments,[9] he denied physical or emotional problems. In a post-deployment health assessment completed in 2010, he also denied being exposed to blasts or explosions. In 2011, the patient was seen several times at a military treatment facility (MTF) for right knee pain. A magnetic resonance imaging (MRI) scan of the right knee showed a small amount of fluid in the joint and a mild medial collateral ligament (MCL) sprain. He was treated with an injection of ketorolac and prescribed oral medications: tramadol, hydrocodone, and ibuprofen.[10] He attended four physical therapy (PT) sessions. The patient was also seen twice at the MTF for insomnia and was prescribed zolpidem and trazodone.

In November 2012, when the patient had his initial encounter with the medical center, he reported that he had experienced blasts and explosions while deployed, but denied having symptoms afterwards. Screenings for depression, PTSD, and alcohol use were negative. The provider's health assessment focused on the patient's complaint of right knee pain, which started in 2007 after a wrestling injury and worsened after playing hockey. The patient reported a pain level of 8 out of 10.[11] The provider reviewed the MTF records and documented that the MRI did not indicate a need for surgery. The provider wrote that the patient "has chronic pain which has only been relieved by a combination of Vicodin® [hydrocodone/acetaminophen] and NSAID [non-steroidal anti-inflammatory drug] in the past." The provider renewed the prescription for hydrocodone 5 mg and an NSAID and ordered x-rays of the right knee. The plan also included a referral for PT, but no consult was entered. The patient was to follow up with primary care at the Oceanside CBOC in 6 months. X-rays of the right knee revealed no abnormalities.

The patient's next appointment was a primary care visit at the Oceanside CBOC soon after the new year in January 2013. His only complaint at that time was right knee pain; he reported a pain level of 8. The patient also informed the primary care provider (PCP) that hydrocodone 5 mg and the NSAID "does not help with the pain." The PCP ordered an MRI of the right knee, increased the hydrocodone to 10 mg, and continued the NSAID. The patient was instructed to return in 12 months. The MRI showed evidence of remote injury in a knee ligament; the PCP notified the patient of the MRI results and ordered PT. The patient canceled the PT appointment that had been scheduled for

[9] Deployment health assessments are completed before and after a soldier is deployed outside of the United States in support of a military operation.
[10] Ketorolac and ibuprofen are nonsteroidal anti-inflammatory drugs (NSAIDs). Tramadol and hydrocodone are opioid (narcotic) medications.
[11] To assess levels of pain, patients are asked to rate their pain on a scale from 1 to 10, with 10 representing the worst pain they have experienced or could imagine.

approximately 10 weeks after the MRI. He did not attend and did not cancel (no showed) the appointment rescheduled for 3 weeks later (see Table 1). In spring, the consult was closed. We did not find evidence in the EHR that the patient attended PT appointments at the system.

In October 2013, the patient was seen for an audiology C&P examination and was diagnosed with hearing loss in both ears. Three months later, the patient was seen for a neurology C&P examination. The neurologist wrote the veteran reported that while deployed overseas:

> *…he was on foot when an IED [improvised explosive device] exploded about 5 feet away. He stated that he remembers the blast and remembers being knocked down by the force of the blast. He thinks that he may have lost consciousness for about 20 seconds. He remembers having ringing in his ears but no other immediate symptoms. He was seen in the field by a corpsman and continued action in the ensuing firefight…He tells me that about two days later he began to have headaches.*

The neurologist diagnosed the patient with TBI and post-traumatic headaches but noted that there were no physical exam findings or evidence of any functional impact from the symptoms. The San Diego VARO subsequently sent a letter to the patient stating that although he would be service connected for TBI with post-traumatic headaches and bilateral hearing loss, he did not qualify for any disability compensation.

In January 2014, the patient was scheduled for his 12-month primary care follow-up appointment. However, the clinic canceled that appointment, and the patient canceled seven subsequent appointments. Six of the appointment cancellations were verified by audio recordings of the dialogue between the patient and Patient Call Center agents. Follow-up appointments were rescheduled with each cancellation, except for the last one.

Although the patient had no face-to-face assessments, monthly hydrocodone prescription refills continued. Prior to each prescription in 2014, the patient sent email messages to the PCP, but only one of these was copied to the EHR.[12] Seven of these monthly messages contained the same wording: "I am continuing to do my physical therapy for my MCL. The process is going good, but my pain level is still very high, and is higher on the PT days. Can you please order my prescription for Hydrocodone 10mg…" Table 1 shows a list of appointments, email messages, and hydrocodone prescriptions.

[12] This email message was sent via My Health***e***Vet Secure Messaging. After receiving and reviewing a secure message, the provider has the option to copy it into the patient's EHR. We found that there is no specific guidance for the provider regarding which secure messages, if any, should be copied into the EHR.

Table 1. Patient Appointments, Messages, and Hydrocodone Prescriptions

Year/Event Number	Primary Care	Physical Therapy	C&P Examination	Prescription
2012	Appt Kept			Hydrocodone 5/APAP 500 mg
2013 #1	Appt Kept			Hydrocodone 10/APAP 500 mg
2013 #2				Hydrocodone 10/APAP 500 mg
2013 #3	Email			Hydrocodone 10/APAP 500 mg
2013 #4	Email			Hydrocodone 10/APAP 500 mg
2013 #5	Email			
2013 #6				Hydrocodone 10/APAP 500 mg
2013 #7		Pt Cancel		
2013 #8	Email			Hydrocodone 10 /APAP 650 mg
2013 #9		No Show		
2013 #10	Email			
2013 #11				Hydrocodone 10 /APAP 650 mg
2013 #12	Email			
2013 #13				Hydrocodone 10 /APAP 650 mg
2013 #14	Email			Hydrocodone 10 /APAP 650 mg
2013 #15	Email			Hydrocodone 10 /APAP 650 mg
2013 #16	Email			Hydrocodone 10 /APAP 650 mg
2013 #17	Email			Hydrocodone 10 /APAP 650 mg
2013 #18	Email		Appt Kept	
2013 #19				Hydrocodone 10 /APAP 650 mg
2013 #20			No Show	
2013 #21			Clinic Cancel	
2013 #22	Email			Hydrocodone 10 /APAP 325 mg
2013 #23			No Show	
2013 #24			No Show	
2013 #25	Email			Hydrocodone 10 /APAP 325 mg
2013 #26	Email			
2014 #1			Pt Cancel	
2014 #2				Hydrocodone 10 /APAP 325 mg
2014 #3	Pt Cancel			
2014 #4			Appt Kept	
2014 #5	Clinic Cancel			
2014 #6	Pt Cancel			
2014 #7	Email			
2014 #8	Pt Cancel			
2014 #9	Email			Hydrocodone 10 /APAP 325 mg
2014 #10	Pt Cancel			
2014 #11	Email			
2014 #12				Hydrocodone 10 /APAP 325 mg
2014 #13	Pt Cancel			
2014 #14	Pt Cancel			
2014 #15	Email			Hydrocodone 10 /APAP 325 mg
2014 #16	Pt Cancel			
2014 #17	Email			
2014 #18				Hydrocodone 10 /APAP 325 mg
2014 #19	Pt Cancel			
2014 #20	Email			Hydrocodone 10 /APAP 325 mg
2014 #21	Email			Hydrocodone 10 /APAP 325 mg
2014 #22	Email			
2014 #23				Hydrocodone 10 /APAP 325 mg
2014 #24	Email*			
2014 #25	Email			
2014 #26				Hydrocodone 10 /APAP 325 mg

All primary care appointments canceled by patient were verified by audio recordings except 2014 #19

All prescriptions were for 120 tablets. APAP = Acetaminophen. Comp & Pen = Compensation & Pension examination.

** This is the only email message that was copied to the EHR.*

Source: EHR, MyHealtheVet, facility

In February 2014, an audiologist responded to a request for an opinion regarding the patient's claim of hearing loss related to noise exposure. The audiologist noted that "there is evidence to conclude hearing loss…is at least as likely as not related to noise exposure in service."

The 2014 #24 note that the patient sent to his PCP through My Health***e***Vet Secure Messaging stated:

> *…I am still in a lot of pain everyday pain Sir but this will be the last Refil* [sic] *I will ask of you for me as I am going to weed* [sic] *myself off of it. Thank you so much for helping me through this process with the pain I'm in Sir and I have all my PT documentation that I am going to bring in to you on our next visit* [sic] *so you can review them.*

The PCP responded that he was out of the office and the covering provider would refill the prescription. The last note in the EHR documents a call from the nurse to inform the patient that his hydrocodone prescription was ready for pick up.

The patient died from a self-inflicted gunshot wound approximately 1 month after his last email message to his physician. The patient did not leave a suicide note, but his wife stated that several days prior to his death, the patient was consumed with survivor's guilt after finding out that a longtime friend had died in Afghanistan.

Inspection Results

Issue 1: Quality of Care

A. Opioid Therapy for Chronic Pain

From January 2013 until his death in 2014, the patient received monthly hydrocodone prescriptions with intermittent anti-inflammatory medication for his chronic knee pain. We queried the CURES database to determine if the patient had any non-VA opioid prescriptions filled. We found that 20 tablets of hydrocodone 10 mg were dispensed 5 days prior to the 2014 #24 message the patient sent to his PCP. According to his wife, the patient went to a local hospital because of severe knee pain and received the prescription for the 20 tablets of hydrocodone. He had last received a 30-day supply of medications from the VA approximately a month before the ED visit (see Table 1, 2014 #23). We determined that several aspects of the patient's pain management care fell outside practice guidelines.

Suicide Risk Assessment

During the January 2013 visit, the patient was screened for alcohol and depression. Although recommended by the VA/DoD Guideline for patients receiving chronic opioid therapy, a suicide risk assessment was not completed.

Opiate Pain Care Agreement/Informed Consent

The VA/DoD Guideline recommends the use of an OPCA prior to the initiation of chronic opioid therapy. The PCP did not initiate an OPCA or document informed consent.

Although the VA/DoD Guideline recommends the use of an OPCA, VHA did not previously require its use. In May 2014, VHA published a policy requiring documented informed consent for long-term opioid therapy in the EHR. This informed consent process and documentation should replace any local OPCAs by May 2015.[13] Medical facility directors were responsible for ensuring that local policy and procedures consistent with this directive were developed and published by November 6, 2014. We found that the system had not developed a local policy but was following a VISN policy dated September 23, 2014.

Urine Drug Testing

The VA/DoD Guideline recommends random UDTs to confirm adherence to treatment and assess for possibility of diversion.[14] The patient did not have any UDT orders nor was this issue discussed in the EHR.

Follow-Up Evaluation

Primary Care. The PCP instructed the patient to follow up in 12 months at the initial visit. A 12-month follow-up appointment was made. The clinic canceled the visit 3 weeks before the scheduled appointment because the PCP would be out of the office. The staff rescheduled the patient for an appointment 4 days earlier, but the patient cancelled. The patient rescheduled eight appointments from January through May 2014. All but the last cancellation were audio-recorded. There were no appointments rescheduled after the patient canceled his last appointment in May 2014 through the web portal.

The patient sent 22 email messages to his PCP through My Health***e***Vet, about once a month, between February 2013 and his death in 2014. Only one of these was reflected in the EHR. In these emails, he described his continued pain and adherence with PT and requested hydrocodone refills. His PCP responded that the medication would be refilled as requested. Except for the emails, we did not find evidence that the patient had other contact with his PCP after the January 2013 appointment

The VA/DOD Guideline recommends an evaluation by the prescribing provider every 1 to 6 months for pain-related function after the patient is on stable opioids. Assessment of function may include employment, emotional distress (depression and anxiety), sleep, and sexual function.

[13] http://vaww.va.gov/PAINMANAGEMENT/docs/OSI_10_FAQ_VHA_Directive_1005_Informed_Consent_for_Long_Term_Opioid_Therapy_for_Pain_92214.pdf. Accessed 2/18/2015.
[14] Ibid. Diversion refers to giving or selling the medication to someone else.

The PCP did not follow the 1 to 6 month recommendation for a follow-up evaluation. The patient had a history of sleep problems while in the military and was on insomnia medication. His wife reported that he continued to have daily issues with sleep. We determined that the patient should have been evaluated more frequently than he was assessed given his chronic pain, sleep problems, and use of opioid medication. Despite the lack of face-to-face assessments for 22 months, the PCP continued to refill the patient's opioid medications.

Physical Therapy. We did not find evidence that the patient had been receiving PT. He did not attend any PT sessions at the VA. The PCP questioned the patient in July 2014 about where he was undergoing PT. The patient wrote that he was being treated by a non-VA physical therapist. The patient's wife stated he received all his care at the VA except for one emergency visit at a local hospital about a month before his death.

Discontinuation of Opioids. The patient informed his PCP in the, 2014 #24 (see Table 1) email message that this would be his last request for hydrocodone refill, he was going to wean himself off the medication and he was "still in a lot of pain every day." We found no evidence in the patient's EHR that the PCP followed up on the patient's desire to self-discontinue the medication. The VA patient information on chronic opioid therapy specifically told patients not to stop taking opioids on their own, as abrupt cessation could cause withdrawal symptoms.[15] We determined that the provider should have reassessed the patient's treatment plan and if the patient still wished to discontinue opioids, offered help with tapering the medication, alternative treatments, and/or specialist referrals.[16]

B. TBI and Post-Traumatic Headaches

In his post-deployment health assessment, the patient reported no exposure to blasts or explosions. However, in the TBI screening questionnaire done during the system's November 2012 intake examination, the patient answered yes to experiencing blasts and explosions during deployment but denied symptoms. The system's procedure for patients who screen positive for blast exposure with subsequent symptoms is follow-up with the TBI program.

Fourteen months later, the patient reported to a neurologist during a C&P examination that he was on foot when an improvised explosive device exploded about 5 feet away while deployed overseas. He also reported losing consciousness for about 20 seconds and daily headaches since 2 days after the incident. The patient was diagnosed with TBI and post-traumatic headaches at the end of the neurology C&P visit, but he received no follow-up care.

[15] VA National Pain Management Program. Taking Opioids Responsibly for Your Safety and the Safety of Others. Patient information Guide on Long Term Opioid Therapy for Chronic Pain. http://www.healthquality.va.gov/guidelines/Pain/cot/OpiodTheraphyforChronicPainPatientTool20May2013print.pdf Accessed 12/8/2015.
[16] VA/DoD Guideline 2010, Pages 11-13.

According to the Chief of C&P, the C&P examiner typically informs the patient at the time of the C&P exam that the evaluation is for compensation and pension purposes only. One or more conditions may be claimed by the patient, and the examiner often does not know if diagnoses are new or established. The examiner advises the patient to follow up with his/her PCP and, if the patient is not already enrolled for VA care, provides a pamphlet with contact information. In this case, we found no documentation that the C&P neurologist notified the patient of the TBI and HA diagnosis as directed in VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009.

Issue 2: VARO Rating Decision

We did not find that the patient's compensation claim decision was incorrect. However, the San Diego VARO decided the patient's claim prematurely without obtaining all relevant service treatment records from DoD. VBA policy requires staff to make as many requests as necessary to obtain relevant records from a Federal department or agency, including service treatment records. Some service treatment records were available at the time VARO staff decided the patient's claim; however, we reviewed the EHR and determined that the service treatment records were incomplete.

The San Diego VARO received the patient's claim in early winter 2012. VARO staff completed a Rating Decision in mid-winter 2014, granting service connection for two conditions, but not to a compensable degree. VARO staff also denied service connection for 10 conditions. VA's letter dated February 19, 2014, notified the patient of the decision and that no monetary compensation was awarded.

We requested that the VARO provide complete copies of the patient's service treatment records. The VARO contacted the Naval Hospital at Camp Pendleton, and they were able to obtain additional service treatment records that were not previously considered by VARO staff. Although the supplemental service treatment records included further evidence relevant to the patient's compensation claim, they did not contain evidence that would have mandated a different result.

Therefore, we did not find that the outcome of the patient's compensation claim was incorrect. We will follow up to review compliance that all raters have all relevant documentation during our next benefits inspection at this VARO.

Conclusions

We determined that the quality of care provided for the patient's chronic pain did not adhere to the VA/DoD *Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*. System providers did not order urine drug testing, complete a suicide risk assessment, or obtain an opioid pain care agreement as part of the patient's chronic pain therapy. The patient continued to receive refills of hydrocodone without a face-to-face assessment with a provider for 22 months. A provider also did not follow up on the patient's message indicating that he wished to discontinue hydrocodone and did not offer assistance in tapering off the medication or suggest alternative treatments.

If the patient had regular follow-up with his PCP for chronic pain, the provider may have identified signs and symptoms of PTSD and depression, and the need for follow-up of TBI and post-traumatic headaches.

We also determined that the patient was diagnosed with TBI and post-traumatic headaches during a C&P examination in winter 2014, but there was no follow-up plan to address these issues. Although the San Diego VARO decided the patient's claim prematurely without obtaining all relevant service treatment records from the DoD, after reviewing these additional records, we did not find that the outcome of the patient's compensation claim was incorrect.

Recommendations

1. We recommended that the Under Secretary for Health ensure that Compensation & Pension examiners document that patients with new diagnoses are counseled on the need for follow-up care and provided assistance in obtaining VA care.

2. We recommended that the Under Secretary for Health ensure that all clinically relevant communications are documented in the electronic health record.

3. We recommended that the System Director implement processes to ensure that providers adhere to the VA/DoD *Clinical Practice Guideline for Management of Opioid Therapy* for Chronic Pain, including follow-up assessment at appropriate intervals, when treating patients with chronic opioid therapy.

4. We recommended that the System Director confer with Regional Counsel for possible disclosure(s) to the surviving family member(s) of the patient.

5. We recommended that the VA Regional Office San Diego Director review a sample of the specific rater's work and determine whether failure to obtain relevant service treatment records is a systemic issue with this rater when making compensation claim decisions.

Appendix A

Sample Opioid Pain Care Agreement[17]

1. I understand that my provider and I will work together to find the most appropriate treatment for my chronic pain. I understand the goals of treatment are not to eliminate pain, but to partially relieve my pain in order to improve my ability to function. Chronic opioid therapy is only ONE part of my overall pain management plan.

2. I understand that my provider and I will continually evaluate the effect of opioids on achieving the treatment goals and make changes as needed. I agree to take the medication at the **dose** and **frequency prescribed** by my provider. I agree not to increase the dose of opioids on my own and understand that doing so may lead to the treatment with opioids being stopped.

3. I understand that the common adverse effects of opioid therapy include constipation, nausea, sweating and itchiness of the skin. Drowsiness may occur when starting opioid therapy or when increasing the dosage. I agree to refrain from driving a motor vehicle or operating dangerous machinery until such drowsiness disappears.

4. I will not seek opioid medications from another physician for the treatment of my chronic pain. Regular follow-up care is required and only my provider will prescribe these medications for my chronic pain for me at scheduled appointments.

5. I will attend all appointments, treatments and consultations as requested by my providers. I will attend all pain appointments and follow pain management recommendations.

6. I will not give or sell my medication to anyone else, including family members; nor will I accept any opioid medication from anyone else. I agree to be responsible for the secure storage of my medication at all times. If these medications are stolen, I will report this to police and my provider and will produce a police report of this event if requested to do so.

7. I understand that if my prescription runs out early for any reason (for example, if I lose the medication or take more than prescribed), my provider may not prescribe extra medication for me. I may have to wait until the next prescription is due.

8. I understand that the use of other medications can cause adverse effects or interfere with opioid therapy. Therefore, I agree to notify my provider of the use of all substances, including marijuana, alcohol, medications not prescribed for me (tranquilizers), and all illicit drugs.

9. I agree to periodic unscheduled drug screens.

[17] VA/DoD Guideline 2010, Page 103.

Appendix A

10. I understand that I may become physically dependent on opioid medications, which in a small number of patients may lead to addiction. I agree that if necessary, I will permit referral to addiction specialists as a condition of my treatment plan.

11. I understand that my failure to meet these requirements may result in my provider choosing to stop writing opioid prescriptions for me. Withdrawal from the medications will be coordinated by the provider and may require specialist referrals.

12. I hereby agree that my provider has the authority to discuss my pain management with other health care professionals and my family members when it is deemed medically necessary in the provider's judgment.

13. My providers may obtain information from State controlled substances databases and other prescription monitoring programs.

Patient Signature: _____

Appendix B

Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: July 15, 2015

From: Under Secretary for Health (10)

Subj: Healthcare Inspection — Poor Follow-Up Care and Incomplete Assessment of Disability, VA San Diego Healthcare System, San Diego, CA (VAIQ 7607410)

To: Assistant Inspector General for Healthcare Inspections

1. Thank you for the opportunity to review the OIG draft report of the Healthcare Inspection Poor Follow-Up Care and Incomplete Assessment of a Disability VA San Diego Healthcare System, San Diego, California.

2. I concur with the findings and recommendations in the draft report.

3. Additionally, I agree with OIG's recent reassignment of the recommendation for guidance on clinical documentation in the health record related to clinical decisions otherwise conveyed through secure messaging and MyHealtheVet to the Under Secretary for Health. VHA will issue national guidance on this topic.

4. The attachment contains VHA's action plans for addressing the two recommendations to the Under Secretary for Health: recommendation 1 and the newly reassigned recommendation 2.

5. Comments in response to recommendation 3, 4 and 5 have been provided to OIG by the facility Director.

6. Please direct questions or concerns regarding the content of this memorandum to Karen Rasmussen, MD, Director, Management Review Service (10AR) at VHA 1OARMRS2@va.gov.

David J. Shulkin, M.D.

Attachment

cc: Director, San Diego Office of Healthcare Inspections (54SD)

Comments to OIG's Report

The following Under Secretary for Health's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the Under Secretary for Health ensure that Compensation & Pension examiners document that patients with new diagnoses are counseled on the need for follow up care and provided assistance in obtaining VA care.

Concur

Target date for completion: December 2015 Status: In process

A Compensation & Pension (C&P) examination may require review of a condition that the Veteran believes already exists. In this circumstance the examination is not diagnostic of a new medical condition, but rather involves a confirmation of whether there is a diagnosis.

As part of reviewing evidence to decide a VA disability benefits claim, VA's Veterans Benefits Administration (VBA) may request a disability examination or a medical opinion if VBA determines it is necessary to adjudicate a claim for VA benefits is pursuant to VA's duty to assist (38 U.S.C. 5103A and 38 CFR 3.159). A disability examination is an accurate and fully descriptive medical documentation of the examinee, with emphasis upon the limitation of activity imposed by the disabling condition conducted for claims adjudication purposes only rather than treatment purposes. The examination is one piece of evidence considered by VBA. After adjudicating the disability benefits claim, VBA will notify the Veteran or claimant of the decision. The C&P disability examination is conducted, if requested, solely within the bounds of the disability benefits claim adjudication and as such is separate and distinct from VA health care.

If there is a noted or suspicious condition discovered during a C&P disability examination requiring further study or treatment , VA should inform the examinee. Notification should take place as directed in *VHA Directive 2009-019, Ordering and Reporting Test Results, March 24, 2009*. This information is included in VHA's Office of Disability and Medical Assessment C&P Disability Examination Procedure Guide, which sets out VHA guidance for administering the disability program, and is one of the many tools used by C&P examiners in conducting disability examinations.

Pursuant to the guidance if the noted or suspicious condition is one that may require medical care, the C&P examiner should:

(a) Direct the Veteran to the enrollment department to provide an opportunity to apply for VA health care and assistance in completing an appropriate application.
(b) If emergent care is required, the Veteran should be escorted to the VA Medical Center (VAMC) "walk-in clinic" or Emergency Department as indicated. The examination appointment should be rescheduled as soon as possible, if not able to be completed at that time.
(c) Document in Computerized Patient Record System (CPRS) the Veteran was notified and what course will be followed.

VHA's Office of Disability and Medical Assessment will remind C&P examiners of the C&P Disability Examination Procedure Guide and VHA Directive 2009-019, with particular emphasis on ensuring the notification to the Veteran is documented in CPRS through written notification and during National calls.

Office of Disability and Medical Assessment will add an element to the Quality Ratability Review that assesses for the C&P examiner's documentation in CPRS that he or she has counselled any patient with a new diagnosis(es) on the need for follow-up care and documented any assistance they provided in obtaining VA care. This new Quality Indicator will be added for fiscal year 2016 .

To complete this recommendation, Office of Disability Management will provide the following documentation:

1. The written notification reminding C&P examiners of policy;
2. The list of national calls when the reminder was mentioned and the call script; and
3. Revisions to the Ratability Review that contain the new requirements for reviewing documentation in CPRS.

Recommendation 2. We recommended that the Under Secretary for Health develop guidance on what clinical information from secure messaging and My HealtheVet must be documented in the EHR.

Concur

Target date for completion: June 2016 Status: In process

The Office of Informatics and Analytics will develop guidance on what clinical information from Secure Messaging and My HealtheVet must be documented in the electronic health record.

To complete action on this recommendation, VHA will provide documentation of guidance issued to all VA Medical Centers.

Appendix C

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: May 27, 2015

From: Director, VA Desert Pacific Healthcare Network (10N22)

Subj: Healthcare Inspection — Poor Follow-Up Care and Incomplete Assessment of Disability, VA San Diego Healthcare System, San Diego, CA

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

1. I concur with the findings and recommendations in the DRAFT Report: Healthcare Inspection-Poor Follow-Up Care and Incomplete Assessment of Disability, VA San Diego Healthcare System, San Diego, CA.

2. If you have any questions regarding our responses and actions to the recommendations in the draft report, please contact me at (562) 826-5963.

Marie L. Weldon

Marie L. Weldon, FACHE
Attachment

Appendix D

System Director Comments

Department of Veterans Affairs

Memorandum

Date: May 19, 2015

From: Director, VA San Diego Healthcare System (664/00)

Subj: Healthcare Inspection — Poor Follow-Up Care and Incomplete Assessment of Disability, VA San Diego Healthcare System, San Diego, CA

To: Director, VA Desert Pacific Healthcare Network (10N22)

1. The event described in this report is a tragedy and it is important to identify opportunities to improve veteran care.

2. While elements of this report identify issues that deserve attention, there are also significant concerns with the methodology and conclusions.

3. The report relies heavily on the language of the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain as the determinant of what care should have been provided without clarity as to when a guideline is applicable or the significant differences between a "guideline for care" and a requirement for care. One of the references quoted in support of the Guideline (Chou R, Turner JA, Devine EB, et al. *The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for* a *National Institutes of Health Pathways to Prevention workshop,* Ann Intern Med. 2015; 162:276-286), while important, was published months after the event and could not have been known to the practitioner or the health care system.

4. In the analysis of Quality of Care issues the report notes that the Veteran was appropriately screened for alcohol and depression at the new patient visit of January 2013. The report then comments that “although recommended by the VA/DOD Guideline for patients receiving chronic opioid therapy, a suicide risk assessment was not

completed." However, at that January, 2013 visit, the patient had not previously received opioid therapy from the Primary Care Provider and had only received one prior prescription for a narcotic-containing medication within the VA San Diego Health Care System. Thus, at that visit, without applying hindsight, the Veteran could not have been said to have a stable or chronic opioid prescription that fell within the purview of the Clinical Practice Guideline.

5. The report comments:

   "The VA/DoD Guideline recommends the use of an OPCA prior to the initiation of chronic opioid therapy. The PCP did not initiate an OPCA or document informed consent." While we agree that an OPCA is appropriate in the setting of chronic opioid therapy, we do not believe it is possible for the Primary Care Provider to have been able to predict the chronicity of opioid therapy at the time of the January visit. Following that visit, as noted in the report, the Veteran cancelled a number of visits at which an OPCA could have been documented. We agree that at some point in the following months, in the setting of ongoing requests by the Veteran to renew the prescription, the provider should have refused to renew the opioid therapy without a face to face visit.

6. In the context of that requirement for a face-to-face visit, although the report notes in the section on Follow Up Activity that the Veteran rescheduled 8 appointment, neither the Executive Summary or the body of the report clearly state that the Veteran cancelled and rescheduled 7 face-to-face visits at which elements of the Clinical Practice Guideline might have been addressed.

7. The report notes that the Veteran was not receiving Physical Therapy (PT) within the VA and notes that the Veteran was communicating to his Primary Care Provider that he had been receiving PT outside the VA However, the Veteran's wife communicated that he was not receiving care from other health care systems. His wife also notes that he had troubled sleep although he did not relate that problem to his Primary Care Provider. The lack of candor by the Veteran with his Primary Care Provider is not commented on in the report.

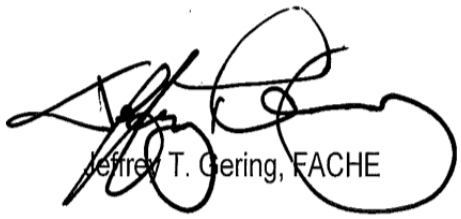
8. We note the absence of clear definition of what a "clinically relevant communication" consists of. While we agree that important communications should be documented in the record, without a standard, it is not possible to define a response to the recommendation to "ensure that all clinically relevant communications are documented in the electronic health record". There does not appear to be any correlation or

causal relationship between the use of the Secure Messaging System in MyhealtheVet to communicate between the provider and the Veteran, and the events in question. MyhealtheVet Secure Messages are available for review and appear to have been used in the preparation of the report.

9. In the Section commenting on TBI and Post-Traumatic Headaches, the report notes the differences between the information provided in the responses to screening questions during a post-deployment assessment and the responses to a neurologist conducting an evaluation for disability related to TBI. The report states:

   "The patient was diagnosed with TBI and post-traumatic headaches at the end of the neurology C&P visit, but he received no follow-up care."

   This statement is at odds with the purpose and context of a disability evaluation. The visit was being conducted to evaluate the Veteran's claim of TBI. Such an evaluation is not diagnostic of a new condition but rather is confirmation (or not) of a condition that the Veteran believes is already existing. It is inappropriate to characterize this as "diagnosis" of TBI.



Appendix E

VA Regional Office San Diego Director Comments

Department of Veterans Affairs

Memorandum

Date: June 3, 2015

From: Director, VA Regional Office San Diego

Subj: Healthcare Inspection — Poor Follow-Up Care and Incomplete Assessment of Disability, VA San Diego Healthcare System, San Diego, CA

To: Assistant Inspector General for Audits and Evaluations (52)

1. The San Diego VARO's comments are attached on the OIG Draft Report: Poor Follow-Up Care and Incomplete Assessment of Disability, VA San Diego Healthcare System, San Diego, CA.

2. Please refer questions to Jan Trausch at 619-400-5410.

(original signed by:)
Patrick C. Prieb
Director
Attachment

Comments to OIG's Report

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

OIG Recommendations

Recommendation 3. We recommended that the System Director implement processes to ensure that providers adhere to the VA/DoD *Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, including follow up assessment at appropriate intervals, when treating patients with chronic opioid therapy.

Concur

Target date for completion: June 30, 2015

Facility response: Care was available to this Veteran, and the other elements of the 2010 VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain have been implemented as part of the VASDHS Opioid Safety Initiative which includes documentation of the OPCA, UDS monitoring, and identification of a single provider for chronic opioid therapy. We will define and implement an additional metric that tracks the frequency of follow up visits with the prescribing provider.

Recommendation 4. We recommended that the System Director confer with Regional Counsel for possible disclosure(s) to the surviving family member(s) of the patient.

Concur

Target date for completion: May 31, 2015

Facility response: We will confer with Regional Counsel as to appropriate disclosure to surviving family members.

Recommendation 5. We recommended that the VA Regional Office San Diego Director review a sample of the specific rater's work and determine whether failure to obtain relevant service treatment records is a systemic issue with this rater when making compensation claim decisions.

Partial Concurrence

Target date for completion: June 30, 2015

VARO response: Due to the unique circumstances in this specific case and pending clarification from Compensation Service regarding STRs in the expanded ADT tab in CAPRI, the SDRO believes it is more appropriate to remind this specific Rater and all SDRO Raters via station training. This will take place no later than June 30, 2015. Training will emphasize the expanded ADT tab in CAPRI.

There is no explicit guidance from the Compensation Bulletin, or in the M21-1 Adjudication Procedures Manual, that directs an employee to develop for additional records based upon information found in the expanded ADT. The Compensation Service Bulletin of November 2013, states the following:

13. Expanded Admission, Discharge, and Transfer (ADT) Button in CAPRI

Target Audience: VSRs, Senior VSRs SVSRs, RVSRs, DROs, Authorization Quality Review Specialists (AQRSs), Rating Quality Review Specialists (RQRSs), and management.

We want to remind ROs to review the information found when clicking the ADT button under the Department of Defense (DoD) Records tab in CAPRI prior to completing decisions in which the member separated from military service and an event, injury, or disease is not shown in the available service treatment records (STRs). The other buttons found under the DoD Records tab, including the Radiology Report, can also reveal pertinent records. The DoD records found by clicking on the Expanded ADT and other buttons could change the outcome of an unfavorable decision when the available STRs are otherwise negative. Therefore, it is important for ROs to review this information."

On January 1, 2013, individual service departments began issuing their own version of a letter that certified the completeness of a service member's STRs. Prior to this date, no requirement for certification existed. Current procedures state, "if a certification letter/DD Form 2963 accompanies STRs that an RO obtains from a service department, the RO should not undertake additional development to obtain STRs unless the claimant alleges treatment at a specific military treatment facility (MTF) during a specific period of time, and records referring to the treatment do not exist in the available STRs, and are not accessible through the Compensation and Pension Record Interchange (CAPRI)." It is important to note, had this claimant been discharged today and certification received, no additional development would have been taken unless the claimant alleged treatment at a specific military treatment facility (MTF) during a specific period of time.

Appendix F

OIG Contact and Staff Acknowledgments

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