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Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Concerns Related to an Inpatient's Response to Oxycodone and Facility Actions at the Baltimore VA Medical Center

Maryland

HEALTHCARE INSPECTION | REPORT #18-05731-176 | JULY 29, 2019

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Baltimore VA Medical Center (facility), Maryland, to evaluate potential treatment delays related to an inpatient's (patient) response to oxycodone—including initial post-surgery care and during an acute change in condition (event). The OIG also assessed management actions taken by facility after the event.

The OIG found that although providers ordered oxycodone consistent with manufacturer's recommendations, the patient developed signs and symptoms of altered mental status, respiratory depression, and hypoxia.[1] Upon administration of naloxone, the patient's symptoms immediately improved. Naloxone has virtually no effect as an antidote in reversing adverse drug event symptoms when given to patients who have not taken opiates. Therefore, naloxone's effectiveness in treating the signs and symptoms supports that the patient was having a response to the medication. Following the naloxone administration, providers adjusted the oxycodone orders including special-order instructions; the patient did not have further episodes of altered mental status, respiratory depression, and hypoxia.

The OIG determined providers assessed and treated the patient's adverse drug event symptoms. The documented symptoms began in the morning and naloxone treatment was administered approximately three hours later. Nursing staff and residents (physicians in training) were monitoring and assessing the patient's treatment over the course of the three hours. The nurse and the residents entered notes reflecting their monitoring of the patient. An attending physician did not review and write a note or addendum, or co-sign the medical resident's note on the patient's symptoms, and the resident's note did not contain the specific elements required for documentation of supervision; however, this did not result in a clinical assessment and treatment delay.

The OIG found that facility managers did not consider the patient's response to oxycodone and a possible delay in treatment as one that required a review to determine causative factors or methods for prevention of similar events.[2] However, facility staff stated they had considered process changes related to this event, such as assessing vital signs before and after administration of an opiate medication, and establishing pain protocols and order sets.

Facility staff did not report this event to the Veterans Health Administration Drug Event Reporting System as an adverse drug event, although the director of patient safety and facility

[1] The patient received 75 mg of oxycodone in a 24-hour period and 130 mg in 48 hours.

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

leaders were aware of the incident.[3] In addition, facility staff did not complete a root cause analysis or aggregate review.[4] The director of quality, safety, and improvement described not having confidence in root cause analyses due to vague conclusions and weak actions. The OIG concluded that a root cause analysis or aggregate review would have allowed for communication between facility staff and leadership about the vulnerabilities of oxycodone and considerations for patient safety improvement in the facility.

The OIG found that, although warranted, a clinical disclosure was not documented.[5] The healthcare team knew the patient's adverse drug event symptoms were related to the pain medication. A clinical disclosure, through a forthright discussion of the risk of harm to the patient, improves care for all patients. An institutional disclosure was completed approximately six weeks after the patient's hospital discharge, after the patient contacted the facility's patient safety staff with concerns about the episode of altered mental status, respiratory depression, and hypoxia.

The OIG reviewed records from a peer review and recommended the facility director ensure compliance with the facility's policy in this case and in the future.[6]

During its review of Surgical Work Group meeting minutes in relation to this patient's event, the OIG determined that the Surgical Work Group did not meet monthly as required. Meeting minutes were documented for 5 of 12 months and when requested, the facility could not provide other definitive evidence that meetings had taken place. The meeting minutes that were documented did not reflect discussion of required performance improvement data. Facility leaders are not able to make informed decisions about surgical service processes without input from front-line staff and managers.

The OIG made six recommendations related to resident supervision; reviewing, capturing, and reporting adverse drug events; documentation of clinical disclosures; peer reviews; and Surgical Work Group meetings and documentation of minutes.

[3] VHA Handbook 1050.01; VHA Directive 1070, *Adverse Drug Event Reporting and Monitoring*, September 12, 2014.

[4] VHA Handbook 1050.01; facility reviewers did not consider the patient's reaction to the medication to be an adverse event.

[5] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. "Requiring documentation of clinical disclosure for all minor events would create a barrier to making such disclosures a part of routine practice. However, as a general rule, documentation of a clinical disclosure is required when harm is more than minor, as evidenced by the fact than an incident report or local equivalent has been created."

[6] Facility Policy Memorandum 512-00/PS-004, *Peer Review Process*, September 2017; the content of this peer review is protected by 38 U.S.C. § 5705, as implemented by 38 C.F.R. Sections 17.500-17.511, and not discussed in this report.

Comments

The Veterans Integrated Service Network and System directors concurred with the recommendations and provided an acceptable action plan. (See appendixes B and C, pages 22–27 for the Directors' comments.) The OIG considers all recommendations open and will follow up on the planned and recently implemented actions to ensure that they have been effective and sustained.

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Contents

Abbreviations

EHR	electronic health record
mg	milligrams
OIG	Office of Inspector General
RCA	root cause analysis
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Baltimore VA Medical Center (facility), Maryland, to evaluate potential treatment delays related to an inpatient's (patient) response to oxycodone (including initial post-surgery care and during an acute change in condition (event)). The OIG also assessed management actions taken by the facility after the event. Although the patient was ordered and given several doses of pain medication, oxycodone, in accordance with manufacturer's recommendations, the patient developed signs and symptoms of altered mental status, respiratory depression, and hypoxia, which resolved after the administration of naloxone. Naloxone reverses the signs and symptoms of certain pain medications.

Background

The VA Maryland Health Care System (system) is composed of the Baltimore, Loch Raven, and Perry Point VA Medical Centers and is affiliated with the University of Maryland School of Medicine and other local colleges and universities. The system is part of the Veterans Integrated Service Network (VISN) 5, VA Capitol Health Care Network, which also includes VA medical centers in Washington, DC, and West Virginia. VA classifies the facility as Level 1b, high complexity, with inpatient, surgical, domiciliary, community living center, and Compensated Work Therapy/Transitional Residence beds.[7] The facility is the acute medical and surgical care facility for the system and offers a full range of inpatient, outpatient, and primary care services.

Oxycodone

Oxycodone hydrochloride (oxycodone), a controlled substance, is a Schedule II opioid analgesic (or opiate), indicated for short-term and long-term relief of moderate to severe pain.[8] Oxycodone doses vary and must be adjusted according to the patient's pain severity, response, and age.

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[7] The Veterans Health Administration (VHA) Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex. https://www.va.gov/health/docs/2012_vha_facility_quality_and_safety_report_final508.pdf. (The website was accessed on April 1, 2019.)

[8] A *controlled substance* is a drug whose use and possession is regulated by law (13 U.S.C. 21), https://www.merriam-webster.com/dictionary/controlled%20substance. (The website was accessed on July 9, 2018.) Schedule II includes oxycodone as controlled drugs and other substances listed as "opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate." 21CFR 1308.12. An *analgesic* is a drug used to relieve and diminish the sensation of pain without loss of consciousness. https://www.merriam-webster.com/dictionary/analgesic. (The website was accessed on June 19, 2018.)

Patients who have not previously taken oxycodone for chronic pain are usually started on doses of 5 to 15 milligrams (mg) every four to six hours as needed. In initiating therapy and adjusting doses, providers should continually re-evaluate patient response and communicate frequently with the patient. The pain treatment objective is to provide adequate pain relief while minimizing adverse reactions to the patient.

Adverse Responses to Oxycodone

Excessive intake of oxycodone may result in signs and symptoms of mild to moderate overmedication including euphoria, drowsiness, constipation, nausea, vomiting, and constricted pupils, which may be managed by observation. Respiratory depression leading to hypoxia, altered mental status, oxygen deficiency, airway obstruction, changes in heart rhythm, coma, and death are symptoms of severe oxycodone overmedication.

Patients may develop an unpredictable adverse response to pain medications (idiosyncratic reaction) or may have medical conditions that make them more susceptible to the effects of medications despite administration at recommended doses. For these patients, signs and symptoms of adverse effects may be the same as those patients who received excessive pain medications.[9]

Treatment for patients who may have received excessive pain medications or those with unpredictable responses may require naloxone, as well as supportive care with oxygen, ventilation, intubation, or advanced life support.

Naloxone

Naloxone, also known as Narcan®, is a medication that is injected or inhaled to block or reverse the adverse reaction of opioids, which includes oxycodone. It is used to treat respiratory depression and sedation associated with opioid administration. The usual intravenous dose is 0.4 to 2 mg, which may be repeated every two to three minutes if necessary. Patients should be carefully monitored if treated with naloxone. Oxycodone has a longer duration than naloxone, and symptoms related to overmedication or an idiosyncratic reaction may reappear requiring additional doses of naloxone.

[9] Uetrecht, Jack and Naisbitt, Dean J. *Idiosyncratic Adverse Drug Reactions: Current Concepts.* Pharmacol Rev. 2013 Apr; 65(2): 779–808. doi: 10.1124/pr.113.007450/.

Adverse Drug Events

Veterans Health Administration (VHA) defines adverse events as harmful occurrences directly associated with facility care or services.[10] Adverse events include adverse drug events and adverse drug reactions.[11] Facility staff use a root cause analysis (RCA) to identify causative factors contributing to adverse events.[12] An aggregated review may be used to analyze a group of similar adverse events to determine causes. "Every fiscal year, each facility must conduct at least one aggregated review in each of three required areas: falls, missing patients, and adverse drug events according to the NCPS [National Center for Patient Safety] schedule."[13]

VHA requires system directors to designate facility staff responsible for capturing and reporting adverse drug events to the national VHA Adverse Drug Event Reporting System.[14]

Adverse Drug Reactions

Adverse drug reactions to oxycodone may be common or serious. Common adverse drug reactions include nausea, constipation, vomiting, headache, itching, insomnia, dizziness, weakness, and drowsiness. Serious adverse drug reactions include respiratory depression, respiratory arrest, circulatory depression, cardiac arrest, hypotension, and shock. Oxycodone prescribing information includes a warning that life-threatening or fatal respiratory depression may occur, even when used as recommended. This risk is highest within the first 24 to 72 hours of initiating therapy and following dose increases. Patients must be monitored and immediately treated for respiratory depression.

Patients 65 years or older may be more sensitive to oxycodone due to reduced kidney or liver functioning, which may reduce the clearance of the medication from the body. This age population is at greatest risk for respiratory depression, and should be initiated on a lower dose, and monitored for respiratory depression and sedation.

Peer Review

According to VHA policy, a peer review for quality management (peer review) requires a healthcare provider to evaluate the performance of another provider. It "is intended to promote confidential and non-punitive processes that…contribute to quality management efforts at the

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

[11] VHA Directive 1070, *Adverse Drug Event Reporting and Monitoring*, September 12, 2014.

[12] VHA Handbook 1050.01.

[13] VHA Handbook 1050.01.

[14] VHA Directive 1070.

individual provider level." Peer reviewers assign a level of provision of care (Level 1–3) as assessed against specific aspects of care.[15]

Disclosures

Adverse events may require clinical and institutional disclosures. In a clinical disclosure, the patient's provider informs the patient that a harmful, or potentially harmful, adverse event has occurred during care, expresses concern, and reassures the patient that the situation is being investigated to remedy any injury and prevent further harm. Institutional disclosure is a formal process used to inform the patient that an adverse event occurred and includes specific information about the patient's rights and recourse.[16]

OIG Concerns

During a document evaluation of another OIG hotline in May 2018, the OIG identified concerns related to a patient, who developed signs and symptoms of an altered mental status, respiratory depression, and low oxygen levels associated with oxycodone tablets administration and was treated with naloxone. The matter was referred to the OIG Hotline for review. An inspection was initiated on August 28, 2018, to evaluate potential treatment delays related to the patient's event and management actions taken by the facility after the event.

[15] VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. This VHA directive was rescinded and replaced with VHA Directive 1190, November 21, 2018. The 2010 directive was in effect at the time of the events discussed in the report and defined the levels as most experienced, competent providers (1) would have managed the patient's care similarly, (2) might have handled the patient's care differently, and (3) would have handled the care differently. The 2018 directive revised level 2 to "most experienced and competent clinicians might have managed the case differently but it remains within the standard of care" (*emphasis in original text*).

[16] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012 (corrected copy October 12, 2012). This handbook was in effect at the time of the events discussed in the report; it was rescinded and replaced by VHA Directive 1004.08, October 31, 2018. The two policies contain the same or similar language defining clinical and institutional disclosures.

Scope and Methodology

The OIG initiated the inspection on August 28, 2018, and conducted a site visit October 16–18, 2018. The event under review occurred during the patient's 2017 hospitalization.

The OIG team interviewed the chief of staff, podiatry and medical providers, nurses, and the Quality, Safety, and Improvement staff. The team reviewed relevant VHA and facility directives, policies, and procedures; the patient's electronic health record (EHR); and committee meeting agendas and minutes.

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

The OIG 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 in their 70s with a history of Type II diabetes, hypertension, obesity, hyperlipidemia, sleep apnea, hypothyroidism, coronary artery disease with a history of stents placed in the right coronary artery and mid-left anterior descending artery in 2002.[17] The patient had carotid arterial disease that was treated with multiple carotid endarterectomy procedures. The patient also had Charcot's arthropathy of the left ankle, and other medical problems managed by medical providers. Surgical procedures included a "re-do" of a right carotid endarterectomy in 2016, cholecystectomy in 2008, bilateral carotid endarterectomy in 2006, cardiac stents as noted above and in 2000, left shoulder surgery (1990s), and a childhood tonsillectomy and adenoidectomy.

On a day in 2017 (Day 1), the patient was admitted to the facility for a left triple arthrodesis revision by Podiatry Service. The surgery was uneventful, and the left lower leg was placed in a hard cast. The patient was given Dilaudid® prior to transfer to the surgical floor. The patient was treated with oxycodone for post-surgical pain.

On Day 4, in the morning, a registered nurse (nurse) observed the patient to have altered mental status and hypoxia. The patient was given 3 liters of oxygen via nasal cannula with resulting improvement of the oxygen saturation. The nurse alerted the Podiatry Service about the patient's symptoms.

In a note entered approximately three hours later, the podiatry resident documented evaluating the patient with a medical resident and described the patient as exhibiting "altered mental status, decreased oxygen saturation. Patient seen at beside [and was] minimally responsive." The podiatry resident ordered blood tests. The medical resident noted that the patient received 75 mg of oxycodone over a 24-hour period for pain. The EHR states "[g]iven this, both the surgical [podiatry] resident and I [the medical resident] requested naloxone 0.2 mg IV [intravenous] push which was given… [The patient] immediately improved with an improvement in [the patient's] AMS [altered mental status] and [a] slight improvement in [the patient's] hypoxia." The podiatry resident ordered a medicine consult to evaluate the patient for altered mental status and hypoxia. The patient was visibly lethargic but answered to the patient's name and other questions. The patient denied chest pain, cough, lightheadedness, and dizziness.

The medical resident's note showed the altered mental status and hypoxia likely were due to "opiate overdose" but other causes for altered mental status were also being considered such as hypoglycemia and infection, including pneumonia. The medical resident considered additional potential causes for hypoxia including an embolus from the post-surgical left leg/ankle to the lung and recommended a chest x-ray, blood tests, and an ultrasound of the left leg to screen for a

[17] The OIG uses the singular form of they in this instance to protect the patient's privacy.

thrombus. The medical resident indicated the patient should be monitored for changes in symptoms which may require further studies.

The blood work was negative for suspected causes of altered mental status but showed electrolyte abnormalities and kidney insufficiency. The patient was treated to correct blood sugar and evaluated for electrolyte abnormalities. Blood that had been drawn for an arterial blood gas measurement clotted and was not reordered.

On Day 5 in the morning, a second medical resident's note indicated that the patient's altered mental status and hypoxia improved after naloxone administration and that the patient no longer required supplemental oxygen. However, the patient complained of foot pain. The patient was also noted to have an episode of elevated blood pressure (197/91) secondary to foot pain. The oxycodone was held due to the episode of altered mental status and hypoxia. The second medical resident recommended replenishment of magnesium, continuation of blood pressure medication, repeat blood work, and a change in diet. The medical attending physician agreed with the assessment and plan. Approximately two hours later, the medical attending physician added an additional EHR note describing the patient's physical complaint as "feeling very jittery and sweaty" and noted the patient was diaphoretic and had diarrhea. The medical attending physician was concerned that the patient's symptoms represented an "infection or an acute cardio-pulmonary process" and recommended a repeat electrocardiogram (EKG), portable chest x-ray, telemetry, aspirin, blood work inclusive of cardiac enzymes, intravenous fluids, discontinuation of medications for constipation, and an extremity duplex doppler to rule out a thrombus in the left leg. A computerized tomography scan of the chest was deferred secondary to kidney insufficiency.

Approximately one hour later, a second podiatry resident ordered blood work, cardiac enzymes, portable chest x-ray, and an aspirin. The blood work showed elevated troponin, elevated blood sugar, low magnesium, and a normal thyroid function test. The chest x-ray result was normal. The EKG was abnormal with indications for cardiac ischemia. The EHR reflected that the second podiatry resident ordered a cardiology consult and a doppler study of the lower extremity and left ankle.

Approximately nine hours later, the second podiatry resident called a third medical resident due to an increase in the troponin level.[18] The patient could converse with the medical resident, and denied chest pain, shortness of breath, cough, nausea, or vomiting. The patient's lungs were clear, and the heart sounds were normal. The repeat EKG was not on the chart. The medical attending physician was contacted, and a STAT EKG was ordered. The patient was recommended for transfer to a higher level of care.

[18] The normal troponin level range at the system is 0-0.028 nanograms per milliliter (ng/mL). The patient's troponin level for this timeframe had increased from 0.261 to 0.328 ng/mL. The troponin was tested three times at six-hour intervals.

An hour and a half later, the patient was transferred to cardiology care due to an increase in troponin levels with uncontrolled blood pressure. The elevated blood pressure was treated with blood pressure medications.

On Day 6 in the early morning, the troponin levels continued to increase.[19] A transthoracic echocardiography study was ordered seven minutes later. The medical resident on duty that day evaluated the patient, blood work results, and EKG. The medical resident noted the patient had elevated blood pressure and increasing troponin level. The EKG was abnormal. The patient was diagnosed with a non-ST-elevation myocardial infarction and uncontrolled blood pressure. The blood pressure was treated with intravenous and oral medications. The troponin levels increased again nine hours later.[20] The patient had repeated EKGs to observe for changes in the electrical conduction to the heart.

An hour and a half later, a cardiology attending evaluated the patient and agreed with treating providers that the patient had a non-ST-elevation myocardial infarction. The doppler study of the left leg/ankle was negative for a deep vein thrombosis. Before the ankle surgery, the patient was treated with Plavix® which was held post-operatively. An EHR note showed the patient developed a non-ST-elevation myocardial infarction post-operatively, and resumption of Plavix® was warranted.

On Day 6 in the mid-day, a transthoracic echocardiography was performed. The report released approximately five hours later showed a normal ejection fraction (65–70 percent) with no regional heart wall abnormalities.

On Day 7 in the morning, the medical resident on duty that day noted that the troponin level decreased during the last blood draw (the evening of Day 6).[21] The patient remained asymptomatic for heart problems during this time; however, continued to have diarrhea four to five times daily. The patient's diarrhea was evaluated and treated with medications after a *Clostridium difficile* culture was negative.

A second cardiology attending physician examined the patient and noted "no evidence for unstable [heart] leasion [*sic*], though HTN [hypertension] may have caused symptoms." The plan was to optimize medications and no further heart testing was required. The patient was treated by medicine, cardiology, and podiatry providers, and received physical therapy. The remainder of the hospital stay was uneventful, and the patient was discharged on Day 9.

[19] The patient's troponin level for this timeframe was 0.549 nanogram/milliliter.
[20] The patient's troponin level for this timeframe was 0.729 nanogram/milliliter.
[21] The patient's troponin level for this timeframe was 0.519 nanogram/milliliter.

Inspection Results

1. Oxycodone Administration and Treatment

The OIG found that the administration of oxycodone to this patient resulted in an adverse drug event requiring naloxone treatment. The patient exhibited symptoms of altered mental status, respiratory depression, and hypoxia consistent with a reaction to oxycodone after receiving 75 mg of oxycodone in 24 hours, and 130 mg in 48 hours. The OIG found that staff were aware of the acute mental status changes in a timely manner, intervened first with oxygen therapy and when that was unsuccessful, ordered naloxone after obtaining a medicine consult. This process took three hours; however, the patient responded well, without apparent adverse effects.

Oxycodone Administration and Adverse Drug Event

Providers enter medication orders in EHRs and nurses administer the ordered medication to patients.[22] Although the oxycodone orders for this patient were consistent with manufacturer's recommendations and nurses administered the medication as ordered, the OIG determined that the patient's reaction to the oxycodone doses resulted in an adverse drug event.

On the day of surgery, the patient received two doses of oxycodone (10 mg each by mouth) in addition to other intravenous medications.[23] Providers ordered oxycodone every four hours for pain and increased the dose a day later while the patient was on the surgical unit.[24] Table 1 shows the daily doses of oxycodone that the patient received from Day 1 through Day 4.

[22] Facility Policy Memorandum 512-118-039, *Bar Code Medication Administration*, December 2014.

[23] Additional intravenous medications given to the patient were two doses of fentanyl 50 mcg and one dose of hydromorphone 0.2 mg.

[24] Patients are asked to rate their pain level from 0 - no pain to 10 - worst pain imaginable. https://www.va.gov/PAINMANAGEMENT/docs/CR_ED_all_CPRS_Pain_Assessment_tool.pdf. (The website was accessed on October 30, 2018.) The oxycodone order was increased to 10 mg for a pain level of 3 to 7, and 15 mg for a pain level greater than 7. The previous oxycodone order was for 5 mg for a pain level of 3 to 7, and 10 mg for a pain level greater than 7.

Table 1. Patient's Daily Dose of Oxycodone Day 1–Day 4

Date	Dose Ordered	Total Daily Dose	Patient's Pain Level
Day 1	5 mg every 4 hours[1] 10 mg every 4 hours[2]	20 mg	7–8
Day 2	10 mg every 4 hours[1,3] 15 mg every 4 hours[2,3]	55 mg	8–10
Day 3	10 mg every 4 hours[1] 15 mg every 4 hours[2]	45 mg	8–9
Day 4[4] **(Day of Event)**	10 mg every 4 hours[1] 15 mg every 4 hours[2]	30 mg	9

[1] For a pain level of 3 to 7 on a 0-10 pain scale
[2] For a pain level greater than 7 on a 0-10 pain scale
[3] Dose was increased in the morning.
[4] Last dose in the early morning.

Source: VA OIG analysis of the patient's EHR

The EHR reflected an initial oxycodone order of 5 mg to 10 mg every four hours as needed. Nurses administered the medication with at least four hours between doses as ordered. However, the patient experienced symptoms of an oxycodone adverse drug event.

The individual patient factors that contributed to the adverse drug event included the patient's lack of opioid tolerance, age, reduced kidney function that may have reduced clearance of oxycodone from the patient's system, and uncontrolled pain that required the provider to appropriately increase the dose of oxycodone the day after surgery despite an initial lower dose.[25]

Upon administration of naloxone, the patient had immediate improvement in respiratory depression symptoms and hypoxia. Naloxone has virtually no effect as an antidote in reversing adverse drug event symptoms when given to patients who have not taken opiates. Therefore, naloxone's effectiveness in treating this patient supports that the patient's signs and symptoms were related to oxycodone.[26]

Following the event and naloxone administration, providers lowered the oxycodone dose and increased the time interval for oxycodone administration. Providers also included special-order instructions to not administer oxycodone if the patient exhibited symptoms of respiratory depression or altered mental status and to notify the provider if the medication is not

[25] Opioid tolerance is assumed in patients taking daily doses of 30 mg oxycodone for ≥ 1 week. https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf#. (The website was accessed on October 4, 2018.)
[26] Provider notes also documented that the symptoms were linked to oxycodone administration.

administered. After these changes and special-order instructions, the patient did not have further episodes of adverse drug effects from oxycodone.[27]

Assessment and Treatment of Adverse Drug Event

The OIG determined that providers assessed and treated the patient's adverse drug event symptoms. The documented symptoms began on Day 4 in the morning and naloxone treatment was administered approximately three hours later. The OIG noted that clinical staff were monitoring and assessing the patient's treatment over the course of the three hours. An attending physician did not review and write a note, an addendum, or co-sign the medical resident's note on the patient's symptoms, and the resident's note did not contain the specific elements required for documentation of supervision; however, this did not result in a clinical assessment and treatment delay.

On the morning of Day 4, the patient was alert and oriented. However, one hour later, the nurse observed the patient to be "very drowsy, unable to comprehend" and alert to name only. Symptoms of altered mental status include inability to focus attention, drowsiness, or coma. Acute altered mental status is a medical emergency and naloxone should be administered if the condition is due to suspected opiate overdose.[28]

Fifteen minutes later, the nurse reported to have paged the podiatry resident who reportedly returned the page immediately and arrived at the facility with the podiatry attending physician.[29] The podiatry attending physician, the podiatry resident, and a medical resident jointly examined the patient to determine the cause of altered mental status and respiratory depression symptoms.

The nurse checked the patient's vital signs and blood oxygen saturation.[30] The patient exhibited symptoms of respiratory depression with a pulse oximeter reading of 82 percent (less than 90 percent is considered low).[31] Facility staff administered oxygen and the patient's pulse oximetry

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[27] The order was changed to 5 mg every six hours for a pain level greater than 7, from 10 mg every four hours for pain level 3-7 or 15 mg every four hours for pain level greater than 7.

[28] Vanja, C. Douglas, MD and S. Andrew Josephson, MD, "Altered Mental Status," *Continuum: Lifelong Learning in Neurology* 17, no. 5 (October 2011):967-983.

[29] The podiatry resident reported arrival at the facility 20 minutes after being paged between 9 a.m. and 10 a.m. and the podiatry attending reported the arrival together between 10 a.m. and 10:30 a.m. An attending is a senior physician who serves as a supervisor to residents, who are in advanced training. https://www.merriam-webster.com/dictionary/attending and https://www.merriam-webster.com/dictionary/residency. (The websites were accessed on December 6, 2018, and April 2, 2019, respectively.)

[30] Vital signs measure pulse rate, respiratory rate, body temperature, and blood pressure of a person. https://www.merriam-webster.com/dictionary/vital%20signs. (The website was accessed on November 9, 2018.)

[31] Pulse oximeter readings measure blood oxygen; measurements under 90 percent are considered low. https://www.mayoclinic.org/symptoms/hypoxemia/basics/definition/sym-20050930. (The website was accessed on November 9, 2018.)

improved. It was unclear whether the nurse initiated oxygen before or after paging the podiatry resident.

The providers (podiatry attending physician, podiatry resident, and medical resident) re-evaluated the patient and the patient's EHR and determined that the symptoms were caused by oxycodone and ordered naloxone to reverse the reaction three hours later. Naloxone was administered within seven minutes. The patient immediately responded to the naloxone with an improvement in altered mental status and slight improvement in hypoxia.

An arterial blood gas, obtained after the naloxone administration, clotted and could not be used, but was not redrawn because the podiatry resident told the nurse it was not needed. Respiratory depression, an indicator of hypoxia, may be diagnosed with pulse oximetry monitoring and arterial blood gas measurements. Airway problems and breathing difficulties, including hypoxia, are a major cause of morbidity and mortality in an adverse drug event related to pain medications.[32] Treatment of hypoxia includes supplemental oxygen. Following the naloxone administration, providers determined the patient's symptoms were stable and did not need further intervention.

In the morning the next day (Day 5), the medical attending physician noted the patient was "jittery and sweaty," had a history of diabetes and coronary artery disease, and initiated a cardiac work-up that showed an abnormal EKG with elevated troponin levels, indicating the symptoms could be cardiac-related. Five minutes later, the podiatry resident transferred the patient to cardiology care due to the elevated troponin levels.

The OIG determined the patient's EHR documentation did not meet requirements for resident supervision. An attending physician did not review and write a note or addendum, or co-sign the medical resident's note on the patient's symptoms of altered mental status and hypoxia, and the resident's note did not contain the specific elements required for documentation of supervision. Facility policy required an attending physician's progress note, addendum note, and/or co-signature or a resident note with documentation of specific elements to confirm supervision by an attending physician.[33] The patient was not seen or evaluated by a medical attending physician until more than 24 hours after the onset of patient symptoms of altered mental status and hypoxia. While lack of resident supervision did not result in a clinical assessment or treatment delay in this instance, timely supervision, including attending physician signature of resident notes, enhance communication, training, quality of care, and safety for patients.[34]

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[32] Kent R. Olson, et al., Comprehensive Evaluation and Treatment," "Emergency Evaluation and Treatment" Poisoning and Drug Overdose, 7e. New York, NY: McGraw-Hill, https://accessmedicine.mhmedical.com/content.aspx?bookid=2284&sectionid=177337821. (The website was accessed on November 8, 2018.)

[33] Facility Policy Memorandum 512-14/E&AA-004, *Resident Supervision*, April 2013.

[34] Facility Policy Memorandum 512-14/E&AA-004.

2. Facility Response

The OIG found that facility leaders and staff did not consider the patient's response to oxycodone and a possible delay in treatment as one that required a review to determine causative factors or implement measures for prevention of similar events as required. However, facility staff stated they had considered facility process changes related to this event, such as assessing vital signs before and after administration of an opiate medication and establishing pain protocols and order sets.[35]

Adverse Drug Event Reporting and Review

The OIG determined facility staff did not report this event as an adverse drug event.[36] Facility policy required all healthcare professionals to report suspected adverse drug events within 24 hours of the event.[37] The director of patient safety and facility leaders were aware of the adverse drug event; however, the OIG learned through interviews that it was not reported in the VHA electronic reporting system.

Patient safety staff did not complete an RCA for the adverse event. VHA requires RCAs for adverse events, including adverse drug events, directly associated with care to prevent similar occurrences in future patients.[38] The Director of Quality, Safety, and Improvement described not having confidence in RCAs due to vague conclusions and weak actions. An RCA would have allowed for communication about the vulnerabilities of oxycodone and considerations for patient safety improvement in the facility.[39]

The director of patient safety described wanting to track and evaluate all naloxone administrations. This type of aggregated review may have met the VHA requirements for an adverse drug event review, but at the time of the OIG site visit, it had not been implemented.[40]

[35] VHA Handbook 1050.01.

[36] VHA Handbook 1050.01; VHA Directive 1070.

[37] Facility Policy Memorandum 512-00/PS-005, *Patient Safety/Risk Management Program*, September 2017; Facility Policy Memorandum 512-119-014 *Allergy and Adverse Drug Event Reporting Program*, May 2015, recertified April 2018.

[38] VHA Handbook 1050.01.

[39] VHA Handbook 1050.01.

[40] VHA Handbook 1050.01.

Disclosures

The OIG found that, although warranted, a clinical disclosure was not documented.[41] VHA policy dictates that a clinical disclosure is warranted when a perceptible effect of an adverse event has occurred.[42] The healthcare team knew the patient's adverse drug event symptoms were related to the oxycodone administration. A clinical disclosure, through a forthright discussion of the risk of harm to the patient, improves care for patients.[43] The OIG was informed that patient safety staff initiated an institutional disclosure six days after the patient's hospital discharge.

Peer Review

The OIG reviewed records from the peer review and recommended that Facility Director ensure compliance with the facility's policy in this case and in the future.[44]

Surgical Work Group Oversight

The OIG determined that the Surgical Work Group did not meet monthly as required as meeting minutes were only documented for 5 of 12 months. Further, the documented meeting minutes did not reflect discussion of required performance improvement data.

VHA requires monthly meetings of the facility Surgical Work Group with documentation of minutes. In addition, the Surgical Work Group must address the implementation and monitoring of surgical performance improvement activities.[45] The podiatry attending physician stated the adverse drug event under review was discussed in a podiatry meeting, including changes in pain protocols and timing of vital signs; however, these changes were not discussed further or implemented. Reviewing, documenting, and tracking adverse drug events and possible resolutions in Surgical Work Group meetings, with review by facility leadership, may have initiated effective change on performance improvement.

[41] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. "Requiring documentation of clinical disclosure for all minor events would create a barrier to making such disclosures a part of routine practice. However, as a general rule, documentation of a clinical disclosure is required when harm is more than minor, as evidenced by the fact than an incident report or local equivalent has been created."

[42] VHA Handbook 1004.08.

[43] VHA Directive 1004.08.

[44] Facility Policy Memorandum 512-00/PS-004, *Peer Review Process*, September 2017; the content of this Peer Review is protected by 38 U.S.C. § 5705, as implemented by 38 C.F.R. Sections 17.500-17.511, and not discussed in this report.

[45] VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013. This VHA Handbook was scheduled for recertification on or before the last working day of January 2018 but has not been recertified.

Conclusion

The OIG found that although providers ordered oxycodone consistent with manufacturer's recommendations, the administration of recommended doses to this patient resulted in an adverse drug event, specifically an adverse drug reaction, requiring naloxone treatment. The patient exhibited signs and symptoms of altered mental status, respiratory depression, and hypoxia consistent with oxycodone administration after receiving 75 mg of oxycodone in 24 hours, and 130 mg in 48 hours. Upon administration of naloxone, the patient's symptoms immediately improved. Naloxone has virtually no effect as an antidote in reversing adverse drug event symptoms when given to patients who have not taken opiates. Therefore, naloxone's effectiveness in treating this patient supports that the adverse reaction was related to the administration of oxycodone. Following the naloxone administration, providers adjusted the oxycodone orders and included special-order instructions. The patient did not have further episodes of signs and symptoms associated with administration of oxycodone.

Providers assessed and treated the patient's adverse drug event symptoms. However, the patient's EHR documentation did not meet requirements for resident supervision. An attending physician did not review and write a note or addendum, or co-sign the medical resident's note on the patient's symptoms of altered mental status and hypoxia, and the resident's note did not contain the specific elements required for documentation of supervision, but this did not result in a clinical assessment or treatment delay.

Facility staff did not report this event to the VHA electronic reporting system as an adverse drug event, although the Director of Patient Safety and facility leaders were aware of the incident. In addition, facility staff did not complete an RCA or aggregate review. The Director of Quality, Safety, and Improvement described not having confidence in RCAs due to vague conclusions and weak actions. The OIG concluded that an RCA would have allowed for communication about the vulnerabilities of oxycodone and considerations for patient safety improvement in the facility.

The OIG found that, although warranted, a clinical disclosure was not documented. The healthcare team knew the patient's adverse drug event symptoms were related to the administration of oxycodone. A clinical disclosure, through a forthright discussion of the harm caused to the patient, improves care for all patients. Patient safety staff informed the OIG that an institutional disclosure was completed approximately six weeks after the patient's hospital discharge, after the patient contacted the facility's patient safety staff with concerns.

The OIG reviewed records from the peer review and recommended that the facility director ensure compliance with facility policy in this case and in the future. The OIG determined that the Surgical Work Group did not meet monthly as required, as only 5 of 12 months of meeting minutes were documented. Further, the meeting minutes did not reflect discussion of required performance improvement data.

Recommendations 1–6

1. The VA Maryland Health Care System director takes steps to ensure resident supervision meets requirements, and monitors for compliance with Veterans Health Administration policy.
2. The VA Maryland Health Care System director verifies the capture and reporting of adverse drug events to the national Veterans Health Administration Adverse Drug Event Reporting System, and monitors for compliance.
3. The VA Maryland Health Care System director ensures staff complete root cause analyses or aggregated reviews for adverse events as required by Veterans Health Administration policy and monitors to ensure completion.
4. The VA Maryland Health Care System director verifies documentation of clinical disclosures when perceptible effects of an adverse event have occurred, as required, and monitors for compliance.
5. The VA Maryland Health Care System director ensures peer reviews are evaluated according to VA Maryland Health Care System policy and monitors for compliance.
6. The VA Maryland Health Care System director verifies that the Surgical Work Group meets and documents minutes as required to include improvement data presentation, discussion, and performance tracking, and monitors for compliance.

Appendix A: Glossary of Terms

An **adenoidectomy** is the surgical removal of the adenoids.[46]

An **adverse drug event** "is an injury resulting from the use of a drug."[47]

An **adverse drug reaction** is an unwanted or harmful reaction experienced following the administration of a drug under normal conditions of use and is suspected to be related to the drug.[48]

Altered mental status is a broad term used to describe a change in cognitive function or level of consciousness. Altered mental status changes in the patient's consciousness, requires an urgent assessment with history, physical exam, and the development a differential diagnosis influenced by the patient's age and medical comorbidities.[49]

Arterial blood gas is a blood sample taken from an artery, used to measure oxygen levels and determine hypoxemia.[50]

Arthrodesis is the surgical immobilization of a joint so that the bones grow solidly together.[51]

Cardiac enzymes are released into the blood when damage to the heart muscle occurs during a heart attack.[52]

Cardiac ischemia also known as myocardial ischemia can damage the heart, reducing its ability to pump blood efficiently.[53]

Cardiopulmonary relates to the heart and lungs.[54]

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[46] https://www.merriam-webster.com/medical/adenoidectomy. (The website was accessed on February 18, 2019.)

[47] https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3043 page 5,7A. (The website was accessed on September 26, 2018.)

[48] https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3043 page 6, Item B. (The website was accessed on September 26, 2018.)

[49] https://insights.ovid.com/pubmed?pmid=22809977 pages 967, 969, 970 (The website was accessed on October 1, 2018.)

[50] https://www.mayoclinic.org/symptoms/hypoxemia/basics/definition/sym-20050930 paragraph 2. (The website was accessed on November 9, 2018.)

[51] https://www.merriam-webster.com/dictionary/arthrodesis. (The website was accessed on September 26, 2018.)

[52] https://www.mayoclinic.org/diseases-conditions/heart-attack/diagnosis-treatment/drc-20373112. (The website was accessed on March 3, 2019.)

[53] https://www.mayoclinic.org/diseases-conditions/myocardial-ischemia/symptoms-causes/syc-20375417. (The website was accessed on October 31, 2018.)

[54] https://www.merriam-webster.com/dictionary/cardiopulmonary?src=search-dict-hed. (The website was accessed on October 31, 2018.)

The **carotid artery** is either of the two main arteries that supply blood to the head.[55]

Carotid endarterectomy is the surgical removal of the inner layer (plaque) of the carotid artery.[56]

Charcot's arthropathy occurs in patients that have loss of sensation caused by multiple conditions.[57]

A **cholecystectomy** is the surgical removal of the gallbladder.[58]

Clostridium Difficile is a bacterium that causes "symptoms ranging from diarrhea to life-threatening inflammation of the colon."[59]

Clotted means the fluid blood becomes a mass, making it not useable for testing.[60]

Computerized tomography is a scan that uses computer processing to combine x-ray images to make a series of detailed pictures of the inside the body.[61]

Coronary artery disease develops when the major blood vessels that supply the heart with blood and oxygen are damaged or diseased.[62]

Deep vein thrombosis is condition in which one or more thrombi develop in a deep vein, most common in the leg or pelvis, and increases the risk of a pulmonary embolus in the lung.[63]

Diabetes is a disease that occurs when the body cannot effectively process sugar (glucose) due to not recognizing or producing little or no insulin, a hormone that regulates blood glucose. Patients with Type 1 diabetes require insulin injections to regulate their blood glucose. Patients with

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[55] https://www.merriam-webster.com/dictionary/carotid%20artery?src=search-dict-hed. (The website was accessed on February 17, 2019.)

[56] https://www.nhlbi.nih.gov/health-topics/carotid-endarterectomy. (The website was accessed on October 31, 2018.)

[57] http://legacy.aofas.org/footcaremd/Pages/footcaremd.aspx. (The website was accessed on October 31, 2018.)

[58] https://www.merriam-webster.com/dictionary/cholecystectomy. (The website was accessed on February 17, 2019.)

[59] https://www.mayoclinic.org/diseases-conditions/c-difficile/symptoms-causes/syc-20351691. (The website was accessed on February 17, 2018.)

[60] https://www.merriam-webster.com/dictionary/clotted. (The website was accessed on December 19, 2018.) and https://www.americannursetoday.com/wp-content/uploads/2016/03/ant3-Lab-Errors-225.pdf. (The website was accessed on April 3, 2019.)

[61] https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675. (The website was accessed on April 3, 2019.)

[62] https://www.mayoclinic.org/diseases-conditions/coronary-artery-disease/symptoms-causes/syc-20350613. (The website was accessed on October 30, 2018.)

[63] https://www.merriam-webster.com/medical/deep%20vein%20thrombosis. (The website was accessed on February 25, 2019.)

Type 2 diabetes, the most common type, initially produce some insulin and may use oral or intravenous medications to regulate blood glucose.[64]

Diaphoretic is increasing perspiration.[65]

Dilaudid® is an opioid analgesic medication.[66]

Duplex doppler is a non-invasive test that uses sound waves (ultrasound) to estimate blood flow through vessels; it's used for multiple reasons including diagnosing poorly functioning leg vein valves and decreased blood circulation in the legs.[67]

An **EKG or ECG**, or an electrocardiogram, is an electrical record used to detect problems with the heart.[68]

Electrolyte(s) "are involved in many essential processes in the body."[69]

Embolus is a blood clot that travels through the bloodstream and lodges in a blood vessel causing blockage.[70]

Hypertension is high blood pressure.[71]

Hyperlipidemia refers to elevated levels of fats in the blood.[72]

Hypoglycemia is an abnormally low level of glucose (blood sugar) in the blood.[73]

Hypothyroidism occurs when the thyroid gland does not make enough thyroid hormone for the body.[74]

Hypoxia is a deficiency of oxygen reaching the tissues of the body.[75]

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[64] https://my.clevelandclinic.org/health/diseases/7104-diabetes-mellitus-an-overview. (The website was accessed on April 3, 2019.)

[65] https://ahdictionary.com/word/search.html?q=diaphoretic. (The website was accessed on October 31, 2018;

[66] https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/019034s018lbl.pdf. (The website was accessed on November 1, 2018.)

[67] https://www.mayoclinic.org/doppler-ultrasound/expert-answers/faq-20058452. (The website was accessed on February 25, 2019.)

[68] https://www.mayoclinic.org/tests-procedures/ekg/about/pac-20384983. (The website was accessed on November 1, 2018.)

[69] https://www.healthline.com/nutrition/electrolytes. (The website was accessed on October 31, 2018.)

[70] https://ahdictionary.com/word/search.html?q=embolus. (The website was accessed on November 1, 2018.)

[71] https://www.merriam-webster.com/dictionary/hypertension. (The website was accessed on December 14, 2018.)

[72] https://www.merriam-webster.com/dictionary/hyperlipidemia. (The website was accessed on December 14, 2018.)

[73] https://ahdictionary.com/word/search.html?q=hypoglycemia. (The website was accessed on November 1, 2018.)

[74] https://www.niddk.nih.gov/health-information/endocrine-diseases/hypothyroidism. (The website was accessed on December 14, 2018.)

[75] https://www.merriam-webster.com/dictionary/hypoxia. (The website was accessed on February 18, 2019.)

Kidney insufficiency, or renal insufficiency, is poor function of the kidneys.[76]

Magnesium plays a key role in a wide range of cellular functions and when low has been implicated in cardiovascular mortality.[77]

A **nasal cannula** is a tube used to deliver oxygen into the nose.[78]

A **non-ST-elevation myocardial infarction** is a partial blockage of a coronary artery shown on an EKG. ST refers to the ST segment, which is part of the EKG heart tracing used to diagnose a heart attack.[79]

An **overdose** refers to an excessive amount of medication given or taken.[80]

Overmedication refers to prescribing and/or receiving too much medication.[81]

Oxygen saturation is the amount of oxygen in the blood.[82]

Plavix® is a drug used to decrease the risk of heart attack and stroke in patients known to have atherosclerosis.[83]

Podiatry is the medicine that provides prevention, diagnosis, and treatment of human foot diseases.[84]

Sleep apnea, the most common form being obstructive, is "a potentially serious sleep disorder in which breathing repeatedly stops and starts."[85]

STAT means immediately.[86]

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[76] https://health.ucdavis.edu/vascular/diseases/renal_insufficiency.html. (The website was accessed on April 4, 2019.)

[77] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4859391/. (The website was accessed on October 31, 2018.)

[78] https://www.merriam-webster.com/dictionary/cannula. https://www.nursingtimes.net/clinical-archive/respiratory/when-should-a-nasal-cannula-be-used-to-deliver-oxygen/5023696.article. (The websites were accessed on April 4, 2019.)

[79] Explanation of ST: https://www.ncbi.nlm.nih.gov/books/NBK459364/. (The website was accessed on April 4, 2019.)

[80] https://www.merriam-webster.com/dictionary/overdose. (The website was accessed on October 30, 2018.)

[81] https://www.merriam-webster.com/dictionary/overmedication. (The website was accessed on October 30, 2018.)

[82] https://www.cancer.gov/publications/dictionaries/cancer-terms/def/oxygen-saturation-test. (The website was accessed on December 17, 2018).

[83] https://pubchem.ncbi.nlm.nih.gov/compound/24883467#section=Drug-Indicationhttps://pubchem.ncbi.nlm.nih.gov/compound/24883467#section=Drug-Indication, section 7.1 Drug Indication. (The website was accessed on December 14, 2018.)

[84] https://ahdictionary.com/word/search.html?q=Podiatry. (The website was accessed on November 1, 2018.)

[85] https://www.mayoclinic.org/diseases-conditions/sleep-apnea/symptoms-causes/syc-20377631 (The website was accessed on December 14, 2018.)

[86] https://www.merriam-webster.com/dictionary/stat. (The website was accessed on October 31, 2018.)

A **stent** is a small wire mesh tube used to prop open an artery.[87]

Transthoracic echocardiography is performed to determine areas of injury to the heart and the heart's ability to pump blood.[88]

Telemetry is the "transmission of cardiac signals…to a receiving location where they are displayed for monitoring."[89]

Thrombus is a blood clot formed within a blood vessel.[90]

Tonsillectomy is the surgical removal of the tonsils.[91]

Troponin is a heart protein released into the blood after a heart attack occurs.[92]

[87] https://www.mayoclinic.org/tests-procedures/coronary-angioplasty/about/pac-20384761. (The website was accessed on October 31, 2018.)

[88] https://www.cedars-sinai.edu/Patients/Programs-and-Services/Imaging-Center/For-Patients/Exams-by-Procedure/Transthoracic-Echocardiogram-TTE.aspx. (The website was accessed on April 4, 2019.)

[89] https://www.medilexicon.com/dictionary/90002. (The website was accessed on October 31, 2018.)

[90] https://www.merriam-webster.com/dictionary/thrombus. (The website was accessed on November 1, 2018.)

[91] https://www.merriam-webster.com/dictionary/tonsillectomy. (The website was accessed on February 25, 2018.)

[92] https://labtestsonline.org/tests/troponin. (The website was accessed on February 25, 2018.)

Appendix B: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: June 24, 2019

From: Director, Capitol Health Care Network (10N5)

Subj: Healthcare Inspection—Concerns Related to an Inpatient' s Response to Oxycodone and Facility Actions at the Baltimore VA Medical Center, Maryland

To: Director, Office of Healthcare Inspections (HL03)

Director, GAO/OIG Accountability Liaison (GOAL) Office (VHA 10EG GOAL Action)

I have reviewed and concur with the findings and recommendations in the

Office of Inspector General's (OIG's) report entitled Healthcare Inspection— Concerns Related to An Inpatient' s Response to Oxycodone and Facility Actions at the Baltimore VA Medical Center, Maryland.

Further, I have reviewed and concur with the VA Maryland Health Care System, Baltimore, Maryland Medical Center Director's response.

Thank you for this opportunity to focus on continuous performance improvement. If you have any questions, please feel free to contact the VISN 5 Office at 410-691-1131.

(Original signed by:)

Robert M. Walton

FACHE

Appendix C: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: June 18, 2019

From: Director, VA Maryland Health Care System (512/00)

Subj: Healthcare Inspection—Concerns Related to an Inpatient's Response to Oxycodone and Facility Actions at the Baltimore VA Medical Center, Maryland

To: Director, VA Capitol Health Care Network (10N5)

1. I would like to express my appreciation to the Office of Inspector General survey team for their professional and comprehensive review conducted on October 16-18, 2018.

2. I have reviewed the draft report for the VA Maryland Health Care System, Baltimore, Maryland, and concur with the findings and recommendations.

3. Please express my gratitude to the survey team for their professionalism and assistance to us in our continuing efforts to provide the best care possible to our Veteran patients.

(Original signed by:)

Adam M. Robinson, Jr., M.D.

Comments to OIG's Report

Recommendation 1

The VA Maryland Health Care System Director takes steps to ensure resident supervision meets requirements, and monitors for compliance with Veterans Health Administration policy.

Concur.

Target date for completion: December 2019

Director Comments

The Office of Quality, Safety and Improvement (QSI) will perform documentation audits to ensure that required attending physician documentation is included into the electronic health record. Monitoring data will be provided to each Clinical Center Director to ensure that deficiencies are addressed timely. In addition, the Director of QSI will be informed of any and all deficiencies. Compliance discrepancies will be addressed by Clinical Center Directors through the management review process. To ensure compliance, Clinical Center Directors will report results of monitoring data as well as management review results to the Deputy Chief of Staff. The Deputy Chief of Staff will report results on a quarterly basis to the Executive Committee of Medical Service (ECMS).

Per Resident Supervision Policy 512-14/E&AA-004, residents are mandated to contact attending physicians 24 hours per day/7 days per week under the following circumstances:

(a) Decompensating patient/need to transfer patient to a higher level of care

(b) Patient death (expected or not)

(c) Patient made DNR or a change in a patient's DNR status

(d) Patient wanting to leave AMA

(e) Patient fall with associated injury or a fall that requires a head CT to rule out intracranial injury

(f) Requests from outside medical facilities to transfer a Veteran to the VAMHCS

(g) Difficulties with patient ownership

Resident deficiencies, overseen by Resident Training Directors will be addressed through resident evaluations and performance reviews.

Recommendation 2

The VA Maryland Health Care System Director verifies the capture and reporting of adverse drug events to the national Veterans Health Administration Adverse Drug Event Reporting System, and monitors for compliance.

Concur.

Target date for completion: Completed as of June 2019

Director Comments

Pharmacy collects all reported adverse drug reactions and reviews the submission for accuracy and validity. The Adverse Drug Reaction is entered into the VA Adverse Drug Event Reporting System and when appropriate the report is submitted to the U.S. Food and Drug Administration's MedWatch program. All Adverse Drug Reaction reports are aggregated and reported quarterly to the VAMHCS Pharmacy and Therapeutics Committee.

OIG Comment

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

Recommendation 3

The VA Maryland Health Care System Director ensures staff complete root cause analysis or aggregated reviews for adverse events as required by Veterans Health Administration policy and monitors to ensure completion.

Concur.

Target date for completion: January 31, 2020

Director Comments

The Patient Safety Program reviews all incidents and/or near misses and assigns the severity score and probability score for determining if a Root Cause Analysis (RCA) is required. The Patient Safety Program facilitates and manages the RCAs for adverse events/near misses and will complete within 45 days of notification of the patient safety incident. Patient Safety leadership is in the process of implementing a Patient Safety Committee. All RCA and aggregate reviews will be reported monthly to the Patient Safety Committee beginning July 2019. To improve the quality and timeliness of RCAs, the following process has been implemented as of June 2019: Patient Safety will notify facility leadership immediately regarding incidents that meet RCA criteria. Upon Director's approval, the RCA will be initiated. Patient Safety staff are required to present results of the RCA fact-finding to QSI

leadership within 35 days of notification of the incident. RCA results will be presented for facility leadership review and concurrence within 42 days of notification of the incident.

An RCA of this incident was completed and signed by the Director on February 21, 2019. The actions for the incident include:

1. Chief of Podiatry to ensure all podiatry patients going for surgical procedures are reviewed and discussed with appropriate provider in attendance during the pre-op meeting: discussion points to include:
    a. Pre-op/Post-op resources and requirements
    b. Patients with medical comorbidities or expectations of complex post-op management will be referred for direct admission to Medicine Service.
2. All inpatient narcotic orders will be linked to an order for Naloxone PRN with order comments mandating the RN to activate Rapid Response Team if Narcan is required. Narcan will be made available in the Omni-Cell for all patient care units.

Recommendation 4

The VA Maryland Health Care System Director verifies documentation of clinical disclosures when perceptible effects of an adverse event have occurred, as required, and monitors for compliance.

Concur.

Target date for completion: Completed June 2019

Director Comments

Risk Management has created a Clinical Disclosure form to use when adverse events are identified. Risk Management investigated the use of a Clinical Note Title with VHA Risk Management Program. A Clinical Disclosure title note is not permitted. Risk Management will review 24- hour nursing reports, Occurrence Screens, and JPSR (electronic incident reports) to determine if an adverse event has occurred and a clinical disclosure was performed. The Chief of Staff and Director of Quality Safety and Improvement will be notified if there is no documentation of the clinical disclosure in the electronic health record of an adverse event. Risk Management will track this information and present to Chief of Staff during the biweekly COS/Quality Staff Meeting.

OIG Comment

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

Recommendation 5

The VA Maryland Health Care System Director ensures peer reviews are evaluated according to VA Maryland Health Care System policy and monitors for compliance.

Concur.

Target date for completion: Completed June 13, 2019

Director Comments

The VA Maryland Health Care System Peer Review policy has been rescinded per VHA Peer Review for Quality Management Directive 1190 requirement. Risk Management will monitor compliance of the Peer Review process utilizing the recently revised Peer Review Assessment Form for completion of the case and follow up of the action plans for Level 2 and Level 3 as applicable.

OIG Comment

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

Recommendation 6

The VA Maryland Health Care System Director verifies that the Surgical Work Group meets and documents minutes as required to include improvement data presentation, discussion, and performance tracking, and monitors for compliance.

Concur.

Target date for completion: Completed June 14, 2019

Director Comments

The VAMHCS Surgical Care Clinical Center has created a share drive folder that stores all Surgical Facility Work Group Minutes. To ensure continuity, staff will be educated on the location of the Surgical Facility Work Group folder and the Minutes will include data, performance tracking, and reflect all relevant discussions.

OIG Comments

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

OIG Contact and Staff Acknowledgments

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