



**Department of Veteran Affairs
Office of Inspector General**

Office of Healthcare Inspections

Report No. 16-04208-30

**Healthcare Inspection
Unexpected Death of a Patient:
Alleged Methadone Overdose
Grand Junction VA Health Care System
Grand Junction, Colorado**

November 30, 2017

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to an allegation received in 2016 that a patient died of an accidental methadone overdose 2 days after receiving a prescription for methadone from a primary care physician (PCP) at the Grand Junction VA Health Care System (System), Grand Junction, CO. We requested the System evaluate the appropriateness of the patient's plan of care for pain and comment specifically on the lack of a cardiac workup given the patient was prescribed methadone. Because methadone is associated with a disturbance in cardiac rhythms, our specific concern was whether the PCP considered the results of either a previous or current electrocardiogram (ECG) in his clinical decision to use methadone to manage the patient's chronic pain.

The System provided an interim response August 15, 2016 followed by a final response on December 16, 2016. While the System's responses included a review of the patient's plan of care for pain, they did not address the issue of whether the PCP considered the results of either a previous or current ECG in his clinical decision to use methadone. Because the VA/Department of Defense (DoD) 2010 Clinical Practice Guideline¹ for the Management of Opioid Therapy for Chronic Pain and current VA and System pharmacy policies recommend obtaining an ECG before starting methadone, we initiated a review to assess the merits of the complaint and evaluate the System's methadone prescribing practices.

We substantiated the allegation that the patient identified in the complaint died 2 days after receiving a prescription for methadone from a System PCP. We were unable to substantiate that methadone contributed to or was the cause of the patient's death. Neither an autopsy or toxicology² study was performed, so additional information was not available.

The PCP for the patient identified in the complaint informed us he was not aware of the VA/DoD 2010 Clinical Practice Guideline recommendation to obtain an ECG before prescribing methadone. He also told us he was taught to get an ECG before starting patients on methadone and it was his usual practice to do so. The PCP further told us that he routinely orders an ECG for patients on long term methadone therapy for chronic pain management; however, for this patient he did not remember reviewing previous ECGs, nor did he obtain a new one. Additionally, we found that from October 2015 through September 2016, other System PCPs did not consistently document ECG assessment before starting patients on methadone for chronic pain management.

The System lacked a process to ensure prescribers were aware of current Veterans Health Administration (VHA) directives, policies, and guidance related to the use of methadone for the management of chronic pain.

¹ VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010.

² Toxicology tests performed for autopsies determine if and what kind of drugs were in a person's system. These tests also measure the amount of drugs to evaluate if the concentration is of a lethal dosage.

The System also did not have a process to ensure providers consider VA/DoD Clinical Practice Guideline recommendations in their clinical decision to prescribe methadone for chronic pain management.

VHA's "Consent for Long-Term Opioid Therapy for Pain" is an electronic document that is used to obtain consent for long-term opioid therapy. Although, the template document may be used as a patient education tool, it does not include risk factors specific for methadone. Providers may enter additional information such as risk factors unique to methadone therapy to the consent form; however, neither the patient's PCP nor other System PCPs were aware of how to add methadone-specific risk factors to the electronic consent form. The patient's PCP did not document educating the patient about the risks of taking methadone for chronic pain management.

After investigating the events surrounding the death of the patient identified in the complaint, System leaders did not confer with the Office of Chief Counsel to determine if an institutional disclosure was necessary.

OIG Update: As of June 2017, the System implemented noteworthy changes to its methadone prescribing practices. The current pharmacy policy requires an ECG before methadone is prescribed, annually thereafter, and more frequently as appropriate. The Pain Pharmacist is monitoring the prescriptions for patients currently receiving methadone for chronic pain management, making recommendations for dose adjustments, and documenting the recommendations in the electronic health record.

We recommended:

- The System Director ensure that providers who prescribe methadone receive education on VA/DoD Clinical Practice Guideline recommendations related to the use of methadone for the management of chronic pain.
- The System Director develop a process to ensure that providers consider VA/DoD Clinical Practice Guideline recommendations, specifically the use of ECGs, in their clinical decision to prescribe methadone for chronic pain management.
- The System Director ensure that patients receiving methadone be informed, not only of complications related to opioids but also, complications specific to methadone and that this discussion is documented.
- The System Director ensure that the consent form for patients receiving methadone for chronic pain management be modified to include methadone-specific risks.
- The System Director confer with the Office of Chief Counsel regarding the patient described in this report for possible institutional disclosure to the designated family member(s), and take action as appropriate.

Comments

The Veterans Integrated Service Network and System Directors concurred with our recommendations and provided acceptable action plans. (See Appendixes B and C, pages 14–18 for the full text of the Directors' comments.) We consider Recommendations 2 and 5 closed. We will follow up on the planned actions for Recommendations 1, 3, and 4 until they are completed.



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Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to an allegation that a patient died of an accidental methadone overdose 2 days after receiving a prescription for methadone from a primary care physician (PCP) at the Grand Junction VA Health Care System (System), Grand Junction, CO. To assess the merits of the complaint, OIG initiated a review of the System's methadone prescribing practices.

Background

The System operates 23 acute care and 30 Transitional Care³ Unit beds and is located 251 miles west of Denver in the rural community of Grand Junction, CO. The System provides primary outpatient care as well as acute inpatient medical, surgical, and psychiatric services for approximately 37,000 patients. A community based outpatient clinic in Montrose, CO, serves patients in southwestern Colorado and a telehealth outreach clinic,⁴ located in Craig, CO, provides services to patients in northwestern Colorado and southwestern Wyoming.

Chronic Pain Treatment

Chronic pain, defined as lasting more than 12 weeks, is most prevalent in Veterans Health Administration (VHA) patients age 45-64.⁵ The goal of treatment is to reduce pain and improve function, so the person can resume day-to-day activities.⁶

Opioid medications (opioids) are effective in treating moderate to severe chronic pain by reducing the intensity of pain signals that reach the brain. Commonly prescribed opioids include: codeine, hydrocodone (Vicodin®), oxycodone (OxyContin®), morphine, hydromorphone (Dilaudid®), methadone, and fentanyl.⁷

Methadone

Methadone is an opioid prescribed for patients with narcotic addiction or moderate to severe chronic pain. While any independent health care provider who is licensed and

³ Transitional care refers to a patient leaving one care setting and moving to another. The System Transitional Care Unit provides care to patients requiring extended rehabilitation and care following surgery or lengthy hospitalizations before returning to independent living.

⁴ Telehealth in VHA is the use of technologies to facilitate access to care and improve the health of designated individuals and populations with the intent of providing the right care in the right place at the right time.

⁵ The Journal of the International Society for Pharmacoeconomics and Research, *Evaluating trends in Chronic Pain prevalence in the United States Veterans Health Administration Population*, May 2015 Volume 18, Issue 3, Page A294.

⁶ NIH Medline Plus, *Chronic Pain: Symptoms, Diagnosis, & Treatment*, Spring 2011 Issue: Volume 6 Number 1 Page 5-6.

⁷ US National Library of Medicine National Institutes of Health. *Correlates of Prescription Opioid Initiation and Long-term Opioid Use in Veterans with Persistent Pain*, Page 6 Table 3.

appropriately registered with the U.S. Drug Enforcement Administration⁸ can prescribe methadone for pain management, administering it for the purposes of treating narcotic addiction requires a separate U.S. Drug Enforcement Administration registration specific for narcotic treatment programs.

Methadone produces insensitivity to pain, a slowing of respirations, lowering of the blood pressure, and slowing of the heart rate. In 2006, the U.S. Food and Drug Administration⁹ alerted physicians to the potential for respiratory depression¹⁰ and cardiac arrhythmias¹¹ in patients taking methadone. The Centers for Disease Control (CDC) estimates that, between 1999 and 2015, more than 183,000 people in the United States died from overdoses related to prescription opioids, and methadone was involved in one third of all opioid-related deaths. The CDC recommends that health care providers who choose to prescribe methadone have substantial experience with its use, follow consensus guidelines for appropriate opioid prescribing, and instruct patients about the potential risks associated with taking methadone.¹²

VHA Publications Related to Methadone

In 2006, VHA Pharmacy Benefits Management Strategic Healthcare Group issued a physician advisory related to methadone that stated the following:¹³

- Before prescribing methadone, providers should familiarize themselves with the unique pharmacologic properties and recommendations and different strategies for dosing methadone.
- The use of methadone for pain should ideally be done in the context of an organized pain clinic or with assistance of local pain management experts, including health care providers or pharmacists, who have experience with methadone use.
- Advise patients on how to take methadone and not to take more than the prescribed amount of methadone without first consulting their health care provider.

Additionally, VA/DoD recommended in May 2010 that before prescribing methadone, healthcare providers inform patients of the risk for arrhythmia and obtain an

⁸ The U.S. Drug Enforcement Administration (DEA) is responsible for enforcing the controlled substance laws of the United States. www.dea.gov/about/mission. Accessed January 9, 2017.

⁹ The U.S. Food and Drug Administration is responsible for the safety of human medicines, medical devices and vaccines.

¹⁰ Opioid-induced respiratory depression is described in terms of a respiratory breath rate less than 12 breaths per minute.

¹¹ The term arrhythmia refers to any condition that causes the heart to beat too fast, slow, or erratically.

¹² Centers for Disease Control, MMWR, *Vital Signs: Risk for Overdose from Methadone Used for Pain Relief— United States, 1999–2010*, July 2012. Page 1.

¹³ Department of Veterans Affairs Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel Center for Medication Safety, *National PBM Bulletin: FDA Public Health Advisory on Methadone*, November 30, 2006.

electrocardiogram (ECG), with an additional ECG once the methadone dose is stabilized and annually thereafter.¹⁴

In July 2016, VA Pharmacy Benefits Management Services provided specific guidance related to methadone that recommended, for patients with cardiac risk factors, obtaining a baseline ECG (an ECG within the previous 3 months was sufficient) and for patients without risk factors, an ECG within the last 12 months; both categories should receive patient education that combining methadone with illicit drugs or alcohol may be fatal.¹⁵

Patient Education and Informed Consent

VHA requires prescribers to educate patients about the risks, benefits, and alternatives to long-term opioid therapy and obtain their signatures on the Department of Veterans Affairs (VA) Form 10-0431c, *Consent for Long-Term Opioid Therapy for Pain*.¹⁶ The consent form, which must be signed using an electronic software package,¹⁷ describes possible alternatives to the use of opioids for pain management and describes the general risks associated with their use. The form, when used together as part of a discussion with the patient, meets VHA's policy requirement for informed consent. Patient education information is included on VA Form 10-0431c, however, the information is not specific for methadone and does not include the risk for respiratory depression or cardiac arrhythmia.

Disclosure of Adverse Events to Patients

VHA requires discussion of clinically significant facts between providers and patients or their personal representative about harmful events that occur while receiving care within the VA healthcare system, including harm that may not be obvious or where there is a potential for harm in the future.¹⁸ This is referred to as a disclosure of adverse events and may take the form of a clinical disclosure or institutional disclosure. A clinical disclosure occurs when the physician informs the patient or the patient's personal representative that a harmful or potentially harmful event occurred during the patient's care. An institutional disclosure is a more formal process by which facility leaders and clinicians, after conferring with the Office of Chief Counsel, inform the patient or personal representative that an event occurred during the patient's care that resulted in or may result in, death or serious injury. For a patient who is deceased, the disclosure must be communicated to the patient's personal representative.¹⁹

¹⁴ VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010. Page 38.

¹⁵ VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives. *Oral Methadone Dosing in Chronic Pain*. July 2016. <http://vawww.pbm.va.gov>. Accessed August 29, 2017.

¹⁶ VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*. May 6, 2014.

¹⁷ VHA Handbook 1004.05. iMedCONSENT™, December 10, 2014. The electronic consent package must be used unless (1) The patient declines to sign using the electronic signature pad; (2) a temporary system failure prohibits proper use of the program; (3) The patient (or surrogate) is giving consent in a situation not supported by the iMedConsent™ software or (4) Use of the program would introduce infection control issues (for example, the patient is in isolation).

¹⁸ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2012.

¹⁹ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*; October 2012. Page 7-10.

Prior Reports

See Appendix A for relevant OIG reports published in the past 3 years.

Allegation

In May 2016, OIG received a complaint alleging that a patient died in 2014 of an accidental methadone overdose 2 days after receiving a prescription for methadone from a System PCP. To assess the merits of the complaint, we requested the System evaluate the patient's plan of care for pain and comment on the lack of a cardiac workup given the patient was prescribed methadone. Because methadone is associated with a disturbance in cardiac rhythms, our specific concern was whether the PCP considered the results of either a previous or current ECG in his clinical decision to use methadone to manage the patient's chronic pain. The System provided an interim response August 15, 2016, followed by a final response on December 16, 2016. The System's responses included a review of the patient's plan of care for pain, but did not address the issue of whether the PCP considered the results of either a previous or current ECG in his clinical decision to prescribe methadone. Because the VA/DoD 2010 Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain and current VA and System pharmacy policies recommended obtaining an ECG before starting methadone, we initiated a healthcare review to assess the merits of the complaint and evaluate the System's methadone prescribing practices. The objectives of the review were to determine if:

- The patient identified in the complaint died of an accidental methadone overdose 2 days after receiving a prescription for methadone from a System PCP.
- The patient identified in the complaint had a cardiac work up, specifically an ECG, and methadone-specific patient education prior to receiving the methadone prescription.
- Other System patients received cardiac work ups, specifically ECGs, as well as methadone-specific education prior to receiving methadone prescriptions.

Scope and Methodology

We initiated our review on January 3, 2017 and conducted a site visit on February 28 and March 1, 2017.

We interviewed the complainant, System leaders, medical, pharmacy, and other staff familiar with the System's methadone prescribing practices. We also reviewed the following:

- VHA directives and handbooks related to informed consent and pain management
- VA/DoD 2010 Clinical Practice Guideline specific for methadone.
- VA Pharmacy 2006 and 2016 methadone prescribing recommendations.

- Relevant medical literature, as well as System policies related to opiate use and in particular methadone prescribing, dosing, and education.
- The training records of the System providers prescribing methadone at the time of the events discussed in this report.
- The electronic health records (EHR) for the 44 System patients with methadone prescriptions between October 1, 2015 and September 30, 2016 (review period).
- The EHRs of the 25 System patients with methadone prescriptions as of March 1, 2017.
- The death certificate, police report, and EHR for the patient identified in the complaint.

Our review focused on the System's methadone prescribing practices for patients with non-cancer chronic pain. We did not include patients receiving methadone prescriptions from non-VA prescribers or pharmacies, or receiving methadone for cancer pain or to treat addiction.

We substantiate allegations when the facts and findings support the alleged events or actions. We do not substantiate allegations when the facts show the allegations are unfounded. We do not substantiate allegations if 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.

Patient Case Summary

The patient was a man in his early 60's with a history of chronic pain syndrome,²⁰ paroxysmal supraventricular tachycardia (PSVT),²¹ chronic obstructive pulmonary disease (COPD),²² and kidney stones.²³ Between 2001 and 2006, the patient's PCP prescribed non-opioid and opioid medications to manage his chronic pain. In 2006, the patient developed "worsening back pain" and received his first prescription for methadone. Four months later, the PCP described the patient's pain as "poorly controlled" and added an opioid medication used for moderate pain (opioid #1) to his standing regimen of methadone 15 mg 3 times per day and another short acting opioid pain medication (opioid #2), up to 6 tablets per day. The patient remained on methadone until 2008 when he relocated and transferred his care to another VAMC. He was not prescribed methadone at the other VAMC and only received opioid #2 for back pain.

In fall 2011, the patient re-established care at the System. He sustained a wrist injury approximately 2 months later and received an opioid pain medication (opioid #3) in the Emergency Department (ED). Due to persisting wrist pain in fall 2012, the PCP increased opioid #3 to one tablet three times per day as needed but noted that it may be necessary to consider a long acting opioid. In fall 2013, the PCP documented the chronic wrist pain as having become worse and noted the presence of a new pain affecting the left hand. The PCP discontinued opioid #3 and started opioid #2, up to six tablets per day as needed. In a telephone contact 2 weeks later, the patient described obtaining pain relief by taking two opioid #2 tablets three times per day.

The patient presented to the System ED in early winter 2013 complaining of a rapid heartbeat but no shortness of breath or chest pain after not taking a medication used to control heart rate for 2 days. An ECG done that day showed a normal sinus rhythm and a QTc²⁴ interval of 447 milli seconds. The patient was restarted on his previous blood pressure medication and discharged.

In early spring 2014, after the patient had stopped his pain medications due to concerns of side effects, he was seen for a routine PCP visit. He continued to have symptoms attributed to the chronic pain syndrome affecting his low back, wrist, and knee. The PCP presented several management options for pain control and the patient elected to resume the regimen of opioid #1 and opioid #2 (at a reduced dose of up to four tablets

²⁰ Pain which lasts longer than 6 months is considered chronic pain. Sometimes, chronic pain subsequently causes complications. These complications, in turn, can make the pain worse. A chronic pain syndrome is the combination of chronic pain and the complications that are making the original pain worse.

²¹ PSVT refers to an episode of rapid heart rate that comes and goes and can cause the heart to beat over 100 and up to as much as 250 beats per minute.

²² COPD is a progressive disease that makes it hard to breathe.

²³ Kidney stones are hard pieces of material that form in one or both of the kidneys. The stones may be small or large; large ones may become lodged in the kidney/renal system and block the flow of urine, causing severe pain.

²⁴ The QT interval represents the period of time it takes for the heart's main blood pumping chambers (ventricles) to contract and recover from contracting. QTc is the corrected QT interval and estimates the QT interval at a heart rate of 60 bpm which allows comparison of QT values over time at different heart rates and improves detection of patients at increased risk for arrhythmias associated with prolonged QT intervals.

per day). A month later, the patient was assigned a new PCP by the System because of internal staff physician changes.

In fall 2014, the new PCP documented the patient's main complaint of "back pain" as severe to the degree that earlier in the day he visited the ED concerned he could again have a kidney stone. Computed tomography²⁵ imaging was done and did not reveal a stone. The PCP noted that the patient expressed a desire "to try something different for his pain...[h]e is tired of taking [opioid #2], [h]e was previously on methadone years ago." The PCP's revised pain management plan consisted of starting methadone 10 mg three times per day, and increasing the prescribed amount of opioid #2 (from 4 to 6 tablets per day, as needed, for breakthrough pain), with clinic follow-up in 3 months. The PCP documented obtaining the patient's signature on the standard Consent for Long Term Opioid Therapy form. Neither the consent form nor the PCP's chart entry contained documentation informing the patient as to the possible adverse respiratory or cardiac effects of methadone. An ECG was not obtained. The most recent ECG available in the EHR had been performed during the 2013 ED visit (normal sinus rhythm, QTc interval 447 milli seconds).

The patient left the primary care clinic appointment with instructions to begin methadone 10 mg 3 times per day and utilize opioid #2, up to 6 tablets per day as needed, for breakthrough pain. The patient filled the methadone and opioid #2 prescriptions at the System pharmacy that day. Two days later, the patient was found by family members dead in his bed. Emergency medical personnel and the police were called and along with the Coroner arrived at the patient's home. The official police report documents the Coroner pronouncing the patient deceased as the result of natural causes; it states that no autopsy would be done. The patient's official death certificate listed COPD as the cause of death and the manner of death as natural.

Inspection Results

Issue 1: Death Due to an Alleged Accidental Methadone Overdose

We substantiated that the patient named in the complaint died 2 days after receiving a prescription for methadone from a System PCP. We were unable to determine that methadone contributed to or was the cause of the patient's death.

The patient's last primary care clinic appointment took place in fall 2014. As detailed in the case summary, the PCP documented the patient's main complaint as "back pain," severe to the degree that earlier in the day he visited the ED concerned he could again have a kidney stone. The PCP noted the patient's desire "to try something different for his pain," revised the pain management plan to include methadone 10 mg 3 times per day, and increased the patient's previously prescribed opioid #2 from 4 to 6 tablets per day, as needed, for breakthrough pain, with clinic follow-up in 3 months. The PCP also documented obtaining the patient's consent for the use of long-term opioids for pain. The patient's methadone prescription was filled by the System

²⁵ Computed tomography (CT) is a special type of x-ray that creates detailed pictures of the body.

pharmacy that day. Two days later, family members found the patient in his bed at home and not breathing. Local emergency services personnel and police were called and upon arrival, determined the patient to be unresponsive and without respirations, blood pressure, or pulse. The official police report states “Coroner arrived and pronounced the patient deceased. Coroner²⁶ determined that it was a natural cause death an [sic] no autopsy would be done.”

The patient’s PCP told us that he only became aware that the patient had died when asked to sign the death certificate. We reviewed a copy of the patient’s official death certificate and found the “immediate cause, final disease or condition resulting in death” documented as “COPD” with manner of death described as “natural.”

Issue 2: ECG and Patient Education for the Identified Patient

The PCP was not aware of VA/DoD’s Clinical Practice Guideline recommendation to obtain an ECG before prescribing methadone. He did not document reviewing the patient’s previous ECGs or ordering a new ECG before starting the patient on methadone. Additionally, the PCP did not document providing patient education specific to the risks associated with methadone.

VA/DoD 2010 Clinical Practice Guideline recommended obtaining an ECG before starting methadone.²⁷

The PCP told us that he was familiar with the patient’s history of COPD and cardiac arrhythmias and he knew these conditions were concerns when prescribing methadone. He also told us that because the patient had taken methadone previously and the COPD and cardiac conditions were stable and being treated, he felt the patient could “handle it.” The PCP told us that although he was not aware of VA/DoD’s Clinical Practice Guideline recommendation to obtain an ECG before prescribing methadone, he “was taught” to get a baseline ECG, it was his usual practice to do so, and that he routinely did one annually for patients on long-term methadone therapy.

The patient’s previous 2004, 2006, and 2013 ECGs were available in the patient’s EHR. Because the PCP did not document that he reviewed the previous ECGs and he could not remember doing so, we could not determine whether he considered them in his clinical decision to prescribe methadone for this patient.

Patient Education and Informed Consent

VHA policy requires patient education and informed consent for opioid therapy for pain.²⁸ The policy directs prescribers to educate patients about the risks, benefits, and alternatives to long-term opioid therapy and obtain the patients signature on the “Consent for Long-Term Opioid Therapy for Pain” form using an iMed electronic

²⁶A coroner is an independent judicial official who investigates human deaths. Most coroners are elected officials who lack the specialized medical training that would allow them to conduct autopsies. That job falls to the medical examiner, who is a physician, and typically serves by appointment.

²⁷ VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010.

²⁸ VHA Directive 1005, *Consent for Long-Term Opioid Therapy for Pain*, May 6, 2016. Pages 1-5.

document.²⁹ The directive further states that only the practitioner authorized to prescribe long-term opioids can complete the informed consent process.

VHA's "Consent for Long Term Opioid Therapy for Pain" form is not specific to methadone and does not include risk factors such as respiratory depression or cardiac arrhythmia. We presented a copy of the consent form to the PCP and asked if he was aware it did not include respiratory depression and cardiac arrhythmia. The PCP stated he was surprised they were not listed and that the form needed to be revised. We pointed out areas on the current form that could be modified to include the methadone-specific risk factors; however the PCP said he was not aware the form could be altered. When asked if he informed the patient of these risks, the PCP stated, "his breathing was fine and I didn't think methadone would cause him any issues." The PCP did not document educating the patient on the risks of taking methadone for chronic pain management.

We also showed the System Chief of Pharmacy a copy of the consent form. He too expressed surprise that respiratory depression and cardiac issues were not listed as potential side effects. He stated that it would make sense to add the risk factors to the comment section and the physicians could do that.

We obtained a copy of the "Consent for Long-Term Opioid Therapy for Pain" form signed by the patient. The signed copy does not list methadone-specific risks. Because the PCP did not document discussing these risks with the patient, we could not be certain the patient was aware of the specific risks associated with methadone.

With regard to both the ECG and patient education, the PCP seemed to place emphasis on the fact the patient had previously taken methadone with no ill effects and relied on this as part of his clinical decision to prescribe methadone to manage the patient's chronic pain.

Issue 3: ECGs and Patient Education for System Patients

System PCPs did not consistently order ECGs or provide patient education prior to prescribing methadone.

The PCPs we interviewed told us they were not aware of VA/DoD's Clinical Practice Guideline recommendation to obtain an ECG before prescribing methadone. However, they routinely ordered ECGs for patients before starting methadone and annually for those taking methadone for long-term pain management. They also told us they provided patient education that included the risks associated with the use of opioids in general and methadone specifically, but may not have always documented the discussions.

To determine if System providers routinely ordered ECGs and provided patient education before starting patients on methadone, we independently reviewed the EHR for every patient who received one or more methadone prescriptions from System

²⁹ VHA Directive 1005, *Consent for Long-Term Opioid Therapy for Pain*, May 6, 2016.

providers from October 1, 2015 through September 30, 2016. Of the 44 patients, one patient was receiving methadone while in hospice care and was therefore excluded from our review. Ten of the remaining 43 patients received their first prescription for methadone during our review period (new methadone patients). Thirty-three patients received methadone prescriptions on a monthly basis prior to the start of our review period (long-term methadone patients). For new methadone patients, we looked to see if an ECG was in the EHR prior to the patient starting methadone. For long-term methadone patients, we looked for evidence of an annual ECG. For all patients we looked for documentation of methadone-specific patient education. Our findings are below.

Table. System Methadone Prescribing Practices: ECG and Patient Education, October 2015 through September 2016

Total Patients (43)*	New Methadone Patients (10)	Long-Term Methadone Patients (33)
ECG in EHR	3/10 (30 percent) with initial ECG	11/33 (33 percent) with annual ECG
Documentation of Patient Education in EHR	5/10 (50 percent)	5/33 (15 percent)

Source: OHI EHR Analysis; *Total number of patients was 44; one patient was excluded.

Additional Finding:

At the time of our onsite interviews in February/March 2017, the System had 26 patients with active methadone prescriptions. The Chief of Staff (COS) told us that after his arrival in early January 2017, he requested that the assigned PCPs review the EHRs for these patients to ensure that ECGs were present. To determine if the COS’s directions were followed, we reviewed the EHRs for the System patients with current methadone prescriptions. We located 25 patients with active methadone prescriptions; however we could not locate ECGs for 5 of those 25 patients. We shared our findings with the COS and asked if there is an administrative process in place to ensure providers consider the VA/DoD Clinical Practice Guideline recommendation to order an ECG in their clinical decision to prescribe methadone for chronic pain management. Per the COS, an administrative process was not in place.

Prior to completing our onsite visit, we discussed our ECG findings for the 25 System patients with active methadone prescriptions with the System Director. She assured us the ECG issue would be promptly addressed. We also asked if, after learning of and investigating the events leading up to the patient’s death, she consulted with Chief Counsel to determine if an institutional disclosure was needed. We were told there was no previous discussion around the issue of institutional disclosure, but she would discuss it with the COS.

OIG Update: As of March 2017, the System implemented noteworthy changes to its methadone prescribing practices. The current pharmacy policy requires an ECG before methadone is prescribed, annually thereafter, and more frequently as appropriate.³⁰ All System patients with current methadone prescriptions now have documentation of an ECG in the EHR. The System pharmacy department is monitoring the prescriptions for patients currently receiving methadone for chronic pain management, making recommendations for dose adjustments, and documenting the recommendations in the EHR.

Conclusions

We substantiated the allegation that the patient identified in the complaint died 2 days after receiving a prescription for methadone from a System PCP. We were unable to substantiate that methadone contributed to or was the cause of the patient's death.

The PCP for the patient identified in the complaint told us he was not aware of the VA/DoD 2010 Clinical Practice Guideline recommendation to obtain an ECG before prescribing methadone. He told us he was taught to get an ECG before starting patients on methadone and it was his usual practice to do so. He also told us that he routinely orders an ECG for patients on long term methadone therapy for chronic pain management; however, for this patient he did not remember reviewing previous ECGs or obtaining a new one. Additionally, other System PCPs did not consistently document a plan to order ECGs before starting patients on methadone for chronic pain management.

The System lacked a process to ensure prescribers were aware of current VHA directives, policies, and guidance related to the use of methadone for the management of chronic pain.

The System did not have a process to ensure providers consider VHA directives, policies, and guidance in their clinical decision to prescribe methadone for chronic pain management.

VHA's "Consent for Long-Term Opioid Therapy for Pain," an electronic document, does not include risk factors specific for methadone. Neither the patient's PCP nor other System PCPs were aware of how to add methadone-specific risk factors to the electronic consent form. The patient's PCP did not document educating the patient about the risks of taking methadone for chronic pain management.

After investigating the events surrounding the death of the patient identified in the complaint, System leaders did not confer with the Office of Chief Counsel to determine if an institutional disclosure was indicated.

We made five recommendations.

³⁰ Grand Junction VA Medical Center Pharmacy Service Policy 119-15, *EKG Requirements for Methadone Prescriptions*. March 2017.

Recommendations

1. We recommended that the System Director ensure that providers who prescribe methadone receive education on VA/DoD Clinical Practice Guideline recommendations related to the use of methadone for the management of chronic pain.
2. We recommended that the System Director develop a process to ensure that providers consider VA/DoD Clinical Practice Guideline recommendations, specifically the use of electrocardiograms, in their clinical decision to prescribe methadone for chronic pain management.
3. We recommended that the System Director ensure that patients receiving methadone be informed, not only of complications related to opioids but also, complications specific to methadone and that this discussion is documented.
4. We recommended that the System Director ensure that the consent form for patients receiving methadone for chronic pain management be modified to include methadone-specific risks.
5. We recommended that the System Director confer with the Office of Chief Counsel regarding the patient described in this report for possible institutional disclosure to the designated family member(s), and take action as appropriate.

Prior OIG Related Reports

System Reports

Healthcare Inspection – Quality of Care Concerns in the Management of a Hepatitis C Patient, Grand Junction Veterans Health Care System, Grand Junction, Colorado

5/11/2016 | 15-01599-289

Combined Assessment Program Review of the Grand Junction VA Medical Center, Grand Junction, Colorado

9/2/2014 | 14-02068-264

Community Based Outpatient Clinic and Primary Care Clinic Reviews at Grand Junction VA Medical Center, Grand Junction, Colorado

7/16/2014 | 14-00918-204

Topic Related Reports

Healthcare Inspection - Alleged Inappropriate Opioid Prescribing Practices, Rutherford County Community Based Outpatient Clinic, Rutherfordton, North Carolina

9/29/2016 | 15-01982-113

Healthcare Inspection – Unexpected Death of a Patient During Treatment with Multiple Medications, Tomah VA Medical Center, Tomah, WI

8/6/2015 | 15-02131-471

Independent Review of VA's FY 2015 Performance Summary Report to the Office of National Drug Control Policy

3/17/2016 | 16-01031-142

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VISN Director Comments

Department of Patients Affairs

Memorandum

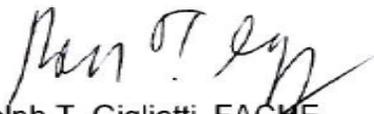
Date: September 14, 2017

From: Director, Veterans Integrated Service Network 19 (10N19)

Subj: Healthcare Inspection—Unexpected Death of a Patient: Alleged Methadone Overdose Grand Junction Health Care System, Grand Junction, Colorado

To: Director, Rapid Response Office of Healthcare Inspections (54RR)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank-you for the opportunity to review and respond to the OIG report.
2. I have reviewed and concur with the facility responses and action plans.


Ralph T. Gigliotti, FACHE
Director, VA Rocky Mountain Network (10N19)

System Director Comments

**Department of
Patients Affairs**

Memorandum

Date: September 7, 2017

From: Director, Grand Junction Health Care System (575/00)

Subj: Healthcare Inspection— Unexpected Death of a Patient: Alleged Methadone Overdose Grand Junction Health Care System, Grand Junction, Colorado

To: Director, Veterans Integrated Service Network 19 (10N19)

1. Thank you for the opportunity to submit responses and provide comment to this report.
2. I have reviewed and concur with the five (5) findings and recommendations presented in the report received from the Office of the Inspector General for the healthcare inspection conducted the week of February 28, 2017.
3. Corrective action plans and compliance monitoring have been established and target completion dates have been set for the recommendations as detailed in the attached report.
4. Please contact our facility for any additional questions or if further information is required.


Michael T. Kilmer
Director

Comments to OIG's Report

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

OIG Recommendations

Recommendation 1. We recommended that the System Director ensure that providers who prescribe methadone receive education on VA/DoD Clinical Practice Guideline recommendations related to the use of methadone for the management of chronic pain.

Concur

Target date for completion: January 15, 2018

Facility response: Training covering the recommendations related to the prescribing of methadone for treatment of chronic pain (from VA/DoD 2010 Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain), will be given to all facility providers who prescribe methadone, and will be assigned to all incoming providers as part of their new employee orientation process.

Recommendation 2. We recommended that the System Director develop a process to ensure that providers consider VA/DoD Clinical Practice Guideline recommendations, specifically the use of electrocardiograms, in their clinical decision to prescribe methadone for chronic pain management.

Concur

Target date for completion: Completed

Facility response: A process was implemented on 3-22-17 in which the Pharmacy service reviews all methadone prescriptions. Prescriptions for Methadone are not filled unless a current ECG is on file. Pharmacy is to contact the prescribing provider if a current ECG is not on file, and will fill the prescription once a current ECG is available in the medical record. We are requesting closure of this recommendation.

OIG Comment: The system defined "current ECG" in the facility Pharmacy Service Policy 119-15 dated March 2017. We consider this recommendation closed.

Recommendation 3. We recommended the System Director ensure that patients receiving methadone be informed, not only of complications related to opioids, but also complications specific to methadone and that this discussion is documented.

Concur

Target date for completion: July 31, 2018

Facility response: An electronic template will be developed which will guide prescribing providers in relaying patient education on complications related to opioid medications and complications specific to use methadone, and ensure documentation of this discussion in the medical record. Staff will be educated on the requirement and rationale for ensuring documentation of methadone specific complications when prescribing or renewing this medication. A random sample of Methadone prescriptions will be audited for 6-months, with a goal of 90% or greater compliance with the new education template. The results of the audits will be reported monthly to the Clinical Executive Board (CEB).

Recommendation 4. We recommended that the System Director ensure that the consent form for patients receiving methadone for chronic pain management be modified to include methadone-specific risks.

Concur

Target date for completion: July 31, 2018

Facility Response: The Pharmacy Service and QSV staff are researching whether changes can be made to the nationally required Consent for Long-Term Opioid Therapy for Pain (VA form 10-0431c) consent form, to add methadone specific-risks. If not, the facility will develop a supplementary Methadone I-med consent form which will contain methadone specific risks and considerations. Staff will be educated on the requirement and rationale for ensuring documented discussion of methadone specific-risks in the consent for treatment form. A random sample of Methadone prescriptions will be audited for 6-months, with a goal of 90% or greater compliance with the new consent form. The results of the audits will be reported monthly to the Clinical Executive Board (CEB).

Recommendation 5. We recommended that the System Director confer with the Office of Chief Counsel regarding the patient described in this report for possible institutional disclosure to the designated family member(s), and take action as appropriate.

Concur

Target date for completion: October 31, 2017

Facility Response: The facility Risk Manager contacted the OGC to review the case and discuss if an institutional disclosure was warranted. After this discussion, the Risk Manager and Chief of Staff felt that an Institutional Disclosure should be pursued.

The Risk Manager subsequently attempted to locate contact information for the family after initial attempts to contact via the information on record in our files, was unsuccessful. The Risk Manager contacted the VBA to identify if they had any current information in their benefits file; none of the numbers they provided were current.

The Risk Manager finally attempted to use internet resources to locate the patient's immediate family and located a possible contact number. Thus ultimately proved unsuccessful as the number was disconnected and no longer in service.

The facility has attempted reasonable and diligent efforts to identify immediate family members to provide an Institutional Disclosure. Given the inability to locate family members despite these efforts, the facility is requesting closure of this recommendation.

OIG Comment: Based on information provided by the facility, we consider this recommendation closed.

OIG Contact and Staff Acknowledgments

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