Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 16-00462-192

Healthcare Inspection

Opioid Prescribing Practice Concerns
VA Illiana Health Care System
Danville, Illinois

March 30, 2017

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General conducted a healthcare inspection to assess an alleged unsafe opioid prescribing practice of a primary care provider (PCP) at the VA Illiana Health Care System, Danville, IL. The specific allegation related to the initiation of a fentanyl patch to treat pain in a patient with a complex mental health history who subsequently died of fentanyl toxicity.

The events described in this hotline report refer to two PCPs, PCP A and PCP B. Our concerns focused on the prescribing practices of PCP B who was treating the patient at the time of his death. Our review revealed that the patient had a complicated mental health history with documented evidence of abuse of medications for mental health, opioid medications for pain, and illicit drugs. The patient was followed closely by mental health and PCPs.

We found PCP B considered the use of non-steroidal anti-inflammatory medications for pain but was concerned about the interaction with one of the patient's other prescribed medications. The patient signed an opioid consent and was informed of alternative treatments available. Fentanyl is typically prescribed to alleviate severe pain; it is not indicated for the management of acute pain or in opioid naïve patients. This patient had received opioid medications in the past for chronic pain issues and would be considered opioid tolerant. Although PCP B documented in the electronic health record that the patient's pain level was mild to moderate, PCP B had safety concerns regarding oral opioid analgesics and prescribed a low dose fentanyl patch in a small supply for this patient. The autopsy report showed pieces of fentanyl patches in the patient's gastric contents, indicating that the patient likely ingested one or more patches. The patient also had two patches on his back; one of which he obtained outside the VA as the dose on one of the patches was approximately eight times the dose the VA PCP had ordered. Facility pharmacy staff performed an opioid medications audit and confirmed that each fentanyl patch ordered by the VA PCP had been dispensed to the patient with the prescribed lower dose.

We did not substantiate that PCP B engaged in unsafe opioid prescribing practices, specifically regarding the initiation of a fentanyl patch to treat pain in a patient with a complex mental health history who subsequently died of fentanyl toxicity. The provider followed the 2010 *VA/Department of Defense Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain* recommendations when initiating the patient's opioid therapy. If used appropriately, the low dose fentanyl patches would not likely have resulted in fentanyl toxicity or death.

We made no recommendations.

Comments

The Veterans Integrated Service Network and Facility Directors reviewed the report and concurred with the findings (see Appendixes A and B, pp. 8–9).

JOHN D. DAIGH, JR., M.D
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General conducted a healthcare inspection to assess an alleged unsafe opioid prescribing practice of a primary care provider (PCP) at the VA Illiana Health Care System, (facility) Danville, IL for a patient who expired due to fentanyl toxicity.[1]

Background

The facility is part of Veterans Integrated Service Network (VISN) 12 and provides acute medical, surgical, community based outpatient, and mental health (MH) care. The facility has 42 hospital, 156 community living center, and 35 Psychosocial Residential Rehabilitation Treatment Program beds, and community based outpatient clinics in Decatur, Mattoon, Peoria, and Springfield, IL. Additionally, an outpatient clinic is located in West Lafayette, IN.[2] In fiscal year (FY) 2015, the facility served a population of 33,268 unique patients and provided 377,432 outpatient visits.[3]

References and Guidance. The Veterans Health Administration (VHA) Pain Management Directive, published in October 2009, established policy and procedures for the improvement of pain management in VA facilities. It calls for the use of published clinical guidelines for pain management protocols.[4] The directive states that in addition to obtaining a medical history, routine screening for pain, and a comprehensive pain assessment, an individualized plan of care should address the feasibility of non-pharmacologic interventions.[5]

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 dose adjustments of pain medications (opioids)[6] to maximize pain control.[7] To reduce the risk of opioid misuse or adverse outcomes, the VA/DoD

[1] Fentanyl is a powerful synthetic opiate analgesic similar to but more potent than morphine. National Institute on Drug Abuse Web site. https://www.drugabuse.gov/drugs-abuse/fentanyl. Accessed December 22, 2015.
[2] VA Iliana Health Care System, Danville, Illinois. http://www.danville.va.gov/. Accessed January 5, 2016.
[3] VHA Support Service Center (VSSC), Trip Pack Report II-FY2016 through November. http://reports2.vssc.med.va.gov/ReportServer/Pages/ReportViewer.aspx?%2fMgmtReports%2fTripPack%2fTripPackII&rs:Command=Render. Accessed January 5, 2016.
[4] VHA Directive 2009-053, *Pain Management*, October 28, 2009. This VHA Directive expired October 31, 2014 and has not been updated.
[5] Non-pharmacologic interventions include education interventions to improve self-management, psychological and family interventions, community support, rehabilitation, complementary therapies, and pain medicine specialty procedures such as injections, nerve blocks, ablations, and neuromodulation. VHA Directive 2009-053, *Pain Management*. p.A-5.
[6] Opioids are a class of drugs that include the illegal drug heroin as well as powerful pain relievers available legally by prescription, such as oxycodone (OxyContin®), hydrocodone (Vicodin®), codeine, morphine, fentanyl, and many others. National Institute on Drug Abuse, National Institute of Health, https://www.drugabuse.gov/drugs-abuse/opioids. Accessed on May 10, 2016.
[7] *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, Version 2.0, May 2010.

Guideline recommends that prescribers of 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 patients for evidence of opioid misuse or substance abuse, conduct a suicide risk assessment at the onset of therapy and regularly thereafter, and consider the use of written opioid pain care agreements (OPCAs) and periodic urine drug testing. OPCAs generally listed expectations for providers and patients, such as following dosing recommendations, random urine drug testing, and having only one prescriber for opioids to prevent multiple prescriptions.

Due to concerns that local OPCAs may contain language considered threatening to the patient-physician therapeutic relationship, VHA established policy in May 2014 regarding informed consent for long-term opioid therapy that would take the place of local OPCAs. The National Pain Management Program and the National Center for Ethics in Health Care jointly developed, with input from other national program offices and VHA medical facility staff, a patient information guide and a form titled, "Consent for Long-Term Opioid Therapy for Pain" (consent). Prior to initiating long-term opioid therapy, prescribers must complete the informed consent process whereby they discuss the risks, benefits, and alternatives of the treatment with patients.[8]

Allegation. We received an allegation that a PCP engaged in an unsafe opioid prescribing practice when initiating a fentanyl patch to treat pain in a patient with a complex mental health history who subsequently died of fentanyl toxicity.

Scope and Methodology

We conducted our review from October 2015 through March 2016. We made a site visit the week of February 11, 2016.

We interviewed facility leadership, PCPs, pharmacists, and other individuals knowledgeable about the events discussed in this report. We reviewed relevant VHA and facility policies and procedures, credentialing and privileging profiles, scopes of practice, and the patient's electronic health record (EHR) and autopsy report.[9] The events described in this hotline report refer to two PCPs, PCP A and PCP B. Our concerns focused on the prescribing practices of PCP B who was treating the patient at the time of his death.

VHA Directive 2009-053, *Pain Management*, October 28, 2009, cited in this report, expired October 31, 2014. We considered the policy to be in effect as it had not been superseded by more recent policy or guidance. In a June 29, 2016, memorandum to supplement policy provided by VHA Directive 6330(1),[10] the VA Under Secretary for

[8] VHA Directive 1005, *Informed Consent for Long –Term Opioid Therapy for Pain*, May 6 2014.
[9] An autopsy is a medical exam of the body of a person who has died. An autopsy includes an external and internal inspection of the body, and may include samples for analysis of tissue and body fluids. *Autopsy Pathology: A Manual and Atlas*, Chapter 15, 178–185.
[10] VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 11, 2017.

Health (USH) mandated the "…continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."[11] The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "…the timely rescission or recertification of policy documents over which their program offices have primary responsibility."[12]

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

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

[11] VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.
[12] Ibid.

Case Summary

The patient was in his late 20s at the time of his death in 2015. He was receiving treatment at the facility for several MH and medical conditions including chronic low back pain. Since late 2014, the patient had been prescribed an opioid medication orally once daily as needed for pain. He signed a consent for long-term opioid therapy with PCP A.

In 2015, the patient was also seen regularly by a facility MH provider who conducted suicide risk assessments. The patient's suicide risk was found to be moderate.[13] A Safety-Crisis Management Plan was in place.

In early 2015, the patient admitted to his MH provider that he had recently attempted to overdose on one of his MH medications and was using an illegal drug. Approximately 8 days later, the patient informed his MH provider he was buying opioid medications and benzodiazepines[14] from a friend. This information was documented by the MH provider in the patient's EHR and acknowledged by PCP A.

Two days later, the patient stopped by and spoke to a nurse at the primary care clinic. The nurse informed the patient that he would not be receiving opioids from the clinic because it was unsafe to take illicit drugs with prescribed opioids. The nurse documented that the taking of illicit drugs was in violation of the patient's consent with PCP A. The nurse offered the patient a referral to the Substance Abuse Rehabilitation Program, but the patient declined. The nurse notified PCP A who discontinued the patient's prescribed opioid medication.

Approximately one month later, the patient presented to PCP B, complaining of chronic low back pain and requesting reinstatement of opioid medication. PCP B documented the patient's pain as mild to moderate and considered treatment with non-steroidal anti-inflammatory drugs (NSAIDS) and "maybe some duralgesic [*sic*] pain."[15] PCP B indicated in the consent form the patient signed, that the patient was not a candidate for NSAIDS because these drugs could interact with one of the patient's other medications; nor was he a candidate for oral opioid medications because of a history of drug overdose with oral medications. PCP B prescribed a low dose transdermal fentanyl patch with instructions for application every 72 hours. The patient signed a new

[13] Moderate risk is defined in the PTSD/SUD General Note in the EHR as, "Under right conditions patient could be managed as outpatient with a safety plan, willingness to engage in treatment, social support in place, suicidal risk factors, but significant protective factors."
[14] Benzodiazepines are depressants that produce sedation, induce sleep, relieve anxiety and muscle spasms, and prevent seizures. *Drug Fact Sheet.* Drug Enforcement Administration. http://www.dea.gov/druginfo/drug_data_sheets/Benzodiazepines.pdf. Accessed December 22, 2015.
[15] Duragesic® is a patch applied to the skin that contains fentanyl (an opioid) for the management of persistent, moderate to severe chronic pain. U.S. Drug and Food Administration. http://www.fda.gov/downloads/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm051978.pdf. Accessed March 21, 2016.

consent for long-term opioid therapy which included a list of alternative treatments, and PCP B ordered a urine drug test which was negative for opiates.[16]

Five days later, a patient aligned care team (PACT) nurse documented in a clinic note that the patient stated the fentanyl patch was working well. Upon the patient's return to the clinic the next day, he requested a refill of the fentanyl patches as he was initially given a 6-day supply consisting of two patches. The request was granted and he was prescribed five low dose fentanyl patches. Approximately 2 weeks later, he again presented to his PACT nurse, requesting another 2-week refill of the patches. He stated that the patches were helping, but he was still having breakthrough pain and suggested that he may need an increased dose. PCP B wrote a refill order for five low dose fentanyl patches but the patient did not receive an increased dose.

Six days later, the patient presented to the facility's Urgent Care Clinic concerned about a medication reaction; he informed staff that he had been changed to fentanyl patches a month ago. A nurse documented that the patient was sitting quietly in the chair and reported the following: "having trouble sleeping, wakes up with a jolt, having anxious periods, and sometimes has uncontrolled shaking when standing. No signs or symptoms of these issues at this time." The Urgent Care Clinic triage nurse advised him to report to his primary care clinic, which had extended hours on that day. Upon checking in to the primary care clinic, he was told he would have to wait since he did not have an appointment. According to the EHR, after waiting approximately 20 minutes, the patient informed the clerk he could not wait any longer but would come back the next day for a scheduled appointment with his MH provider.

The following morning, the patient was found dead in his home. The autopsy report listed the cause of death as fentanyl intoxication. The autopsy report showed pieces of fentanyl patches in the patient's gastric contents indicating that he had ingested one or more patches. The patient also had two patches on his back; one of which he obtained outside the VA as the dose on one of the patches was approximately eight times the dose the VA PCP had ordered. Facility pharmacy staff performed an opioid medications audit and confirmed that each fentanyl patch ordered by the VA PCP had been dispensed to the patient with the prescribed lower dose.

Inspection Results

We did not substantiate that PCP B engaged in an unsafe opioid prescribing practice when initiating a fentanyl patch to treat pain in a patient with a complex mental health history who subsequently died of fentanyl toxicity.

Our review of the patient's chronic pain management revealed that the patient had a complicated MH history with documented evidence of abuse of medications for mental health, opioids for pain, and illicit drugs. We found evidence of collaboration between

[16] Opiates are derived from opium, while opioids generally refer to the synthetic form of the drug. In this report, the terms are used interchangeably.

MH and the primary care team (see case summary). The MH staff followed the patient closely, and evidence within the EHR suggests the patient attended MH appointments at least weekly. The patient refused previous offers of physical therapy to improve his pain.

On the day the patient informed his MH provider about his illicit drug use, he also indicated that he had taken approximately 50 tablets of one of his prescribed MH medications, 5-6 shots of liquor, and an illegal substance. He further stated that he promptly made himself vomit and did not seek medical attention. After the MH provider determined that the patient was not at imminent risk for suicide, he/she provided supportive counseling and amended the patient's safety plan. This encounter was documented in the patient's EHR and electronically acknowledged by PCP A. The patient was informed at his next primary care encounter that because he violated his consent, PCP A would no longer refill his opioid prescription.

When the patient presented to PCP B the next month, complaining of chronic low back pain and requesting reinstatement of opioid medication, PCP B documented a reasonable approach to initiating opioid therapy. Fentanyl is typically prescribed to alleviate severe pain and is not indicated for the management of acute pain or in opioid naïve patients. This patient had received opioids in the past for chronic pain issues and would be considered opioid tolerant. Although PCP B documented that the patient's pain level was mild to moderate, PCP B indicated during an interview that because of the patient's history of misuse of oral medications, a tamper resistant duragesic patch (fentanyl) seemed a safer option than restarting oral opioid therapy.

The patient had no absolute contraindications for fentanyl and, when used as instructed, the low dose fentanyl patches would not likely reach toxic levels within the bloodstream. The autopsy report showed pieces of fentanyl patches in the patient's gastric contents, indicating that the patient likely ingested one or more patches. The patient also had two patches on his back; one of which he obtained outside the VA as the dose on the patch was approximately eight times the dose that the VA PCP had ordered. Facility pharmacy staff performed an opioid medications audit and confirmed that each fentanyl patch ordered by the VA PCP had been dispensed to the patient with the prescribed lower dose.

We found that PCP B followed the VA/DoD Guideline for the initiation and early monitoring of a patient on opioid therapy. PCP B assessed the patient, considered NSAIDS and other alternative treatments, ordered a urine drug screen, which was negative for opiates, obtained the patient's signed consent for long-term opioid therapy, and ordered appropriate and timely supplies of low-dose fentanyl. MH staff conducted multiple suicide risk assessments in the weeks prior to the patient's death, and various PACT team members discussed the patient's new medication with him on several occasions. If used appropriately the low dose fentanyl patches would not likely have resulted in fentanyl toxicity or death.

Conclusions

We did not substantiate that PCP B engaged in unsafe opioid prescribing practices, when initiating a fentanyl patch to treat pain in a patient with a complex mental health history who subsequently died of fentanyl toxicity.

In light of this patient's complex MH history and previous documented evidence of abuse of medications for MH, opioids for pain, and illicit drugs, we considered whether alternative treatment options for management may have been more appropriate. We found PCP B was concerned about the use of NSAIDs to avoid a possible interaction with one of the patient's prescribed medications. The patient signed an opioid consent and was informed of alternative treatments available.

The patient was given low dose fentanyl patches initially in small (6 day) supplies, had an initial urine drug test, signed a consent for opioid therapy which included information regarding alternative treatments, underwent regular suicide risk assessments, and had several follow-up encounters with various PACT team members to discuss his response to the new medication. The autopsy report showed pieces of fentanyl patches in the patient's gastric contents, indicating that the patient likely ingested one or more patches. The patient also had two patches on his back; one of which he obtained outside the VA as the dose on one of the patches was approximately eight times the dose that the VA PCP had ordered. Facility pharmacy staff performed an opioid medications audit and validated that each fentanyl patch ordered by the VA PCP had been dispensed to the patient with the prescribed lower dose.

We determined PCP B followed the 2010 VA/DoD Guideline recommendations when initiating opioid therapy for this patient. If used appropriately, the low dose fentanyl patches would not likely have resulted in fentanyl toxicity or death. We made no recommendations.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: January 24, 2017

From: Director, VISN 12 (12N12)

Subj: Healthcare Inspection—Opioid Prescribing Practice Concerns, VA Illiana Health Care System, Danville, Illinois

To: Director, Denver Regional Office, Office of Healthcare Inspections (54DV)
Director, Management Review Service (VHA 10E1D MRS Action)

1. I have reviewed and concur with the findings and with the conclusions of no recommendations regarding the Office of Inspector General Healthcare Inspection conducted the week of February 11, 2016.

2. If you have any questions or concerns, please contact Chris Iacovetti, VISN 12 Deputy Quality Management Officer, at 708-492-3918.

Renee Oshinski
Network Director, VISN 12

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: January 24, 2017

From: Director, VA Illiana Health Care System (550/00)

Subj: Healthcare Inspection—Opioid Prescribing Practice Concerns, VA Illiana Health Care System, Danville, Illinois

To: Director, VISN 12 (12N12)

1. I have reviewed and concur with the findings and with the conclusion of no recommendations regarding the Office of Inspector General Healthcare Inspection conducted the week of February 11, 216.

2. If you have any questions, please contact Alissa Broderick, Chief of Quality Management, at 217-554-5082.

Stephanie Young
Medical Center Director

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Ann Ver Linden, RN, MBA, Team Leader Julie Kroviak, MD Jennifer Kubiak, RN, MPH Glen Trupp, RN, MHSM

Appendix D

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