



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Quality of Care and Patient
Safety Concerns on the
Acute Behavioral Health Unit
at the Corporal Michael J.
Crescenz VA Medical Center
Philadelphia, Pennsylvania



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Corporal Michael J. Crescenz VA Medical Center (facility), Philadelphia, Pennsylvania, to review quality of care and patient safety concerns identified by an OIG medical consultant following assistance provided during a VA OIG Office of Investigations inquiry into an unexpected patient death.

In late 2017, facility VA police alerted the Office of Investigations, per VA policy, that a patient in their mid-30s died unexpectedly while on the acute behavioral health unit (Unit 7E).¹ In late 2018, following the completion of an investigation by the Office of Investigations, the OIG opened a healthcare inspection to evaluate quality of care and patient safety concerns related to this patient and across Unit 7E. Specifically, the OIG reviewed

- Quality of care deficiencies that may have contributed to the patient's death,
- Internal reviews and regulatory reporting, and
- Patient observation and methadone administration.

The patient, with a past medical history that included a kidney transplant in 2013 and opioid dependence, presented to the facility's walk-in mental health outpatient clinic in late 2017 requesting supervised medical withdrawal (detoxification) from acetaminophen/oxycodone.² After emergency department medical clearance and behavioral health triage assessment, the patient was admitted to Unit 7E and received methadone detoxification.³ After detoxification, and while still on Unit 7E, the patient began medication assisted treatment with methadone.

The OIG determined that quality of care deficiencies may have contributed to the patient's death during the Unit 7E admission. The pharmacy resident documented on the day of admission, that several of the patient's 17 active medications had potential for causing electrocardiogram (EKG) abnormalities and recommended EKG monitoring. However, Unit 7E providers did not monitor the patient for EKG changes or drug-drug interactions including overlapping drug effects and toxicities. Although Unit 7E staff and providers repeatedly documented signs consistent with oversedation, staff and providers failed to intervene, communicate directly with each other on what they documented, or request team members as additional signers.⁴ On the morning of the patient's death, the on-call provider and the primary provider entered differing methadone administration notes within 90 minutes of each other. The two providers did not communicate directly with each other. Communication of these significant health indicators may have

¹ The OIG uses the singular form of they (their/them) to protect the patient's privacy.

² The drug combination of acetaminophen/oxycodone is a generic type of opioid.

³ Methadone is also used for medically-supervised withdrawal, or detoxification, from opioids.

⁴ Signs of oversedation are low blood pressure, slowing of the heart rate, and respiratory depression.

provided opportunities for earlier interventions in the patient's care. In response to the patient's death, Unit 7E leaders implemented daily hospitalist morning meetings and a new nursing handoff document to be used at shift changes to improve team communication.

Although the facility responded to the patient's death with timely reviews, the OIG found the issue brief did not report accurate information including completed peer reviews and an institutional disclosure.⁵ A root cause analysis (RCA) did not comply with Veterans Health Administration (VHA) policy because providers directly involved in the patient's care participated in the RCA.⁶ The inclusion of these two providers could have compromised the analysis and recommended actions of the RCA. Facility leaders did not conduct peer reviews on all providers directly involved in the patient's care.⁷ The leaders disclosed the adverse events that led to the patient's death to the patient's representative.⁸

To determine if other adverse events related to methadone usage occurred for patients on Unit 7E, the OIG reviewed

- Patients admitted to Unit 7E who were initiated on methadone for a select time from October 1, 2016, through September 30, 2018;
- Unit 7E rapid response team /code blue events from October 1, 2016, through September 30, 2018; and
- Unit 7E Incident Reports from October 1, 2017, through September 30, 2018.

The OIG identified no evidence of adverse events on Unit 7E aside from the identified patient's adverse event.⁹

The OIG determined that Unit 7E staff did not comply with the facility's observation policy.¹⁰ The OIG reviewed the video surveillance recording for a 15-hour period prior to the rapid

⁵ Deputy Under Secretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs*, June 26, 2017. Issue briefs provide facility, Veterans Integrated Service Network, and VHA leaders clear, concise, and accurate information about a situation or an event.

⁶ VHA Handbook 1050.01. An RCA is a protected and confidential focused review used to analyze events or close calls. The content of the RCA 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.

⁷ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. These two documents contain similar language related to the definition of a focused peer review. Peer review for quality management is done by an individual healthcare professional or select committee to evaluate the performance of other professionals.

⁸ Facility MCM No. 11-95, *Disclosure of Adverse Events to Patients*, February 2016.

⁹ VHA Handbook 1050.01. An adverse event includes accidental, unintentional, or untoward incidents, injuries, or other occurrences of harm or potential harm associated with patient care or services provided at a VHA facility.

¹⁰ Facility Standard Operating Procedure (SOP) BH-60, *Inpatient Psychiatric Patient Observation Procedure*, April 7, 2016. Observation, also known as nursing rounds, is a procedure in which nursing staff have direct visual contact with a patient and take note of the patient, situation, and environment to ensure safety of the patient and others.

response team being called for the patient. The 15-hour period breaks down to 60 15-minute required rounding segments. The OIG determined that nursing staff rounded on the patient 26 out of 60 segments (47 percent).

Nursing leaders and management implemented measures to address deficiencies including equipment issues identified by the rapid response team and training needs to mitigate the potential for future patient safety events. According to the nurse manager, Unit 7E introduced the total patient care model beginning in March 2019. The total patient care model allows for the assigned nurse to provide both patient care and medication administration, rather than a fragmented or task-oriented patient care.

A review of patients for a selected time from October 1, 2016, through September 30, 2018, showed that facility staff generally complied with Unit 7E admission criteria requiring EKGs and urine drug screens prior to admission. Providers did not comply with VHA and facility policies requiring discussion, documentation, and a patient-signed informed consent prior to initiating methadone treatment.¹¹

The OIG made nine recommendations to the Facility Director related to (1) monitoring cardiac changes, drug-drug interactions, and signs of oversedation; (2) monitoring improved provider communication for patients with complex care needs; (3) updating of the issue brief; (4) ensuring RCA integrity review; (5) reviewing RCA team composition; (6) completing additional peer reviews; (7) ensuring education and compliance with the observation policy; (8) completing actions initiated or taken to resolve identified deficiencies; and (9) ensuring provider education for signed informed consent prior to initiating methadone treatment, and compliance with obtaining and documenting all aspects of signed informed consent prior to initiating methadone treatment.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided acceptable action plans. (See appendixes B and C, pages 24–32.) The OIG will follow up on the planned actions until they are completed.



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¹¹ VHA Handbook 1004.01, *Informed Consent for Clinical Treatment and Procedures*, revised September 20, 2017. Facility MCM 11-59, *Informed Consent for Clinical Treatment and Procedures*, May 2017.

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Abbreviations

DSM	Diagnostic and Statistical Manual
EHR	electronic health record
EKG	electrocardiogram
Mg	milligrams
OIG	Office of Inspector General
RCA	root cause analysis
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Corporal Michael J. Crescenz VA Medical Center (facility), Philadelphia, Pennsylvania, to review quality of care and patient safety concerns identified by an OIG medical consultant following a VA OIG Office of Investigations inquiry into the unexpected death of a patient.

Background

The facility is part of Veterans Integrated Service Network (VISN) 4. The facility serves as an acute referral center for VA healthcare facilities in Eastern Pennsylvania, Delaware, and Southern New Jersey, and operates four community based outpatient clinics. From October 1, 2016, through September 30, 2017, the facility served 56,953 patients and had a total of 423 hospital operating beds, including 143 inpatient beds, 40 domiciliary beds, and 240 community living center beds. Affiliated with the University of Pennsylvania and numerous other allied health schools and colleges, the facility offers comprehensive surgical, medical, and behavioral health care including substance use disorder treatment.

Unit 7E

Unit 7E is a 20-bed acute behavioral health unit at the facility that provides intensive short-term diagnostic evaluation, stabilization, and treatment for patients with acute behavioral health disorders and substance use disorders. Patients meeting Unit 7E admission criteria include those who cannot be safely managed in a less restrictive environment and those needing medical withdrawal management. One admission route to Unit 7E is through the Behavioral Health Emergency Care Unit (behavioral health unit), located within the emergency department.¹² Prior to admission, the emergency department provider completes a physical exam, and orders an electrocardiogram (EKG) and a urine drug screen.¹³ Once medically cleared by the emergency department provider, the behavioral health unit provider determines if the patient will be admitted; if admitted, the behavioral health unit provider writes the admissions orders including the patient's active medications.

While on Unit 7E, patients receive care and medications for their admitting diagnoses, withdrawal management, stabilization treatment team meetings, therapeutic groups, discharge planning participation, and linkage to outpatient or community-based programs. Discharge plans

¹² Patients may also be admitted from one of the other inpatient units within the facility or transferred from another VA medical center.

¹³ An EKG measures the electrical activity of the heart and is a diagnostic tool used by providers to evaluate and monitor cardiac status. A urine drug screen can detect a range of drugs and can be part of a general medical clearance prior to admission.

from Unit 7E may include outpatient services, residential rehabilitation, or community-based programs.

Concerns

In late 2017, the Office of Investigations was alerted by the VA police that a patient in their mid-30s died unexpectedly while on Unit 7E.¹⁴ In early 2018, the Office of Investigations requested assistance from the Office of Healthcare Inspections in reviewing the patient's death.

Following the completion of an investigation by the Office of Investigations, the OIG opened a healthcare inspection to review quality of care and patient safety concerns related to this patient and throughout Unit 7E. Specifically, the OIG reviewed

- Quality of care deficiencies that may have contributed to the patient's death,
- Internal reviews and regulatory reporting, and
- Patient observation and methadone administration.

Scope and Methodology

The OIG team completed a site visit the week of December 10, 2018, and conducted 33 interviews including Unit 7E providers and nursing staff, facility leaders, Chiefs of Behavioral Health and VA Police, Chair of the Code Committee, the Risk Manager, the Patient Safety Manager, and other relevant staff. The OIG team observed Unit 7E's environment of care.

The OIG team reviewed VHA and facility policies and practices related to the use of methadone in treating patients admitted for substance use disorder on Unit 7E, the identified patient's electronic health record (EHR), and other relevant documents to determine the events leading up to the patient's death. The OIG evaluated the quality of care the patient received on Unit 7E and the facility's responses to the patient's death to determine if the death was reviewed and reported as required. The OIG reviewed nursing staff training records including basic life support certification.¹⁵ The OIG analyzed patients initiated on methadone from July 1, 2017, through September 30, 2017, and July 1, 2018, through September 30, 2018, to determine if other patients experienced or could have experienced an adverse event, as well as to determine compliance with Unit 7E's admission criteria and initiation of methadone.¹⁶

¹⁴ The OIG uses the singular form of they (their/them) to protect the patient's privacy.

¹⁵ Basic life support is the most common certification for life saving training that involves the ability to revive, resuscitate, or sustain a person in cardiopulmonary arrest or respiratory failure.

¹⁶ VHA Handbook 1050.01. An adverse event includes accidental, unintentional, or untoward incidents, injuries, or other occurrences of harm or potential harm associated with patient care or services provided at a VHA facility.

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 mid-30's with a past medical history that included a kidney transplant in 2013 and opioid dependence presented to the facility's walk-in Mental Health Outpatient Clinic on a day in late 2017 (day 1). The patient was initially seen by a walk-in Mental Health Outpatient Clinic psychiatrist and described using acetaminophen/oxycodone 30 milligrams (mg), four to five times per day, and was requesting medically-supervised withdrawal as "[the patient] could not do it on [their] own."¹⁷ The walk-in Mental Health Outpatient Clinic psychiatrist referred the patient for admission evaluation in the behavioral health unit. A behavioral health unit psychiatrist evaluated the patient and documented the case as medically complicated and endorsed a management plan for inpatient medically-supervised opiate withdrawal on Unit 7E. The patient's admitting urine drug screen was positive for oxycodone.¹⁸ While awaiting admission, another behavioral health unit provider completed the patient's admission orders and entered a one-time dose of methadone (20 mg). The patient received this dose upon admission to Unit 7E, but prior to being seen by the inpatient psychiatrist.

On day 2, a Unit 7E psychiatrist assumed primary responsibility for the patient's hospital care. The patient received daily methadone doses ranging from 5 mg to 50 mg from day 2 to day 10. The patient's EHR did not contain a signed informed consent for methadone use or a discussion of the potential risks for cardiac arrhythmia, central nervous system depression, respiratory depression, or drug-drug interactions.¹⁹

Also on day 2, a pharmacy resident, under the supervision of a clinical pharmacy specialist, met with the patient to review the medications. The pharmacy resident documented the patient was prescribed 17 "active inpatient medications" and cited that many of the medications could cause additive central nervous system depressant effects, and several of the drugs could, through drug-drug interactions, increase the risk of QTc segment prolongation.²⁰ The pharmacy resident documented that the patient's EKG from day 2 was "NSR [normal sinus rhythm], normal ECG

¹⁷ The drug combination of acetaminophen/oxycodone is a type of opioid.

¹⁸ No further urine drug screens were ordered during the patient's hospitalization.

¹⁹ The central nervous system consists of the brain and spinal cord. The brain signals the heart to beat and lungs to breath. The spinal cord handles nerve impulses which allows the brain to communicate with the body. Central nervous system depression is when the central nervous system functions slow down.

²⁰ In cardiology, the QT interval is a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle. The QT interval represents electrical depolarization and repolarization of the ventricles. QTc is the QT interval corrected for heart rate. Normal QTc interval in an adult male is 350-440 millisecond; a prolonged QTc value can be a marker for development of a ventricular arrhythmia. Johnson, J. N. and Ackerman, M. J. (2009). "QTc: how long is too long?" *British Journal of Sports Medicine*, 43, no. 9 (September): 657-662. 10.1136/bjism.2008.054734.

[electrocardiogram], QTc=437.”²¹ The pharmacy resident recommended to “continue to monitor the EKG for QTc prolongation.”²²

Over the course of the patient’s hospitalization, various providers described the patient as increasingly inactive and somnolent. During a mid-day psychology group session note on day 6, the psychology fellow documented that the patient “alternated between appearing to be asleep and being awake but appearing drowsy.” Nursing notes written on day 6, day 7, and day 8 described the patient as having “slept at long intervals through the [evening] shift.” A nursing note during the day on day 8 referenced the patient as “nodding off” during a spirituality exercise. On day 9, the mid-day psychology group session note described the patient as having “alternated between being drowsy/asleep and being awake” and that “at the end of group, [the patient] apologized to the facilitator for falling asleep, noting that morning medication might be making [the patient] drowsy.” In the afternoon of day 9, a nursing assistant documented “morning medication is making [the patient] drowsy during the day [the patient] was observed dosing [*sic*] off a bit during psychology group.”

On the morning of day 10, two psychiatrists made separate EHR entries mentioning the patient’s somnolence, though the plan for methadone management differed in the respective notes. At 6:54 a.m., a Unit 7E overnight covering psychiatrist, following a telephone call with a Unit 7E nurse, documented that the patient had a rapid heart rate, elevated blood pressure, and an unsteady gait.²³ A 7:10 a.m. addendum to the overnight covering psychiatrist’s note stated, “due to drowsiness, methadone and gabapentin are being held.”²⁴ At 8:47 a.m. the Unit 7E psychiatrist met with the patient and documented that the patient was “confused and somnolence [*sic*],” and specified the methadone management plan as, “hold methadone at 40 mg daily for now.”

At 1:45 p.m., nursing staff documented that the “[P]atient did not attend groups this a.m. Patient has been in bed most of the day, did not eat lunch.” Another nursing note at 7:32 p.m. stated, “[P]atient observed in room appears to be sleeping deeply, attempted numerous times to wake for meals and meds.” The patient remained asleep for the rest of the evening. At 8:50 p.m., a nurse attempted to wake the patient through “vocal and tactile stimuli to include deep sternal rub,” but the patient did not respond.²⁵

²¹ An ECG is equivalent to EKG. Normal sinus rhythm describes the characteristic rhythms of a normal healthy heart.

²² Despite the pharmacy resident’s recommendation, a repeat EKG was not initiated.

²³ No EKG was ordered.

²⁴ Gabapentin is a medication used to control seizures and relieve pain in some neurologic conditions.

²⁵ A nursing staff member entered the EHR note several days after the patient’s death. Although the staff member documented 8:50 p.m. as the time, video surveillance footage showed that the staff member entered the room at 9:01 p.m.

At approximately 9:07 p.m., Unit 7E staff called for the rapid response team.²⁶ The rapid response team described the patient as “unresponsive, cyanotic, and covered in [their] own vomit...with agonal breathing.”²⁷ The rapid response team also cited that there was “no monitoring equipment in the patient’s room, no immediate vital signs available...no backboard or stretcher on the unit; the cardiac monitor was not working, and no one could immediately provide any corroborating information.” The patient was moved to the medical intensive care unit with a weak pulse and low blood pressure. The patient then experienced a cardiopulmonary arrest and advanced cardiac life support measures were administered, but resuscitative efforts were not successful.²⁸ The patient was pronounced dead at 10:55 p.m. on day 10.

The Office of Medical Examiner performed a complete autopsy. The immediate cause of death was noted as “Hypertensive Cardiovascular Disease,” and the manner of death as “Natural.” The medical examiner’s toxicology report listed levels of four prescribed drugs as present: methadone, cyclobenzaprine, citalopram, and trazodone.²⁹ Illicit agents, or non-prescribed medications, as tested, were not found.

Inspection Results

Veterans Health Administration (VHA) policy states that substance use disorders, “encompass the family of alcohol and other drug use illnesses that meet diagnostic criteria according to the American Psychiatric Association Diagnostic and Statistical Manual (DSM-IV).”³⁰ Patients diagnosed with substance use disorder include those who meet criteria for abuse or dependence on alcohol, tobacco products, illegal substances, and psychoactive medications.³¹ VA patients

²⁶ A rapid response team, or medical emergency team, is comprised of doctors, nurses, and respiratory therapists with advanced lifesaving skills, who respond to emergency calls within the hospital.

²⁷ Merriam-Webster defines cyanotic as a bluish or purplish discoloration of the skin due to lack of oxygen in the blood. Agonal breathing is an abnormal type of respiration that is labored and gasping and inadequate for effective aeration; it is often indicative of a severe medical emergency, such as cardiac arrest.

²⁸ Cardiopulmonary arrest is the abrupt loss of heart function, breathing, and consciousness. Advanced cardiac life support incorporates basic life support skills as well as recognition and early management of respiratory and cardiac arrest, peri-arrest conditions (for example symptomatic low blood pressure), airway management; pharmacology, and effective communication as a member of a resuscitation team.

²⁹ Cyclobenzaprine is a medication used to help relax certain muscles in the body. It helps relieve pain, stiffness, and discomfort by acting on the central nervous system to produce its muscle relaxant effects. Citalopram and trazodone are used to treat depression.

³⁰ VHA Handbook 1160.04, *VHA Programs for Veterans with Substance Use Disorder (SUD)*, March 7, 2012. This handbook expired on March 31, 2017, and has not been recertified or replaced. On May 18, 2013, the American Psychiatric Association published the DSM-V. The DSM-V combined substance use and substance use dependence into a single disorder.

³¹ Merriam-Webster defines psychoactive as “affecting the mind or behavior.”

diagnosed with substance use disorder often have complicating factors including psychosocial deficits, behavioral health disorders, and co-morbid medical conditions.

VHA requires VA medical facilities to make substance use disorder services available for patients in need.³² To meet this requirement, VA medical facilities offer a variety of substance use disorder services including acute hospitalization, outpatient services, intensive outpatient programs, residential rehabilitation, and medication assisted therapies. The facility offers three options under medication assisted therapies including methadone, buprenorphine/naloxone, or naltrexone-extended release.³³

1. Quality of Care Deficiencies that may have Contributed to the Patient's Death

Altered Mental Status, Drug Effects, and Drug-Drug Interactions

The OIG determined that quality of care deficiencies may have contributed to the patient's death during the Unit 7E admission. Unit 7E providers did not properly evaluate the patient's altered mental status, progressive lethargy, and somnolence. There was a lack of consideration as to possible drug effects and drug-drug interactions involving methadone and the other central nervous system depressant medications the patient received.

Methadone

Methadone is a synthetic (man-made) opioid prescribed for patients with moderate to severe chronic pain and opiate addiction.³⁴ When prescribed for the treatment of an opiate addiction, methadone lessens the symptoms of withdrawal and blocks the euphoric effects of the drug. Methadone produces insensitivity to pain, a slowing of respirations, lowering of the blood pressure, and slowing of the heart. Methadone is also used for medically-supervised withdrawal, or detoxification, from opioids, and when used in this way, the dosing level decreases. After detoxification, if a patient chooses to remain on medication assisted therapies, the provider will titrate the methadone to the appropriate level.

³² VHA Handbook 1160.04.

³³ Buprenorphine/naloxone is a combination medication used to treat opioid dependence and addiction, and to reverse the effects of opioid overdose. Naltrexone is a medication that blocks the effects of narcotics or the "high" feeling. It is started only after a person completes the withdrawal process off opioids. The medication helps keep people from using opioids.

³⁴ Opioids are a class of drugs that include prescription pain relievers such as oxycodone, hydrocodone, morphine, codeine, and fentanyl, as well as the illicit drug heroin. With prolonged use, physical or psychological dependence can occur.

Because of the unique pharmacokinetic and pharmacodynamic properties of methadone, the general principles used in dosing are different than those of other opioids.³⁵ One such example is dose titration, which should occur after at least five–seven days on a designated dose.³⁶

Below is a list of warnings, guidance, and recommendations issued for prescribing methadone:

- In 2006, the US Food and Drug Administration alerted physicians to the potential for respiratory depression and cardiac arrhythmias for patients taking methadone.³⁷
- In 2010, the VA and the Department of Defense recommended that before prescribing methadone, healthcare providers inform patients of the risk of arrhythmia and obtain an EKG and consider an additional EKG once the methadone dose is stabilized, and annually thereafter.
- In 2012, the Centers for Disease Control recommended that healthcare providers who prescribe methadone are experienced in its use, follow consensus guidelines for initiation and titration, and instruct patients about the potential risks of the medication.
- In 2015, the VA and the Department of Defense published guidelines on dosing and administering methadone with the initial (initiation) dose at 15–20 mg and to titrate carefully because methadone has a delayed cumulative effect.
- In 2016, VHA Pharmacy Benefits Management Services provided specific guidance related to methadone that recommended, for patients with cardiac risk factors, obtaining a baseline EKG (EKG within the previous three months is sufficient), and for patients without risk factors, an EKG within the last 12 months; all patients should receive education that the combination of methadone with illegal drugs or alcohol may be fatal.

Pharmacology

Knowledge of methadone pharmacology is critical to its effective use. During methadone initiation, deaths may occur from methadone overdosing or interaction with another drug. When increased too rapidly, methadone doses can accumulate over several days and toxicity can develop. For example, according to an American Society of Addiction Medicine journal article

³⁵ Merriam-Webster defines *pharmacokinetics* as, “the characteristic interactions of a drug and the body in terms of its absorption, distribution, metabolism and excretion.” The biochemical, physiologic, and molecular effects of a drug on a body, also described as what a drug does to a body, is known as pharmacodynamics.

³⁶ *Titration* is when a medication dose is either progressively increased or decreased in response to a patient’s status.

³⁷ Respiratory depression, also known as hypoventilation, means that the lungs are deficient in their ability to ventilate. The result of this is a reduction of oxygen and/or increase in carbon dioxide in a person’s blood. Respiratory depression is characterized as slow and ineffective breathing. Merriam-Webster defines cardiac arrhythmia as “an irregular heartbeat.”

day one “...dose is not lethal, tomorrow’s dose is not lethal, but the entire third day’s dose combined with half of the second day’s dose and one quarter of the first day’s dose accumulate to a lethal level.”³⁸ In addition, it is important for the provider to consider the potential for drug-drug interactions, and the possibility of overlapping drug effects (symptoms may include QTc prolongation with the potential for arrhythmia) and overlapping toxicities (symptoms may include somnolence and respiratory depression).³⁹

While methadone can be used in combination with other central nervous system depressant medications, a greater level of toxicity or lethality may result. As noted in the pharmacy resident’s assessment of the patient on day 2, “the patient is on many medications that could cause additive CNS [central nervous system] depressant effects.” Among the 17 active medications at the time of that observation, five could cause or aggravate central nervous system depressant effects.⁴⁰ In addition, on day 3, another drug (cyclobenzaprine) with central nervous system depressant effects was added to the regimen.

On day 5, the patient completed detoxification with methadone. On day 6, the Unit 7E psychiatrist initiated methadone as a medication assisted therapy, which included an aggressive increased titration. Following methadone initiation, the patient exhibited signs of oversedation including progressive somnolence, inactivity, and, ultimately, unresponsiveness. (See appendix A for additional information related to the patient’s signs and symptoms.)

On day 8, the daytime covering psychiatrist increased the patient’s cyclobenzaprine from 10 mg as needed to 10 mg twice a day due to back pain.

On day 10, nursing staff reported that the patient was “hard to wake up.” At 6:25 a.m., video surveillance footage confirmed that the patient left the room and walked unsteadily down the hall holding the side rails. At 6:30 a.m., two nurses escorted the patient back to the room with each holding an arm. Since the patient’s blood pressure and heart rate were elevated, nursing staff contacted the overnight covering psychiatrist to meet with the patient. The overnight covering

³⁸ Baxter et al. “Safe Methadone Induction and Stabilization Report of an Expert Panel.” *Journal of Addiction Medicine*, Volume 7, Number 6, (November/December 2013):379.

³⁹ The QTc interval represents the time required for ventricular depolarization and repolarization corrected for heart rate. A QTc of 450 milliseconds for females and 430 milliseconds or less for males is considered normal. QTc prolongation is the delayed ventricular repolarization. According to U.S. Department of Health and Human Services, “Drug-drug interaction is a change in a drug’s effect on the body when the drug is taken together with a second drug. It can delay, decrease, or enhance the absorption of either or both drugs, or cause adverse effects.” Merriam-Webster defines somnolence as, “a state of being drowsy or heavy sleep.”

⁴⁰ The five medications included methadone, gabapentin, hydroxyzine, escitalopram, and trazodone.

psychiatrist informed the nursing staff that due to shift change, the Unit 7E psychiatrist would be in to evaluate the patient.⁴¹

The overnight covering psychiatrist did not see the patient but documented and signed the following note at 7:11 a.m.

This Writer asked nursing to recheck vitals...Vitals rechecked about 10 minutes later. New vitals 125/82 HR [heart rate]-109...Due to patient's drowsiness, Methadone and Gabapentin held. Informed RN [registered nurse] that should patient's presentation improve, then to provide medications.

Approximately 90 minutes after the overnight covering psychiatrist ordered the methadone to not be administered until the patient's presentation improved, the Unit 7E psychiatrist ordered the methadone to be administered. The Unit 7E psychiatrist, who had not seen the patient since day 6, met with the patient at approximately 8:41 a.m., and entered the following documentation in the EHR at 8:47 a.m.,

Continues to feel confused...[the patient] presents as confused and somnolence...Hold Methadone at 40 mg daily for now...

The Unit 7E psychiatrist informed the OIG that, prior to prescribing the methadone on day 10, "I took [the patient] out of the room and walked [the patient]... At first, [the patient] was confused and somnolent, but [the patient] was alert and oriented by the end of my visit." The Unit 7E psychiatrist acknowledged not documenting the patient's improved mental status in the EHR. The Unit 7E psychiatrist told the OIG that based on the patient's vital signs and assessment, the Unit 7E psychiatrist ordered the patient's methadone, but at a reduced dosage due to cardiac concerns, and discontinued the escitalopram due to somnolence.⁴² The Unit 7E psychiatrist also documented discontinuing the patient's gabapentin, and decreased cyclobenzaprine from 10 mg twice per day to 5 mg three times per day and trazodone from 150 mg to 100 mg.

The Unit 7E psychiatrist's rationale for administering the methadone was partly based on the report that the patient's vital signs had returned to normal. However, the OIG determined that although the patient's blood pressure had normalized, the heart rate remained rapid at 109 beats per minute. Since the patient had been administered methadone for four days, the expectation would have been a slower heart rate if not a normal heart rate. The patient's increased heart rate should have prompted an EKG.

⁴¹ In late 2017, providers covering overnight shifts on Thursdays and Fridays in Unit 7E worked from 5:30 p.m.–8:00 a.m.

⁴² Escitalopram is a medication used to treat depression and anxiety.

During OIG interviews, the Unit 7E psychiatrist stated the patient was symptomatic and sick for the patient's age, and was used to feeling sleepy because of the medications. The Unit 7E psychiatrist acknowledged the drug-drug interactions of the patient's medications but told the OIG of being primarily concerned with the patient's use of escitalopram. The OIG recognizes that the patient may have been used to feeling sleepy on the immunosuppressant and antidepressant/antianxiety medications; however, the patient had not previously been on these medications and methadone at the same time and was in no position to judge whether somnolence was a cause for concern. In consideration of the patient's extensive and complex drug regimen, the OIG determined a potential existed for overlapping drug effects and toxicities.

Lack of Staff Communication

Although Unit 7E nursing staff and providers documented signs of the patient's progressive somnolence and inactivity, staff did not alert other staff or providers by adding them as additional signers to their notes or directly communicating with each other. Communication of these significant health indicators may have provided opportunities for earlier interventions in the patient's care.⁴³

The Joint Commission identified communication issues as a common root cause of preventable patient harm incidents. Communication between healthcare providers is essential to delivering quality care.

Unit 7E staff consistently documented the patient's progressive somnolence and inactivity; however, none of the 15 notes contained requests for additional signers by team members. In addition, the OIG noted a lack of communication in the following examples:

- The pharmacy resident documented key clinical information about the patient's medications, yet no providers were added as additional signers. The note included a warning about potential drug-drug interactions that could cause additive central nervous system depressant effects, and a recommendation to monitor the EKG given that several of the patient's medications could cause QTc prolongation. The supervising clinical pharmacy specialist told the OIG it was generally not the practice for clinical pharmacy specialists to add providers as co-signers because pharmacists were considered consultants and not team members.
- Within the patient's treatment plan, insomnia was documented as a problem from day 3 through day 10. Although the treatment plan documented insomnia, staff consistently

⁴³ VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015. VHA uses the additional signer function of the EHR as "a communication tool to alert a clinician about information pertaining to the patient. This functionality is designed to allow clinicians to call attention to specific documents and for recipients to acknowledge receipt of the information."

reported the patient as having progressive signs of somnolence, inactivity, or oversedation. The treatment plan did not include these progressive signs.

In response to the patient's death, the Associate Chief Nurse and Unit 7E Nurse Manager reported implementation of a daily hospitalist morning meeting whereby hospitalists can be consulted to see patients for medical issues, and a new nursing handoff document to be used at shift changes to improve communication.⁴⁴

Cardiac Monitoring

Unit 7E providers and staff did not properly evaluate the patient's rapid heart rate on the morning of day 10. The patient's EKG revealed a high normal QTc interval before methadone was begun, and there was no assessment of further QTc prolongation, other EKG changes, or other reasons for the development of a rapid heart rate. The OIG determined that further assessment of the patient's rapid heart rate would have been reasonable given the patient's most recent EKG results and methadone induction.

VA Pharmacy Benefits Management Services issued guidance with general principles for methadone dosing:

- Potential drug interactions and QTc prolongation must be given careful consideration.⁴⁵
- If a patient's methadone dose is being escalated, then the provider should obtain a follow-up EKG when methadone reaches 30–40 mg per day, and again if the methadone reaches 100 mg per day, or if the patient has new risk factors or exhibits signs or symptoms suggestive of arrhythmia.

When the patient presented to the behavioral health unit, a behavioral health unit psychiatrist noted the patient was “medically complicated” due to a kidney transplant in 2013. Though not experiencing active problems related to the transplant, the patient was maintained on a daily regimen of immunosuppressive agents, including tacrolimus.⁴⁶ The pharmacy resident documented that several of the patient's prescribed medications (escitalopram, hydroxyzine, methadone, and trazodone) could increase the risk of QTc prolongation when given concurrently

⁴⁴ “A hospitalist is a physician who specializes in treating hospitalized patients of other physicians in order to minimize the number of hospital visits by other physicians.” <https://www.merriam-webster.com/dictionary/hospitalist>. (The website was accessed on March 25, 2019.)

⁴⁵ VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives, *Oral Methadone Dosing Recommendations for the Treatment of Chronic Pain*, July 2016.

⁴⁶ Immunosuppressive agents are commonly used in kidney transplantations to reduce the rejection rates and improve graft survival of the transplanted kidney. Tacrolimus is a medication to treat itching, redness, and inflammation that is caused by a patient's reaction to other medications.

with tacrolimus.⁴⁷ The pharmacy resident recommended to “continue to monitor the EKG for QTc prolongation.” Providers did not order follow-up EKG monitoring during the patient’s admission.

Methadone was used for the patient’s drug detoxification from day 2 through day 5. Over 4 days, the patient’s methadone dosage decreased from 20 mg to 10 mg to 5 mg. On day 6), the patient was initiated on methadone at 20 mg as medication assisted therapies, and remained on methadone through day 10). On day 7), the patient’s methadone dosage was increased to 40 mg and escalated to 50 mg for the subsequent two days before being reduced back to 40 mg on day 10). No providers ordered an EKG during the escalation of the patient’s methadone induction despite VA guidance.

Response to a Medical Emergency

Unit 7E was not prepared to effectively respond to the patient’s cardiopulmonary arrest on day 10).

VHA requires all medical facilities to have a plan to rapidly initiate the appropriate emergency response for an individual who suffers a cardiopulmonary arrest.⁴⁸ All clinically-active staff must be certified in basic life support, unless required to be certified in advanced cardiac life support.

Facility policy states that upon identification of a medical emergency, staff contact the facility operator to request the type of assistance needed and all basic life support trained staff are expected to render assistance by providing basic life support until relieved by a member of the medical emergency response team.⁴⁹ Nurse managers and service and section chiefs are responsible for monitoring staff basic life support training and currency.

At approximately 9:10 p.m. on day 10, Unit 7E staff called for the rapid response team.⁵⁰ The rapid response team described the patient as “unresponsive, cyanotic, and covered in [the

⁴⁷ Hydroxyzine is a medication used to help control anxiety and tension, relieve symptoms of an allergic reaction, and produce sleep prior to surgery.

⁴⁸ VHA Directive 1177, *Cardiopulmonary Resuscitation, Basic Life Support, and Advanced Cardiac Life Support Training for Staff*, November 6, 2014, was in place at the time of the patient’s death. This directive was rescinded and replaced by VHA Directive 1177, *Cardiopulmonary Resuscitation*, August 28, 2018, and contains same or similar language on staff training.

⁴⁹ Facility MCM 11-23, *Medical Emergencies*, March 2018.

⁵⁰ A rapid response team, or medical emergency team, is comprised of doctors, nurses, and respiratory therapists with advanced lifesaving skills, who respond to emergency calls within a hospital.

patient's] own vomit...with agonal breathing.”⁵¹ The rapid response team also cited that there was “no monitoring equipment in the patient’s room, no immediate vital signs available...no backboard or stretcher on the unit; the cardiac monitor was not working, and no one could immediately provide any corroborating information.” The patient was moved to the medical intensive care unit with a weak pulse and low blood pressure. The patient then experienced a cardiopulmonary arrest and advanced cardiac life support measures were administered, but resuscitative efforts were not successful.⁵² The patient was pronounced dead at 10:55 p.m. on day 10.

Actions Taken After the Patient’s Death

Nursing leaders and Units 7E and 7W management implemented measures to address deficiencies including equipment issues identified by the rapid response team and training needs to mitigate the potential for future patient safety events. According to the nurse manager, Unit 7E introduced the total patient care model beginning in March 2019. The total patient care model allows for the assigned nurse to provide both patient care and medication administration, rather than a fragmented or task-oriented patient care.

The OIG noted that the issue of total patient care nursing assignments had not been resolved. According to the Unit 7E nurse manager, total patient care nursing assignments for the night shift was implemented, and the goal was to implement this practice with the evening shift by April 9, 2019, and the day shift by the end of April.

2. Facility Reviews of the Patient’s Death and Unit 7E

Facility leaders did not comply with all reviews following the patient’s death.

Facility Reviews

Issue Brief

Issue briefs provide facility, VISN, and VHA leaders clear, concise, and accurate information about a situation or an event. Issue briefs are used to report on deaths, unusual events, disasters,

⁵¹ Merriam-Webster defines *cyanotic* as a bluish or purplish discoloration of the skin due to lack of oxygen in the blood. Agonal breathing is an abnormal type of respiration, labored and gasping and inadequate for effective aeration; it is often indicative of a severe medical emergency, such as cardiac arrest.

⁵² Cardiopulmonary arrest is when the abrupt loss of heart function, breathing, and consciousness. Advanced cardiac life support incorporates basic life support skills as well as recognition and early management of respiratory and cardiac arrest, peri-arrest conditions (i.e., symptomatic low blood pressure), airway management, pharmacology, and effective communication as a member of a resuscitation team.

or anything that may cause media attention or impact patient care.⁵³ Issue briefs should be started as early as possible and updated with new information as necessary.

Following the patient's death, the facility completed an issue brief the next day, and updated it three times and closed it 13 months later.⁵⁴

The OIG found that the facility leaders completed an RCA, but also conducted peer reviews, and facilitated an institutional disclosure with the patient's representative; however, did not update the issue brief with accurate information. Updated issue briefs provide complete information about an adverse event that enables the Under Secretary for Health for Operations and Management to determine if the adverse event was not an isolated case but instead a systems issue affecting multiple patients.

RCA

An RCA is a protected and confidential focused review used to analyze adverse events or close calls.⁵⁵ Through interviews and analysis of relevant information, a multidisciplinary RCA team aims to identify the basic or contributing factors associated with adverse events or close calls. By addressing these identified factors, facility leaders strive to prevent the same or similar situations from reoccurring. VHA requires that an RCA team be interdisciplinary in nature and focus primarily on processes and systems, rather than individual involvement.⁵⁶ To be considered credible, RCAs should, in part, exclude individuals directly involved in the adverse event or close call, and be timely with the Facility Director signing off and submitting the RCA to the National Center for Patient Safety within 45 days of becoming aware that an RCA is required.

Facility leaders became aware of the patient's death and chartered an RCA four days after the death to review the systems and processes that contributed to the patient's death. The content of the RCA 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; however, the OIG identified issues with the RCA process.

⁵³ Deputy Under Secretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs*, June 26, 2017.

⁵⁴ An institutional disclosure occurs when an adverse event results in, or is reasonably expected to result in, death or serious injury to a patient. Facility leaders and the provider disclose to the patient or their representatives that an adverse event occurred and provide specific information about the patient or their representatives rights and recourse. In early 2018, facility leaders and relevant staff conducted an institutional disclosure with the patient's representative.

⁵⁵ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This handbook expired in March 2016 and has not been recertified or replaced.

⁵⁶ VHA Handbook 1050.01.

Facility staff completed the RCA timely and the team was interdisciplinary in composition; however, providers that treated the patient were members of the team. The Patient Safety Manager acknowledged that the participation of these providers in the RCA was concerning, but did not believe that the potential bias impacted the outcome of the RCA. Involving providers that cared for the patient may have compromised the RCA analysis and recommended action plans.⁵⁷

Peer Review

VHA states that a peer review, when conducted as part of a facility's quality management program, is a confidential, non-punitive review process. Peer review focuses on improving the quality of health care or utilization of resources. Specifically, a peer review focuses on whether an individual provider's clinical decisions and actions during an episode of care met the standard of care.⁵⁸ VHA identifies clinical events that require peer review to include lack of documentation of a patient's clinical deterioration during the 48 hours preceding death; a significant change in a patient's clinical condition without evidence of appropriate intervention; and a patient death that appears related to a hospital-incurred incident or a complication of treatment.⁵⁹

The OIG acknowledges that facility leaders conducted peer reviews following the patient's death, and that the peer reviews included the relevant issues related to the quality of care the patient received. However, facility leaders failed to conduct peer reviews on all providers that had direct care of the patient. Without review of all relevant providers, the facility does not ensure a comprehensive review of a patient's care to identify and address any deficiencies.

Review of Methadone Patients and Adverse Events and Reporting

The OIG reviewed Unit 7E admissions of patients initiated on methadone, rapid response team/code blue events, and incident reports to determine if other patients experienced adverse events.⁶⁰ The OIG team found the following:

- Patients admitted to Unit 7E and initiated on methadone from July 1, 2017, through September 30, 2017, and July 1, 2018, through September 30, 2018, did not experience adverse events.

⁵⁷ VHA Handbook 1050.01.

⁵⁸ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010 was in place at the time of the event. This directive was rescinded and replaced by VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. These two documents contain similar language regarding the focus of a peer review.

⁵⁹ VHA Directive 2010-025; VHA Directive 1190.

⁶⁰ Code blue is an emergency code used in hospitals to alert all staff of a medical emergency. Most associate code blue with a cardiac arrest of a patient. Code blue may also involve patient family members.

- Unit 7E had 16 rapid response team /code blue events from October 1, 2016, through September 30, 2018, with only the identified patient experiencing an adverse event.
- Unit 7E's incident reports from October 1, 2017, through September 30, 2018, were categorized as close calls or near misses.⁶¹ None were categorized as adverse events.

For the select review period, the OIG noted that no patients admitted to Unit 7E and initiated on methadone, aside from the identified patient, experienced an adverse event or close call.

3. Patient Observation and Methadone Administration

Observation Policy

The OIG determined that Unit 7E staff did not comply with the facility's observation policy.⁶² Because of the policy noncompliance, staff were unaware of the patient's deteriorating medical condition, which contributed to missed opportunities to provide medical interventions that may have changed the outcome for this patient.

Unit 7E staff are required to complete unit and patient observation "rounds" every 15 minutes and document their findings on a rounding sheet. Rounding is a shared responsibility among nursing staff.⁶³ The charge nurse assigns duties at the start of each shift and staff are typically assigned to round for one to two hours at a time. While rounding, staff are expected to ensure all patients are accounted for and engaged in safe activities, and that the Unit 7E environment is clean and safe. Nursing staff who are assigned rounding duties are expected to record patient observations by documenting the location and behavior of each patient on an observation sheet.⁶⁴ While staff are not expected to wake a patient, they are required to monitor either three rises and falls of the torso to indicate respirations, or to observe a change in position of a patient. If concerned about a patient, staff should notify the charge nurse for guidance.

Following the patient's death, the VA police and nursing leaders conducted separate reviews of the Unit 7E video surveillance recordings from the day of the patient's death. Based on those reviews, facility leaders concluded that the evening shift nursing staff assigned to conduct rounds falsified documentation and did not follow patient observation policy.

⁶¹ Close calls (or near misses) are events or situations that could have resulted in an adverse event, but did not, either by chance or through timely intervention.

⁶² Reference to "Unit 7E staff" includes Registered Nurses, Licensed Practical Nurses, and Certified Nursing Assistants who are assigned clinical responsibilities on unit 7E.

⁶³ Facility Standard Operating Procedure (SOP) BH-60, *Inpatient Psychiatric Patient Observation Procedure*, April 7, 2016.

⁶⁴ Staff are required to document a patient's behavior either "awake" or "sleeping" and location as bedroom, common area, treatment area, activity room, or off unit on the rounding sheet.

The OIG also reviewed the video surveillance recordings over a 15-hour period prior to the rapid response team being called for the patient at approximately 9:10 p.m. The 15-hour period breaks down to 60 15-minute required rounding segments. The OIG determined that nursing staff rounded on the patient 28 of 60 segments (47 percent), with only one rounding segment between 6:00 p.m. and 9:00 p.m. Aside from three instances between 4:00 p.m. and 6:00 p.m. when staff reported or documented attempts to wake the patient, staff documented from 1:00 p.m.–9:00 p.m. that the patient was asleep in the room. During this time frame, the patient did not wake for meals, medications, or attend groups. Because staff reported the patient was in the room, snoring loudly, and not appearing in distress, they did not assess the patient further. Staff's noncompliance with the observation policy could have led to missed opportunities to intervene earlier for this patient.

Methadone Administration

EKGs and Urine Drug Screens

The OIG team confirmed that the facility generally complied with Unit 7E admission criteria in obtaining an EKG and urine drug screen.

VHA and facility policy requires that a patient receive an EKG and urine drug screen prior to admission to an acute behavioral health unit. The OIG found that the patient had required admission tests. To evaluate the facility compliance with obtaining an EKG and a urine drug screen on other patients initiated on methadone admitted to Unit 7E, the OIG reviewed EHRs from July 1, 2017, through September 30, 2017, and July 1, 2018, through September 30, 2018. In 2017, 12 of 15 patients (80 percent) received an EKG and 14 of 15 patients (93 percent) received a urine drug screen prior to admission. In 2018, all six patients received an EKG and a urine drug screen prior to admission. The OIG concluded that generally the facility complied with obtaining EKGs and urine drug screens prior to admission to Unit 7E.

Informed Consent

The OIG team concluded that facility staff did not comply with VHA and facility informed consent policies for methadone treatment.

VHA promotes a health care environment that respects and supports a patient's right to participate in their health care decisions.⁶⁵ The provider ensures a thorough discussion and that

⁶⁵ VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, revised September 20, 2017. This version of the handbook was in place at the time of the events in this report. The handbook was revised again April 4, 2019 and contains same or similar language regarding informed consent for methadone.

the patient understands the risks and benefits associated with medical care, surgical interventions, and treatment and medication options. In general, VHA requires providers to obtain voluntary patient informed consent prior to initiating treatment or a procedure.⁶⁶ Informed consent may be obtained either verbally or in writing, and must be documented in the patient's EHR. Documentation of informed consent includes, but is not limited to, the clinical reasons for use, benefits, risk, and alternatives in language the patient can understand; that the patient is encouraged to ask questions and indicates an understanding of the discussion; and that the provider notates all actions, as appropriate, including the patient's signature. For complex care, including medications such as methadone, patient written and signed consent is required.

The Director of Inpatient Behavioral Health stated that informed consent is obtained through a discussion between the provider and the patient about the three available medication assisted therapies options. The discussion includes the advantages, disadvantages, and indication for each option. The provider documents in the EHR that the discussion occurred, including the list of the major side effects of the medications. The Director of Inpatient Behavioral Health acknowledged that informed consent should be obtained by the provider initiating methadone. The Director of Inpatient Behavioral Health was unaware of the use of signed informed consent forms for medications. Additionally, during an OIG interview, a behavioral health provider stated that while discussing methadone specific complications such as respiratory depression and QTc prolongation with the patient, it was not the provider's clinical practice to document the details of the discussion in the patient's EHR, or to obtain a signed informed consent document prior to initiating medication assisted therapies.

Prior to the initiation of methadone on day 2, no provider obtained a signed informed consent from the patient. The EHR showed no documented evidence of a discussion with the patient about the clinical reasons for prescribing methadone, the benefits, the risks, and alternatives; or that the patient was encouraged to ask questions and indicated an understanding of the discussion.

To determine if providers obtained a signed informed consent prior to initiation of methadone and that the signed consent included the above-mentioned requirements for other patients, the OIG reviewed the EHRs of patients initiated on methadone admitted to Unit 7E from July 1, 2017, through September 30, 2017, and July 1, 2018, through September 30, 2018.

Of the 15 EHRs reviewed for 2017, the OIG identified the following:

- Two (13 percent) contained a signed informed consent.

⁶⁶ VHA Handbook 1004.01.

- None contained documented evidence of a discussion with the patient about the clinical reasons for prescribing methadone, the benefits, the risks, and alternatives; nor that the patient was encouraged to ask questions and indicated an understanding of the discussion.

Of the six EHRs reviewed for 2018, the OIG identified the following:

- None contained a signed informed consent.
- One (17 percent) contained documented evidence of a discussion with the patient about the clinical reasons for prescribing methadone, the benefits, the risks, and alternatives; that the patient was encouraged to ask questions and indicated an understanding of the discussion.

Conclusion

During methadone initiation, deaths may occur from overdosing, or when methadone interacts with another drug. When increased too rapidly, methadone doses can accumulate over several days and cause toxicity. In addition, it is important for the provider to consider the potential for drug-drug interactions, and the possibility of overlapping drug effects and overlapping toxicities. The lack of communication that included differing methadone orders, absence of additional signers within the EHR, and the absence of direct communication among staff may have contributed to the patient's death.

Although the facility responded to the patient's death with timely reviews, the OIG found the RCA did not comply with VHA policy and potentially compromised its analysis and recommended actions. Further, all providers involved in the patient's care were not peer reviewed. A review of patients admitted to Unit 7E initiated on methadone for a select time in 2017 and 2018 showed no adverse events aside from the identified patient's event.

Quality of care deficiencies on Unit 7E included a failure by staff to recognize signs of somnolence and inactivity as consistent with the patient's oversedation during the last five days of the admission; and a failure by staff to conduct patient observation rounds. When the patient was found unresponsive on Unit 7E and the rapid response team arrived, conditions already likely existed for a failure to rescue because of the lack of care.

Nursing leaders and Units 7E and 7W management implemented measures to address deficiencies including equipment issues identified by the rapid response team and training needs to mitigate the potential for future patient safety events. The OIG noted that the issue of total patient care nursing assignments had not been resolved

A review of patients for a selected time in from October 1, 2016, through September 31, 2018, showed the facility generally complied with Unit 7E admission criteria that required EKGs and urine drug screens prior to admission for patients on methadone.

The facility did not comply with policies requiring providers to obtain signed informed consent prior to initiating methadone treatment for substance use disorder.

Recommendations 1–9

1. The Corporal Michael J. Crescenz VA Medical Center Director ensures that providers understand the importance of monitoring for cardiac changes, drug-drug interactions, and signs of oversedation when initiating patients on methadone.
2. The Corporal Michael J. Crescenz VA Medical Center Director monitors that providers and clinical staff effectively and directly communicate with one another when providing complex patient care.
3. The Corporal Michael J. Crescenz VA Medical Center Director confirms that the issue brief submitted on the identified patient contains accurate information.
4. The Corporal Michael J. Crescenz VA Medical Center Director reviews the root cause analysis related to the identified patient to determine if the team composition compromised the integrity of the root cause analysis and take appropriate action if necessary.
5. The Corporal Michael J. Crescenz VA Medical Center Director ensures that root cause analysis team compositions include appropriate staff and monitor compliance.
6. The Corporal Michael J. Crescenz VA Medical Center Director considers Peer Review for Quality Management for the additional two providers identified in this report.
7. The Corporal Michael J. Crescenz VA Medical Center Director ensures that Unit 7E staff are knowledgeable of the observation policy, and nursing leaders are monitoring staff compliance when assigned rounding responsibilities.
8. The Corporal Michael J. Crescenz VA Medical Center Director completes actions initiated or taken to resolve identified deficiencies that contributed to the events discussed in this report, and monitors for compliance.
9. The Corporal Michael J. Crescenz VA Medical Center Director certifies that providers receive ongoing education on the required elements of a signed written consent prior to the initiation of methadone and ensures that providers comply with VA policy and monitors for compliance.

Appendix A: Patient Signs of Oversedation

Table A.1. Staff Documentation of Signs of Oversedation

Hospital Day	Staff Observations
Day 6	During group therapy, the patient “alternated between appearing to be asleep and being awake but appearing drowsy.”
Day 6	Nursing documented the patient as “having slept at long interval through the shift.”
Day 7	Nursing documented the patient “appears to have slept at long interval through the shift.”
Day 8	Patient “nodding off” during spirituality exercise and reported having an unusual day.
Day 8	Nursing documented the patient as “having slept at long interval through the shift.”
Day 9	During group therapy, the patient “alternated between being drowsy/asleep and being awake... At the end of group, [the patient] apologized to the facilitator for falling asleep, noting that [the patient] thinks [their] morning medication might be making [them]drowsy.”
Day 9	Nursing assistant documented “Vet expressed that [they] believes that [their] morning medication is making [them] drowsy during the day [the patient] was observed dosing [sic] off a bit during psychology group.”
Day 10	Nursing documented the patient as “having slept at long interval through the shift.”
Day 10	The overnight covering psychiatrist documented “Due to patient’s drowsiness, Methadone and Gabapentin held.”
Day 10	The Unit 7E psychiatrist documented the patient “presents as confused and somnolence [sic].”
Day 10	Nursing documented “[P]atient did not attend groups this am. [P]atient been in bed most of the day. [P]atient did not eat lunch.”
Day 10	Nursing documented “[P]atient observed in room appears to be sleeping deeply attempted numerous times to wake for meals and meds.”
Day 10	Nursing documented the patient was observed “sleeping in room, snoring loudly” and “did not respond to verbal stimuli when asked to present for 1700 medications.”
Day 10	Nursing documented the patient “was observed still sleeping in room for dinner.”
Day 10	Nursing stated attempted to wake the patient from a sleep, but the patient was “unresponsive to a vigorous sternal rub.”

Source: Identified patient’s EHR

Appendix B: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: 8/19/19

From: Director, VA Healthcare (VISN 04)

Subj: Healthcare Inspection— Quality of Care and Patient Safety Concerns on the Acute Behavioral Health Unit at the Corporal Michael J. Crescenz VA Medical Center, Philadelphia, Pennsylvania

To: Director, Healthcare Inspections, (54HL08)
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. I have reviewed the responses provided by the Corporal Michael J. Crescenz VA Medical Center, Philadelphia, Pennsylvania and I am submitting to your office as requested. I concur with their response.

(Original signed by:)

Charles R. Thilges
Acting Network Director VISN 4

Appendix C: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: August 9, 2019

From: Director, Corporal Michael J. Crescenz VA Medical Center (642/00)

Subj: Healthcare Inspection— Quality of Care and Patient Safety Concerns on the Acute Behavioral Health Unit at the Corporal Michael J. Crescenz VA Medical Center, Philadelphia, Pennsylvania

To: Director, VA Healthcare (VISN 04)

1. Thank you for the opportunity to review and comment on the draft report, Quality of Care and Patient Safety Concerns on the Acute Behavioral Health Unit at the Corporal Michael J. Crescenz VA Medical Center, Philadelphia, Pennsylvania.
2. I have reviewed and concur with the status of the actions and recommendations as submitted.

(Original signed by:)

Karen Flaherty-Oxler, MSN, RN
Director, Corporal Michael J. Crescenz VA Medical Center

Comments to OIG's Report

Recommendation 1

The Corporal Michael J. Crescenzo VA Medical Center Director ensures that providers understand the importance of monitoring for cardiac changes, drug-drug interactions, and signs of oversedation when initiating patients on methadone.

Concur.

Target date for completion: Completed

Director Comments

Since the event, Corporal Michael J. Crescenzo VA Medical Center (CMCVAMC) has made several improvements to ensure better provider communication.

These include:

- Establishment of a standard order set for initiating methadone. The goal of the standardized order set is to establish a safe standard of care that is utilized for all patients who receive methadone. The medical staff leadership agree with the standard approach for initiating methadone detox therapy for all patients on the Behavioral Health unit.
- Establishment of a Behavioral Health Co-Management Medicine Service. Staffing permitting, a dedicated Hospitalist Medicine Attending rounds daily with the Behavioral Health Team. Hospital Medicine is available around the clock for consultative management and review of all cases. To expedite this important clinical coverage, the initial design and roll-out of this service has been focused on ensuring consistent coverage during the highest volume time for admissions to the CMCVAMC, Monday through Friday. All patients requiring medical follow-up are handed off to the onsite hospitalist for continuity of care in off-hour shifts and are seen by Hospital Medicine Attendings. Hospital Medicine continues to provide continuous coverage during off-hour shifts for all medical questions and concerns.
- Implementation of a Total Patient Care Model. CMCVAMC identified an issue with hand-off communication, interdisciplinary collaboration, accountability, and continuity of care between shifts and across the Behavioral Health unit. An interdisciplinary workgroup rebuilt the rounding and care model on the Behavioral Health unit to foster culture change and improve the identified issues by moving to Total Patient Care. Implementation of the Total Patient Care Model for inpatient Behavioral Health units started in March 2018 and is currently fully operational. This model supports the assignment of a specific RN to manage each patient's total care needs. The model also mandates daily huddles with other interdisciplinary team members and high-quality

handoff communication. Total Patient Care ensures unfragmented and continuous care, and improves care continuity, accountability, and quality. To support this endeavor, new medication carts have been purchased and implemented on the units. As of July 2019, an Assistant Nurse Manager is being oriented for the evening shift to support and sustain clinical expectations. The individual medication carts help the nurse deliver medications (e.g. Methadone) to the group of patients he/she is most familiar with, thereby reducing the risk of adverse medication outcomes. The addition of an Assistant Nurse Manager for the off-shift hours, will reinforce the Total Patient Care Model, improve staff communication, and assist in supporting accountability through the assessment of clinical competency (via direct observation) and response time to medical emergencies.

OIG Comment

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

Recommendation 2

The Corporal Michael J. Crescenzo VA Medical Center Director monitors that providers and clinical staff effectively and directly communicate with one another when providing complex patient care.

Concur.

Target date for completion: Partially completed, anticipate full completion August 27, 2019

Director Comments

- CMCVAMC has implemented the Total Patient Care Model of care (as described above in Recommendation 1).
- CMCVAMC established an interdisciplinary workgroup to improve communication and developed a new interdisciplinary rounding model (planned full implementation on August 27, 2019). Members of the rounding team include: floor nurses, Nurse Managers, Behavioral Health Physician, Psychology staff, Trainees, Social Work staff, Hospital Medicine Physician, Recreational Therapy staff, Pharmacy staff, and Utilization Management staff. Rounds occur at a set time Monday through Friday. A modified interdisciplinary rounding model occurs with the care team on Saturday and Sunday. The rounding model is designed to improve quality of hand-off communication and the interdisciplinary management of complex patients.
- CMCVAMC has implemented a Behavioral Health Co-Management Medicine Service (as described above in Recommendation 1).

- Situation Background Assessment and Recommendation (SBAR)-based handoff communication has been standard practice on the Behavioral Health unit since March 2018, utilizing a paper handoff tool. CMCVAMC leadership has mandated the use of a standard SBAR-based communication method. In the current CPRS (Computerized Patient Record System) EHR, the handoff tool is not a permanent part of the medical record. As CMCVAMC prepares to transition to the Cerner EHR, CMCVAMC is investigating electronic options to continue to improve handoff quality.

Recommendation 3

The Corporal Michael J. Crescenzo VA Medical Center Director confirms that the issue brief submitted on the identified patient contains accurate information.

Concur.

Target date for completion: Completed

Director Comments

The initial and subsequent issue briefs regarding this event are not written in a manner that easily presents the sequential events and the ongoing assessment and actions taken over the roughly two years that this Issue Brief remained open. During this timeframe, the issue brief was manually migrated from an old issue brief tracker system to a new tracker system. At current reading it appears that the information is accurate and includes the final decision regarding the need for Peer Review (completed on four providers on March 8, 2018) and the need for Institutional Disclosure (completed on April 24, 2018).

OIG Comment

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

Recommendation 4

The Corporal Michael J. Crescenzo VA Medical Center Director reviews the root cause analysis related to the identified patient to determine if the team composition compromised the integrity of the root cause analysis and take appropriate action if necessary.

Concur.

Target date for completion: Completed

Director Comments

The extensive RCA that was performed was broadly focused and included issues related to the rapid response/emergency response in addition to the quality of the clinical care provided on the Behavioral Health unit. CMCVAMC believes that the findings and action items from the RCA did meet the objective purpose of the RCA and that the chartered members of the RCA did not negatively impact the integrity of the analysis therefore no further action is required.

OIG Comment

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

Recommendation 5

The Corporal Michael J. Crescenz VA Medical Center Director ensures that root cause analysis team compositions include appropriate staff and monitor compliance.

Concur.

Target date for completion: Completed

Director Comments

The CMCVAMC believes that part of becoming a High Reliability Organization (HRO) includes extensive frontline staff involvement in safety assessments including RCAs, if that involvement doesn't harm the provider nor the objectivity of the analysis. As noted in Recommendation 4, CMCVAMC believes that the findings and action items from the RCA did meet the objective purpose of the RCA and that the chartered members of the RCA did not negatively impact the integrity of the analysis therefore no further action is required.

Supporting Literature:

Joint Commission: High Reliability Healthcare

https://www.jointcommission.org/high_reliability_healthcare/

Swarming to Improve Patient Care: A Novel Approach to Root Cause Analysis

<https://psnet.ahrq.gov/resources/resource/29489/SWARMing-to-improve-patient-care-a-novel-approach-to-root-cause-analysis?q=root+cause+analysis+front+line+staff>

OIG Comment

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

Recommendation 6

The Corporal Michael J. Crescenz VA Medical Center Director considers Peer Review for Quality Management for the other two providers identified in this report.

Concur.

Target date for completion: Completed

Director Comments

The CMCVAMC determined that care documented by four of the six possible providers associated with the care of the patient at the time of this event required Peer Review. After careful consideration and extensive discussion with Risk Management it was determined that the four completed Peer Reviews on March 8, 2018, were adequate to review the quality of practice of the providers involved. Peer Review is meant as a non-punitive examination of clinical practice meant to enhance quality-of-care and to learn and identify opportunities for clinical improvement. Other conduct, managerial, and professionalism issues were addressed through different mechanisms as needed.

OIG Comment

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

Recommendation 7

The Corporal Michael J. Crescenz VA Medical Center Director ensures that Unit 7E staff are knowledgeable of the observation policy, and nursing leaders are monitoring staff compliance when assigned rounding responsibilities.

Concur.

Target date for completion: Completed with ongoing monitoring.

Director Comments

The Inpatient Psychiatric Patient Observation Procedure was reviewed and revised for signatures on December 5, 2018. The revised SOP (Standard Operating Procedure) with expectations for practice was disseminated to all Inpatient Behavioral Health nursing staff on March 8, 2019. A random sample of 20 patient rounding observation sheets is to be audited monthly by the local nursing leaders utilizing a formalized audit to monitor ongoing compliance with rounds. Identified deficiencies will be addressed by the Nurse Manager. The goal for ongoing monitoring is 100% compliance.

OIG Comment

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

Recommendation 8

The Corporal Michael J. Crescenz VA Medical Center Director completes actions initiated or taken to resolve identified deficiencies that contributed to the events discussed in this report, and monitors for compliance.

Concur.

Target date for completion: Completed

Director Comments

Several action items for improvement in quality of care:

- Mock code program for Behavioral Health Staff: 100% compliance in training and participation by Behavioral Health Staff by March 27, 2018 and ongoing.
- Standardized methadone ordering process and mandated order sets: monitored for full calendar quarter with 100% compliance, completed December 2018. (Recommendation 1)
- Remove all obstacles for urgent/emergent clinical care: all beds unbolted from floor in Behavioral Health Unit, confirmed completion December 29, 2017. Furthermore, a 2017 emergency mitigation plan included simulations conducted using the Ferno Power Flex Stretcher. A Continuous Mitigation Plan was assigned to the local nursing and physician leadership. Since that time mock codes are regularly performed in the unit, as are regular q15 minute rounds, both to ensure patient safety.
- Utilization of an SBAR-based shift handoff tool: 100% sampling compliance documented on March 26, 2018. (Recommendation 1 and 2)
- Improve nursing assessment skills via education and training: 100% of Behavioral Health Staff completed training on August 29, 2018. (Recommendation 1 and 2)

OIG Comment

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

Recommendation 9

The Corporal Michael J. Crescenzo VA Medical Center Director certifies that providers receive ongoing education on the required elements of a signed written consent prior to the initiation of methadone and ensures that providers comply with VA policy and monitors for compliance.

Concur.

Target date for completion: December 1, 2019

Director Comments

The Opioid Treatment Program (OTP) has been and is following the informed written consent policy for initiation of high-risk medications but doing so in paper format with the consents scanned into the medical record. At the time of the incident the inpatient Behavioral Health unit was not following the policy requiring a signed written consent with the universal use of iMed and concurrent compliance monitoring. These items have been identified as opportunities for improvement. The need for informed consent using iMed technology will be presented to and approved by the P&T (Pharmacy & Therapeutics) Committee on August 19, 2019. Following this presentation, iMed devices will be operationalized with the expected completion of December 1, 2019. Once the technology is fully implemented, a standardized note template will be deployed to ensure compliance with consent policy and allow for appropriate monitoring. The goal will be to review 30 high-risk medication prescriptions each month, with success measured by 90% of those patients having the appropriate iMed consent documented. Once achieved, monitoring will continue as a review of 30 high-risk medication prescriptions over 90 days until reaching the same 90% threshold. Monitoring will begin on January 1, 2020.

OIG Contact and Staff Acknowledgments

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