



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Medication Management,
Dispensing, and
Administration Deficiencies
at the VA Maryland Health
Care System

Perry Point, Maryland



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a request from the OIG Office of Investigations to review the care of a hospice patient who died in 2017 at the Perry Point VA Medical Center (facility), part of the VA Maryland Health Care System (system), after receiving a potential overdose of a pain medication solution (oxycodone). The specific question was whether a certain dose of the oxycodone solution, a controlled substance, could have contributed to the death of a patient.

The OIG determined that the patient may have received a potential overdose of 11 milliliters (mL) (220 milligrams) of oxycodone solution. Due to the medication management issues described below, the OIG was unable to determine whether an overdose occurred or a potential overdose contributed to the patient's death. During the review, deficiencies were identified in multiple facility medication management processes and patient safety measures, including facility leaders' actions taken after the patient's death.

Medication Management

The facility's lack of the most ready-to-administer dosage packaging (unit dose) oxycodone solution contributed to processes that increased risks in all phases of medication management.

The facility Pharmacy Service staff's dispensing of 30 mL (20 mg/mL) bulk bottles of oxycodone solution to inpatient units contributed to inventory discrepancies and patient risk due to an inability to determine the remaining amount in the bottles. The facility staff used 30 mL bulk bottles on the hospice unit for multiple patients, which created a potential for contamination of bulk bottles. Other possible dosage forms included oxycodone solution unit doses prepared by the manufacturer or by the facility's pharmacy staff. However, unit doses for oxycodone solution were not available from the manufacturer, and pharmacy leaders reported multiple reasons the manufacturing of unit doses was not considered an option, such as shorter expiration dates and staffing issues.

The OIG determined that 35 percent (7 of 20) of the system's reported controlled substance discrepancies from October 2016 through June 2017 were attributed to bulk bottles of controlled liquid solutions, including three oxycodone solution discrepancies.¹ The percentage of discrepancies for bulk bottles of controlled liquid solutions suggested a lack of adequate controls.

¹ Facility staff tracked discrepancies for solutions (liquids), medication counts, and wrong drugs or labels.

Dispensing

The OIG determined the facility's Pharmacy Service staff's dispensing of 30 mL bulk bottles of oxycodone solution (20 mg/mL), instead of pre-packaged unit doses, contributed to inventory discrepancies. Bulk bottles add to challenges with accuracy and difficulty determining the remaining amount in the bottle, whereas pre-packaged unit doses of oxycodone solution allow for improved overall drug control and drug use monitoring, and greater adaptability to automated systems, such as the automated dispensing cabinet (ADC).²

Facility leaders did not consider the loss of small amounts of medication as waste and, therefore, such losses were not consistently controlled or evaluated for diversion. Nursing staff stated they had noted crusting on the rim of the oxycodone solution bottles, which they credited for discrepancies in measurements. Nursing staff also stated that sometimes small amounts of medication solution would spill in the ADC, but reported these spills were not accounted for through the same process as wasted medications. Nursing managers described working with Pharmacy Service to improve the oxycodone solution administration concerns related to accuracy of measurement.

In response to issues noted after the identified patient's death, Pharmacy Service staff ordered and began the use of adapters, manufacturer-provided calibrated syringes, and zero-space syringes to improve the accuracy of dose measurement and administration.³ However, the OIG team determined that the calibrated syringe did not improve the accuracy for measurement because the 2.5 mg (0.13 mL) amount ordered was less than the smallest dose marker of 5 mg (0.25 mL) on the calibrated syringe.

The OIG identified errors with the pharmacy inpatient medication order entry process. Pharmacists inconsistently processed orders for the same medication and strength. These errors and inconsistencies highlighted the difficulty and risk in both dispensing and administering medication orders as written.

Administration

The OIG found that the facility's established process for administering oxycodone solution contributed to additional risk for discrepancies in measurements. The nursing staff did not have the tools required to accurately measure ordered doses from the bulk bottle of oxycodone

² ASHP Statement on Unit Dose Drug Distribution. <https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/unit-dose-drug-distribution.ashx>. (The website was accessed on June 13, 2018.)

³ Adapters connect the bottle mouth with the syringe. <https://www.merriam-webster.com/dictionary/adaptor>. (The website was accessed on August 23, 2018.) Zero-space syringes prevent fluid from being left in the syringe after the plunger has been pushed down completely. *Medication Waste Attributed to Syringe Dead Space, Abandoned Initial Fills*, Pharmacy Times, July 5, 2016. <https://www.pharmacytimes.com/contributor/katherine-yang-pharmd-candidate-2018/2016/07/medication-waste-attributed-to-syringe-dead-space-abandoned-initial-fills>. (The website was accessed on August 24, 2018.)

solution for administration to multiple patients. While medication management and dispensing are the role of a pharmacist, medication administration from the ADC to the patient is primarily a nursing function.

For the identified patient, a registered nurse (RN) did not follow the process used on the hospice unit to draw up the ordered dose of oxycodone solution and did not withdraw the correct medication amount ordered by the physician. Nursing staff reported that the syringes for this medication were not in the ADC so the RN at issue looked for, and possibly used, a larger syringe from another unit to administer the potential medication overdose. Without a definitive cause established for the medication discrepancy and 11 mL of oxycodone solution still unaccounted for, staff identified a concern that the RN may have diverted the medication. The OIG determined that the facility did not adequately respond to the potential that the RN diverted the oxycodone solution.

Patient Safety and Other Findings

Facility leaders and Patient Safety program staff failed to recognize the inherent risks in medication administration and did not evaluate the identified patient's potential medication overdose to determine the causes, system issues, and continued risk. Facility staff said they were waiting for completion of investigations by the VA Police and OIG Office of Investigations before taking further action. However, Veterans Health Administration (VHA) policy provides opportunities for facility leaders to complete concurrent reviews and investigations to evaluate potential and actual risk to patients.⁴

Facility leaders did not complete clinical and institutional disclosures, including the discussion of the potential overdose with the patient's family. The OIG determined that a root cause analysis (RCA), or other quality or management review, of this event was not completed. Patient Safety staff did not advocate for, and facility leaders did not ensure, completion of an RCA. Staff said they believed this event to be "a one off" or a medication error of one nurse. Additionally, a peer review was also not completed.

The potential overdose was not reported as an adverse drug event as required.⁵ The OIG team determined that an adverse drug event assessment may have assisted the facility in determining the cause of the potential overdose and the continued medication risk.

Facility leaders did not complete other actions that impact patient safety including failures to ensure the RN at issue had recent acute care experience, orient the RN to the hospice unit's complex medication administration process, or assess the RN's competency for administering the

⁴ VHA Handbook, 1050.01; VHA Directive 2010-025.

⁵ VHA Directive 1070, *Adverse Drug Event Reporting and Monitoring*, September 12, 2014. Adverse drug events must be reported to the national VA Adverse Drug Event Reporting System and the Food and Drug Administration (FDA) MedWatch system.

high-alert medication in the multi-step process used in the hospice unit. Facility leaders reported that after the potential overdose, the RN at issue resigned, and the RN's care provided to other patients was not evaluated to determine if other instances, errors, or trends of practice issues occurred.

The OIG determined facility leaders did not ensure contact with the Medical Examiner as required once the potential medication overdose was identified. Facility leaders did not follow VHA policy in reviewing the suspicious death to determine if an autopsy was required. The OIG Office of Investigations staff discussed the need to notify the Medical Examiner with the Chief of Police at the time of the patient's death. The Facility Director did not recall any involvement in decisions regarding the patient's death, including notifying the Medical Examiner.

The OIG made one recommendation to the Veterans Integrated Service Network (VISN) Director related to evaluating and addressing the inaccuracies and risks involved with use of bulk bottles of oxycodone solution. The OIG made seven recommendations to the System Director regarding an interdisciplinary review of unit dose and multi-dose oxycodone solution dispensing and administration; conducting a full quality review of the patient's death, including reporting and disclosure requirements; ensuring requirements for nurse hiring and competencies for high-alert medications are met; evaluating the care provided to other patients by the RN who administered the potential overdose for other possible practice issues; and ensuring evaluation by nursing leaders to determine the need for reporting the RN to the State Licensing Board.

Comments

The Veterans Integrated Service Network and System Directors concurred with the OIG's recommendations and submitted acceptable action plans. (See Appendixes B and C, pages 27–35 for the comments.) The OIG considers recommendations 3 and 8 closed and will follow up on the planned actions for the remaining recommendations until they are completed.



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Contents

Executive Summary	i
Abbreviations	vi
Introduction	1
Scope and Methodology	7
Patient Case Summary	8
Inspection Results	10
Issue 1: Medication Management Deficiencies.....	11
Issue 2: Controlled Substance Dispensing Deficiencies	12
Issue 3: Oxycodone Solution Administration Inaccuracies	15
Issue 4: Patient Safety	16
Patient Safety Processes	17
Conclusion	23
Recommendations 1–8.....	24
Appendix A: Process of Oxycodone Solution Administration	25
Appendix B: VISN Director Comments	27
Appendix C: System Director Comments.....	30
OIG Contact and Staff Acknowledgments	36
Report Distribution	37

Abbreviations

ADC	automated dispensing cabinet
ADE	adverse drug event
ADPCS	Associate Director for Patient Care Services
ASHP	American Society of Health System Pharmacists
BCMA	Bar Code Medication Administration
CFR	Code of Federal Regulations
CSC	controlled substance coordinator
CSI	controlled substance inspector
CSIP	controlled substance inspection program
EHR	electronic health record
FY	fiscal year
mg	milligram
mL	milliliter
OHI	Office of Healthcare Inspections
OI	Office of Investigations
OIG	Office of Inspector General
RCA	root cause analysis
RN	registered nurse
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VPE	VISN Pharmacy Executive



Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a request from the OIG Office of Investigations to review the care of a hospice patient who died at the Perry Point VA Medical Center (facility), Maryland, in 2017, after receiving a potential overdose of a pain medication solution (oxycodone). The specific question was whether a certain dose of oxycodone solution, a controlled substance, could have contributed to the death of the patient.

The OIG determined that the patient may have received a potential overdose of 11 milliliters (mL) (220 milligrams) of oxycodone solution.⁶ Due to the medication management issues described below, the OIG was unable to determine whether an overdose occurred or a potential overdose contributed to the patient's death.⁷ The OIG identified deficiencies in multiple facility medication management processes and facility leaders' actions taken after the patient's death.

Background

The facility is part of the VA Maryland Health Care System (system), which includes medical facilities in Baltimore and Loch Raven, Maryland, and community based outpatient clinics. The system is aligned under Veterans Integrated Service Network (VISN) 5. The system served 53,539 patients in fiscal year (FY) 2017. The facility and its community based outpatient clinics in Cambridge and Pocomoke City, Maryland, provide a range of inpatient, outpatient, and primary care services, including nursing home care with five inpatient hospice unit beds.⁸ The facility is affiliated with the University of Maryland School of Medicine.

⁶ Milliliters measure volume of liquid and milligrams measure weight. The dose is the weight of the drug. http://www.exchangesupplies.org/article_difference_between_milligrams_and_millilitres.php. (The website was accessed on June 16, 2018.)

⁷ The automated dispensing cabinet log documented 25.23 mL of oxycodone solution, however, an RN initially determined the bottle contained 14 mL. This approximate 11 mL discrepancy resulted in concern that an overdose was given to the patient.

⁸ Hospice is "for patients diagnosed with a known terminal condition and a prognosis of less than 6 months." VHA Directive 1140.11, *Uniform Geriatrics and Extended Care Services in VA Medical Centers*, October 11, 2016.

Oxycodone

Oxycodone, a controlled substance, is a Schedule II opioid analgesic indicated for relief of moderate to severe pain.⁹ Oxycodone is available in solution and tablet formulations.

Oxycodone doses vary and must be adjusted according to the patient's pain severity, response, and size. If the pain becomes more severe or tolerance occurs, a gradual dose increase may be required.¹⁰ Patients who have not taken oxycodone for chronic pain should be started on 5 mg to 15 mg doses; patients who have received oxycodone for chronic pain management can be dosed at 10 mg to 30 mg. Patients with more severe pain may require 30 milligrams (mg) or more every four to six hours.¹¹

Unit Dose Medication

The Veterans Health Administration (VHA) requires that Pharmacy Service comply with the American Society of Health System Pharmacists (ASHP) Statements and Guidelines, which consider the unit dose system to be an essential part of drug distribution and control in organized healthcare settings. VHA also requires medications be dispensed in ready-to-administer packages (unit dose) when possible. The unit dose drug distribution system is the primary distribution system for all inpatient areas.¹² The ASHP concludes that compared to other drug distribution methods, unit dose drug distribution systems are (1) safer for the patient, (2) more efficient and economical for the organization, and (3) a more effective method of utilizing professional resources.¹³

Medication Safety

VHA policy states that the safe and effective use of opioids for the management of pain, particularly complex chronic pain conditions, requires special attention to personal and public

⁹ A controlled substance is a drug whose use and possession is regulated by law (as title 21, chapter 13 of the U.S. Code), <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." 21 Code of Federal Regulations (CFR) 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.)

¹⁰ Tolerance is the capacity of the body to endure or become less responsive to a substance (such as a drug). <https://www.merriam-webster.com/dictionary/tolerance>. (The website was accessed on June 14, 2018.)

¹¹ Manufacturer Medication Insert for oxycodone oral solution. (The website was accessed on December 7, 2017.)

¹² VHA Directive 1108.06, *Inpatient Pharmacy Services*, February 8, 2017.

¹³ ASHP Statement on Unit Dose Drug Distribution. <https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/unit-dose-drug-distribution.ashx>. (The website was accessed on June 13, 2018.)

health risks. These risks include diversion of prescribed opioid medications, which are controlled substances.¹⁴

Controlled substance discrepancies in medication administration are a deviation from the expected findings of medication stocks and indicate potential loss of, diversion of, or missing medication. For example, staff may count more or less than what was recorded in the automated dispensing cabinet (ADC). Discrepancies are resolved when there is no evidence of suspected diversion or suspicious loss. Unresolved discrepancies are a variance that cannot be explained despite further investigation.¹⁵ Any unresolved discrepancy in inventory must be reported immediately to the nurse manager for follow-up and resolution, and must be reported to the facility director and VA Police within three business days.¹⁶

For further inventory control and safety, VHA requires a Controlled Substance Inspection Program (CSIP) to provide oversight of a medical facility's controlled substances. As part of CSIP, the medical facility director appoints facility staff who have no access or involvement with controlled substance dispensing, administration, prescribing, or procurement as Controlled Substance Coordinators (CSCs) and Controlled Substance Inspector (CSIs).¹⁷ CSC responsibilities include monthly inspections and quarterly trend reports for review by facility and system leaders.¹⁸ CSIs perform random unannounced monthly inspections of controlled substance storage areas within the pharmacy department and in ADCs throughout the facility.¹⁹

Barcode Medication Administration (BCMA) is software used by VHA to improve medication administration accuracy and generate online records. BCMA enables users to electronically document the administration of medications at the bedside or other points of care.²⁰ Barcode

¹⁴ VHA Directive 2009-053 *Pain Management*, October 28, 2009. This directive expired October 31, 2014, and has not been updated.

¹⁵ VHA Directive 1108.02(1) *Inspection of Controlled Substances*, November 28, 2016, amended March 6, 2017.

¹⁶ VHA Directive 1108.01, *Controlled Substances (Pharmacy Stock)*, November 16, 2010. This directive was scheduled for recertification on/or before the last working day of November 2015 but has not been recertified; VHA Directive 1108.02(1).

¹⁷ VHA Directive 1108.02(1).

¹⁸ System Policy Memorandum 512-001/OPS-003, *Inspection for Controlled Substances*, April 2017.

¹⁹ VHA Directive 1108.02(1); System SOP No. 119-015, *Controlled Substances Handling, October 2014*.

²⁰ Wideman, Mary V, Whittler, Michael E., and Anderson, Timothy M. *Barcode Medication Administration: Lessons Learned from an Intensive Care Unit Implementation in Advances in Patient Safety*: In: Henriksen K, Battles JB, Marks ES, et al., editors. Advances in Patient Safety: From Research to Implementation, Volume 3. (Rockville: Agency for Healthcare Research and Quality, 2005).

medications are delivered to the inpatient unit's ADC.²¹ Nurses scan the barcode medication and the patient armband to verify correct patient and correct medication prior to administration.²²

Patient Safety

The goal of the VHA Patient Safety Program is to prevent harm to patients and take appropriate steps to form a "culture of safety."²³ VHA requires compliance with The Joint Commission standards including that "leaders create and maintain a culture of safety and quality throughout the hospital."²⁴ According to the Agency for Healthcare Research and Quality, the key components of a "culture of safety" are to prevent or reduce errors and improve overall health care quality through

1. Acknowledgement of the high-risk nature of healthcare activities and the determination to achieve consistently safe operations,
2. A blame-free environment,
3. Encouragement of collaboration across disciplines to seek solutions to patient safety problems, and
4. Organizational commitment of resources to address safety concerns.²⁵

Advancing to a safety culture is impaired by the traditional culture of individual blame. A safety culture approach seeks to identify and address systems issues that lead individuals to engage in unsafe behaviors, while maintaining individual accountability.²⁶

Clinical and Institutional Disclosures

VHA policy states that clinical disclosure is a process where the patient's clinician informs the patient, or the patient's personal representative, that a harmful or potentially harmful adverse event has occurred during care.²⁷

²¹ VHA Directive 1108.06.

²² VAMHCS Policy Memorandum 512-118-016, *Barcode Medication Administration*, November 2017.

²³ 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.

²⁴ The Joint Commission standard LD.03.01.01. <https://e-dition.jcrinc.com>. (The website was accessed on July 6, 2018); VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Program*, May 9, 2017.

²⁵ Agency for Healthcare Research and Quality (AHRQ) Patient Safety Network, *Culture of Safety*, June 2017. <https://psnet.ahrq.gov/primers/primer/5/culture-of-safety>. (The website was accessed on July 3, 2018.)

²⁶ AHRQ Patient Safety Network, *Culture of Safety*.

²⁷ VHA Handbook 1004.08, *Disclosure of Adverse Events*, October 2, 2012, corrected copy October 12, 2012. This handbook was rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events*, October 31, 2018. The 2018 directive contains the same or similar language regarding clinical disclosure.

VHA policy also states that institutional disclosure is a formal process used to inform the patient, or the patient's personal representative, that an adverse event occurred. Institutional disclosure includes specific information about the patient's and/or the patient's personal representative's rights and recourse.²⁸

Adverse and Sentinel Events

VHA defines adverse events that may require a root cause analysis (RCA) as “untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within a VHA facility.”²⁹ Sentinel events are types of adverse events defined as unexpected occurrences involving death, serious physical or psychological injury, requiring immediate investigation and response, for example an RCA.³⁰

Peer Review

According to VHA, the peer review process 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 individual provider level. Documents generated by a peer review may not be used in disciplinary actions.³¹ The diagnosis of a terminal illness or a “Do Not Resuscitate” status, as with the identified patient, are not considered exceptions from peer review.³²

OIG Concerns

In September 2017, facility nursing staff discovered a discrepancy between the amount of oxycodone solution that was expected to be found in a multi-dose bottle and the amount present. A few hours after nursing staff discovered the discrepancy, a hospice unit patient who had been administered oxycodone solution from the multi-dose bottle died. Nursing staff reported the discrepancy to the VA Police after the patient's death. The patient's electronic health record

²⁸ VHA Handbook 1004.08; VHA Directive 1004.08 contains the same or similar language regarding institutional disclosure.

²⁹ Iatrogenic means inadvertent or unintentional illnesses, infections, or injuries that often occur as a result from being in a hospital. <https://www.merriam-webster.com/dictionary/iatrogenic>. (The website was accessed May 24, 2018); VHA Handbook, 1050.01.

³⁰ VHA Handbook 1050.01.

³¹ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. Documents prepared for the purpose of improving the quality of health care, improving the utilization of health care resources, and that identify either implicitly or explicitly, individual providers or other employees, patients, or reviewers are considered privileged under 38 U.S.C. § 5705, and its implementing regulations. This directive was rescinded and replaced by VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018 that contains the same or similar language on the matter of confidentiality.

³² When designated as “Do Not Resuscitate (DNR),” patients do not receive cardiopulmonary resuscitation (CPR), administration of electrical shock to restart the heart, and/or medications.

(EHR) showed administration of a dose of oxycodone approximately five and a half hours before the patient's death. VA Police contacted OIG Office of Investigations (OI), who requested assistance from the Office of Healthcare Inspections (OHI) medical consultants regarding the oxycodone dose. Specifically, OIG OI asked if "an 11-mL dose [at a 20 mg/mL concentration] of oxycodone solution could contribute to the death of a patient." According to OIG OI, the suspicious death may have been caused by a potential overdose of oxycodone solution.

While reviewing the circumstances surrounding the patient's death, OHI staff identified concerns related to medication management, controlled substance dispensing, and oxycodone solution administration. OHI also identified patient safety concerns, including the review and reporting of the event, and the assessment of the nurse's competency in the hospice unit's multi-step process for administering the high-alert medication.

Scope and Methodology

The OIG initiated the inspection on May 1, 2018, and conducted an unannounced site visit May 14–16, 2018. The OIG team interviewed the VISN 5 Pharmacy Executive, Acting Director, Associate Director for Patient Care Services (ADPCS), risk manager, Facility Police Chief and a Detective, a hospice unit physician, CSIP staff, Human Resources, Nursing, and Pharmacy Service staff, and other staff knowledgeable about facility processes.

The team reviewed relevant facility, system, and VHA policies and procedures, patients' EHRs, quality management documents, nurse competency and training records, police reports, and Omnicell®, medication inventory and inspection records. In addition, team members reviewed the OIG OI investigative file.

Documentation of a second patient identified by facility staff as receiving an overdose of oxycodone tablets was identified and referred to the OIG Hotline Division.

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, whose medical history included liver cancer diagnosed in 2013 that had spread to other areas and had been treated with combined chemotherapy and radiation, was in his/her 70s.³³ The patient's other medical issues included a lung mass, heart disease, high blood pressure, and vascular dementia.³⁴

Following a hospitalization and imaging tests that showed progression of the liver cancer, the Baltimore VA Medical Center transferred the patient to the facility's hospice unit for long-term comfort care in summer 2017 (Day 1). The patient received oxycodone for pain management and had orders for both solution and pill forms of the medication. One week after the transfer (Day 7), a physician ordered the following doses of oxycodone solution:

- Oxycodone oral ****conc**** soln [liquid concentrate solution] (20 mg/mL) 5 mg/0.25 mL po prn pain/SOB q1h [by mouth as needed for pain or shortness of breath], if unable to swallow tablet.
- Oxycodone oral ****conc**** soln [liquid concentrate solution] (20 mg/mL) 2.5 mg BUCC q 8h [inside the cheek every 8 hours].

The EHR indicated the patient received doses of oxycodone solution 20 mg/mL as follows: three doses on Day 8, three doses on Day 9, four doses on Day 10, and two doses on Day 11. Between Day 8 and Day 10, the patient received 7.5 mg to 10 mg daily of oxycodone.

On Day 11, at approximately 6:00 a.m., an intermittent registered nurse (RN1) documented in the EHR that the patient was given all routine medications, including oxycodone. An hour later, RN1's note showed the patient did not have signs or symptoms of distress. At 7:50 a.m., a note by a second nurse (RN2) showed the patient was "unresponsive with a respiratory rate [RR] of 18–20, labored with periods of apnea 8 sec[onds] using...accessory muscles." RN2 administered oxygen as ordered by the physician. At 8:32 a.m., the patient was given lorazepam for shortness of breath.³⁵

³³ The OIG uses gender neutral language to protect patients' privacy.

³⁴ A lung mass is a type of tumor bigger than 3 centimeters in diameter.

<https://my.clevelandclinic.org/health/diseases/15023-benign-lung-tumors>. (The website was accessed on June 27, 2018.) Vascular dementia is a non-specific term that encompasses problems in reasoning, memory, judgement, and other thought processes from brain damage caused by impaired blood flow to the brain, such as by multiple strokes. <https://www.mayoclinic.org/diseases-conditions/vascular-dementia/symptoms-causes/syc-20378793>. (The website was accessed on June 27, 2018.)

³⁵ Lorazepam is a medication used to treat anxiety disorders.

https://www.mayo.edu/research?_ga=2.170444709.404616313.1531951451-247001900.1504020750. (The website was accessed on July 18, 2018.)

At 9:50 a.m., the family reported a change in the patient's breathing. RN2 "found him with increased labored RR 22–24 per minute and using...accessory muscles." RN2 educated the family on end-of-life symptoms and explained the patient would receive oxycodone as a comfort measure.

When RN2 accessed the Omnicell® at 10:00 a.m., a medication discrepancy was identified. Specifically, the nursing staff found an 11 mL (220 mg) oxycodone solution discrepancy between the Omnicell® records and the amount remaining in the 30 mL bulk bottle of oxycodone solution after RN1 administered medication. Nursing staff determined the discrepancy was possibly the result of the patient receiving an 11 mL dose of oxycodone equivalent to 220 mg.

The family summoned RN2 at 11:50 a.m. because the patient had changes in symptoms. RN2 found the patient peaceful with shallow breaths. Staff were with the patient and family when the patient expired at 12:05 p.m., approximately six hours after potentially receiving 11 mL's of oxycodone.

Inspection Results

The OIG identified deficiencies in multiple facility medication management processes including the use of 30 mL bulk bottles of oxycodone solution for multiple patients rather than unit dose (management), discrepancies in controlled substance inventories related to the use of bulk bottles of oxycodone solution (dispensing), and risks related to the inability to accurately measure oxycodone solution (administration). Other concerns the OIG identified were the facility leaders' lack of actions after the patient's death, including disclosure to the patient's spouse that a possible medication error had occurred, and the lack of quality reviews and reporting related to this event. The facility failed to notify the Medical Examiner and obtain an autopsy as required by VHA policy.

The facility Pharmacy Service stocked a 30 mL bulk bottle of oxycodone solution (20 mg/mL) in the hospice unit ADC that was used for any hospice unit patient ordered this concentration of medication. For the identified patient, providers ordered 2.5 mg (0.13 mL) into the cheek every 8 hours and 5 mg (0.25 mL) every 1 hour by mouth as needed for pain or shortness of breath.³⁶

The OIG was unable to determine if the identified patient's death was caused, or hastened, by the potential 11 mL (220 mg) dose of oxycodone solution due to several confounding factors:

- The primary sign of serious overdose of oxycodone is respiratory depression. However, the identified patient had documented respiratory depression (shortness of breath) prior to the potential overdose.
- The hospice unit physician determined the patient was in the active phase of dying.
- Facility staff did not adequately evaluate the circumstances surrounding the patient's death or RN1's care to determine the potential causes, system issues, and continued risk.
- Blood work to detect oxycodone was not performed until three days after the patient's death. The elapsed time between death and the procurement of a blood sample makes an accurate interpretation of blood level oxycodone concentrations impossible.³⁷
- The suspicious death was not reported to the Medical Examiner and an autopsy was not performed.

³⁶ The prescribed amount of oxycodone solution of 2.5 mg (0.13 mL) is equal to one half teaspoon. The amount of the potential overdose of 11 mL (220 mg) is equal to 2.23 teaspoons of the medication. <https://www.metric-conversions.org/volume/milliliters-to-us-teaspoons.htm>. (The website was accessed on July 5, 2018.)

³⁷ Ferner, RE., *Post-Mortem Clinical Pharmacology*, British Journal of Clinical Pharmacology, October 2008.

Issue 1: Medication Management Deficiencies

The OIG found the facility's lack of unit dose oxycodone solution contributed to processes that increased risks in all phases of medication management. The Pharmacy Service did not effectively evaluate or consider the use of other dosage forms for oxycodone solution.³⁸

VHA policy describes medication management as a spectrum of services that are provided by pharmacy staff. The Chief of Pharmacy is responsible for implementing a medication management system that is safe and effective. The facility Pharmacy Service provides direction regarding the receipt, distribution, control, accountability, and quality of medications used throughout the facility.³⁹ VHA policy states that the VISN Office is responsible for taking action when non-adherence trends are identified. Specifically, the VISN Pharmacy Executive (VPE) serves as a liaison to communicate issues and actions between the national Pharmacy Benefits Management Service and the VISN's VA facilities.⁴⁰

The facility Pharmacy Service staff's dispensing of 30 mL bulk bottles of oxycodone solution to inpatient units contributed to inventory discrepancies and patient risk. Other possible dosage forms included oxycodone solution unit doses prepared by the manufacturer or by the facility Pharmacy Service staff. However, unit doses for oxycodone solution were not available from the manufacturer, and a pharmacy leader reported multiple reasons the manufacturing of unit doses were not considered as an option, such as shorter expiration dates and staffing issues.

To determine the extent of discrepancy issues with controlled substance solutions, the OIG reviewed the system's controlled substance reports. The OIG determined that 35 percent (7 of 20) of the system's reported controlled substance discrepancies, from October 2016 through June 2017, were attributed to bulk bottles of controlled liquid solutions, including three oxycodone solution discrepancies.⁴¹ The percent of discrepancies for bulk bottles of controlled liquid solutions suggests there were not adequate controls.

The OIG interviewed the VISN 5 VPE to further understand whether the facility's issues with bulk bottles of oxycodone solution were also issues at other VISN facilities. The VISN 5 VPE discussed the variety of oxycodone strengths, dosage forms, and administrative processes in other VISN 5 facilities; however, there was no apparent consistency amongst facilities. Following the OIG interview with the VISN 5 VPE, a VISN 5 pharmacy manager shared a

³⁸ The facility Pharmacy Service stocked an oxycodone solution of 20 mg per 1 mL. Oxycodone solution was available commercially to the facility, but not stocked, in two other concentrations: 5 mg per 5 mL and 10 mg per 0.5 mL.

³⁹ VHA Directive 1108.06.

⁴⁰ VHA Directive 1108.07, *Pharmacy General Requirements*, March 10, 2017.

⁴¹ Facility staff tracked discrepancies for solutions (liquids), medication counts, and wrong drugs or labels.

potential best practice for a unit dose manufacturing process for oral controlled substances with the other VISN facilities but indicated that this process was not implemented VISN-wide.

Issue 2: Controlled Substance Dispensing Deficiencies

Inventory Discrepancies

The OIG determined the facility's Pharmacy Service staff's dispensing of 30 mL bulk bottles of oxycodone solution (20 mg/mL) to the ADC contributed to the inventory discrepancies, as noted previously. Bulk bottles of oxycodone solution contributed to challenges with accuracy and difficulty determining the remaining amount in the bottle, whereas pre-packaged unit doses of oxycodone solution allow for improved overall drug control and drug use monitoring and greater adaptability to automated systems, such as the ADC.⁴²

VHA policy requires medications be dispensed in the most ready-to-administer forms available or contained in single unit doses that have been pre-packaged by the manufacturer or Pharmacy Service, when feasible.⁴³ Facility policy also requires medications for inpatient use to be dispensed to patient care areas in unit dose packaging, wherever possible.⁴⁴

The 30 mL bulk bottle of oxycodone solution provided by pharmacy in the ADC was difficult to read, making it hard to determine the amount of medication in the bottle both before and after a dose was removed. The oxycodone solution was clear and the volume markings on the side of the bottle were opaque. (See Figure 1.)

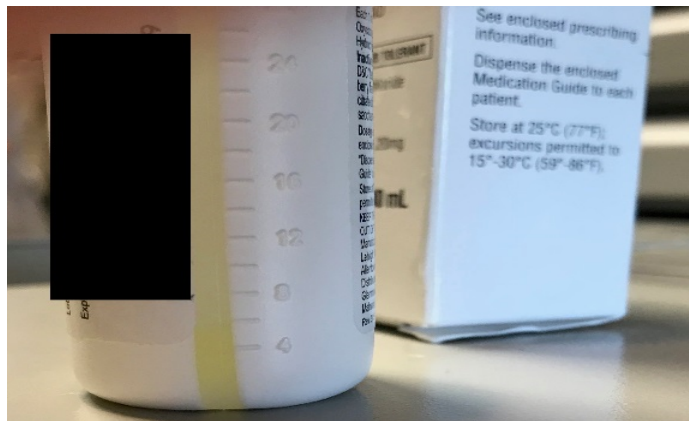


Figure 1. Facility oxycodone solution bottle showing method for reading amount in bottle

Source: VA OIG; Perry Point, MD; May 2018.

⁴² ASHP Statement on Unit Dose Drug Distribution.

⁴³ VHA Directive 1108.06.

⁴⁴ System SOP No. 119-023, *Unit Dose Dispensing*, October 2015.

The OIG determined that the facility's Pharmacy Service had not implemented use of the most ready-to-administer dosage form as required by VHA. Facility pharmacy leaders stated that they believed this patient's death was caused by a nursing error and was not related to a dispensing issue and did not require additional action by pharmacy leaders.

VHA policy requires Pharmacy Services to utilize an ADC system for many pharmaceutical processes including ordering, receiving, stocking, and selecting medications. These systems maintain all transaction information, provide accurate real-time inventory counts, keep medications accessible and secure, and help minimize the risk of diversion.⁴⁵ The facility used an ADC called Omnicell®.⁴⁶

The OIG determined that facility leaders did not consider small amounts of medication loss as waste and, therefore, such losses were not controlled or evaluated for diversion. Nursing staff stated they had noted crusting on the rim of the oxycodone solution bottles. Nursing staff further stated that sometimes small amounts of medication solution spills occurred in the ADC, but reported these spills were not accounted for through the same process as wasted medications. Nursing managers described working with Pharmacy Service to improve the oxycodone solution administration; however, the concerns related to accuracy of measurement were not resolved. Facility policy required a witness and documentation process when staff "wasted," or administered a partial dose of controlled substance, but the policy did not address these spills or crusting.⁴⁷

In response to issues identified after the death of the patient discussed in this report, Pharmacy Service staff ordered and began the use of adapters, the manufacturer provided calibrated syringes, and zero-space syringes to improve the accuracy of dose measurement and administration.⁴⁸ However, the OIG determined that the calibrated syringe did not improve the accuracy for measurement because the 2.5 mg (0.13 mL) amount ordered was less than the smallest dose marker of 5 mg (0.25 mL) on the calibrated syringe. (See Appendix A for photographs of the adapters and syringes, and a description of the process for oxycodone solution administration used at the facility.) The OIG also determined that there were no follow-up communications between pharmacy staff and nursing staff to determine if using the adapters and special syringes resolved the issue.

⁴⁵ VHA Directive 1108.06.

⁴⁶ System Policy Memorandum 512-001/OPS-003.

⁴⁷ System Policy Memorandum 512-119-018, *Controlled Substances Policy*, November 2014.

⁴⁸ Adapters connect the bottle mouth with the syringe. <https://www.merriam-webster.com/dictionary/adapter>. (The website was accessed on August 23, 2018.) Zero-space syringes prevent fluid from being left in the syringe after the plunger has been pushed down completely. *Medication Waste Attributed to Syringe Dead Space, Abandoned Initial Fills*, Pharmacy Times, July 5, 2016. <https://www.pharmacytimes.com/contributor/katherine-yang-pharmd-candidate-2018/2016/07/medication-waste-attributed-to-syringe-dead-space-abandoned-initial-fills>. (The website was accessed August 24, 2018.)

A nurse manager reported the use of the adapters and syringe(s) implemented after the patient's death evolved into a multi-step process because the bottles come with one syringe, which could not be used for more than one patient, causing nurses to have to use zero-space syringes to transfer medication to a cup for administration. Nursing staff reported the adapter helped to resolve the issue with spillage. In OIG interviews, the hospice unit physician and pharmacy leaders said they were unaware of the multiple steps required for nurses to administer oxycodone solutions as ordered and prepared.

Nursing staff explained that due to the small size of the ADC compartments, they could not store the bulk bottle of oxycodone solution upright and instead placed the bottle on its side. Occasionally, this practice caused spillage resulting in discrepancies in inventory measurements and an opportunity for diversion as this spilled amount was not always disposed of with a documented witness.

VHA policy requires facilities to establish procedures for maintaining accountability of all controlled substances.⁴⁹ System CSIs conducted monthly inspections and CSCs reported monthly inspection results and quarterly trend reports for review by facility and system leaders.⁵⁰

In addition, VHA policy requires that any accidental loss, breakage, or destruction of small quantities of Schedule II substances must be resolved, with a brief explanation of the circumstances entered into the ADC and subsequently reported in the monthly controlled substances inspections.⁵¹ Facility policy defined small quantities of Schedule II controlled substances as five dosage forms or less.⁵² On all transactions requiring an override in the ADC, such as adjustments to the inventory, VHA requires strict enforcement of a two-person (facilitator and witness) signature system.⁵³

For the identified patient, RN2 accessed the ADC and noticed that the oxycodone solution bottle showed less than what the ADC documented as the current amount (inventory discrepancy). The ADC documented 25.23 mL of oxycodone solution, however, RN2 determined the bottle contained 14 mL. When the Nurse on Duty re-evaluated with RN2 as required for a discrepancy, they agreed the bottle contained 13 mL of oxycodone solution.

⁴⁹ VHA Handbook 1108.01

⁵⁰ System Policy Memorandum 512-001/OPS-003. CSI responsibilities include a monthly inventory and inspection of controlled substances. CSIs cannot be involved in the procurement, prescribing, dispensing, and administration of controlled substances.

⁵¹ VHA Directive 1108.01.

⁵² System SOP No. 119-015.

⁵³ VHA Directive 1108.01.

Medication Order Entry Errors

The OIG identified errors with the pharmacy inpatient medication order entry process. Pharmacists inconsistently processed orders for the same medication and strength. VHA policy requires that clinical pharmacists verify all inpatient orders including the current diagnosis and indication for each medication. Facility staff used the required electronic order entry, which includes several fields such as medication name, strength, dosage form, units dispensed, and any special instructions needed for nursing staff.⁵⁴

For the identified patient, providers ordered 2.5 mg of oxycodone 20 mg/ml. However, in the “Units of Administration/Dispense Drug” field, pharmacists documented 2.5 mg of oxycodone as values of both 1 and 0.13, reflecting different values for the same amount of medication. In addition, the ADC documented 0.125 (2.5 mg) given for the 0.13 doses ordered, which was unclear whether these were administration errors by the nurses or documentation corrections by the ADC. These errors and inconsistencies highlight the difficulty and risk in both dispensing and administering the medication orders as written.⁵⁵

Issue 3: Oxycodone Solution Administration Inaccuracies

The OIG found that the facility’s established process for administering oxycodone solution contributed to additional risk of discrepancies in measurements. Nursing staff did not have the tools required to accurately measure ordered doses from the bulk bottle of oxycodone solution for administration to multiple patients. While medication management and dispensing are the role of a pharmacist, medication administration from the ADC to the patient is primarily a nursing function. The OIG determined that the facility did not adequately respond to the potential that RN1 diverted the oxycodone solution.

The Institute for Safe Medication Practices lists opioids as high-alert medications in acute care settings. High-alert medications are drugs that have a heightened risk of causing significant patient harm if used in error and require special safeguards to reduce the risk of errors and minimize harm. At the facility, the oxycodone solution medication orders alerted “HI-ALERT MED, Verify correct DRUG & DOSE,” indicating the need for caution. The OIG found an alert on the patient’s medication order to verify drug and dose.

For the identified patient, the OIG determined that RN1 did not follow the process used on the hospice unit to draw up the ordered dose of oxycodone solution and did not withdraw the correct medication amount ordered by the physician (2.5 mg) from the ADC. Nursing staff reported that the syringes for this medication were not in the ADC so RN1 looked for, and possibly used, a larger syringe from another unit to administer the potential medication overdose. RN1 reported

⁵⁴ VHA Directive 1108.06.

⁵⁵ System SOP No. 119-015.

to the supervisor, after the patient's death, of pouring "at least 1 mL" of medication directly into a medicine cup and giving it to the patient. RN1 documented in the ADC that 0.13 mL was administered; however, RN1 documented administering an 11 mL dose in the BCMA. In addition, facility staff reported that a second verifier is required as a safeguard for oxycodone solution administration; however, a second verifier was not used by RN1. Although, sometimes if a patient needed a medication quickly and a second RN was not available, they would administer without a second person, which was the case with the identified patient. This second verifier is regarded as a safeguard and is not part of facility policy.

RN1 then reported during interviews with VA Police and OIG OI that the 11 mL dose documented in the BCMA was a clerical error and that 1 mL was the amount administered; however, the EHR reflected that 2.5 mg (0.13 mL) was the amount ordered.

Without a definitive cause established for the medication discrepancy and 11 mL of oxycodone solution still unaccounted for, staff identified a concern that RN1 may have diverted the medication. The OIG determined that the facility did not adequately respond to the potential that RN1 diverted the oxycodone solution. Opioids, including oxycodone, are one of the drug classes with the highest potential for diversion and abuse. Diversion can occur at any step of the prescription drug supply chain. Warning signs for drug diversion that may warrant urine testing of suspected employees include employees charting larger doses of controlled substances than ordered when the appropriate dose is available and dosage errors on patient medication records, as described with the identified patient. The potential for diversion of oxycodone solution was not evaluated, despite a history of concerns about the facility's established process, including discrepancies in measurements and small amounts of waste. The ADPCS reported a drug screen could have been ordered for anyone under suspicion of drug diversion and acknowledged that one was not ordered for RN1, who administered the potential overdose.

Issue 4: Patient Safety

The OIG determined facility leaders and Patient Safety program staff failed to recognize the inherent risks in medication administration and did not evaluate the identified patient's potential medication overdose to determine the causes, facility or system issues, and continued risk. Facility staff did not disclose the potential overdose to the patient's family, conduct an RCA or a peer review, or report it as an Adverse Drug Event (ADE) to gain further understanding of the reasons and possible actions to mitigate further risk.⁵⁶ In an interview with the OIG, a staff member said that the facility did not have "a very good culture of safety."

Facility leaders did not complete other actions that impact patient safety including failure to ensure RN1 had recent acute care experience, orient RN1 to the hospice unit complex medication administration process, and assess RN1's competency for administering the high-alert

⁵⁶ VHA Handbook, 1050.01.

medication in the multi-step process used in the hospice unit. In addition, facility leaders did not evaluate the care provided to other patients by RN1 to determine if other instances or trends of medication errors occurred. After the patient's suspicious death, facility staff did not notify the Medical Examiner as required or obtain an autopsy.

Facility staff said they were waiting for completion of the VA Police and OIG OI investigation before taking further action, such as completing a quality review or making a disclosure to the patient's family. However, VHA policy provides opportunities for facility leaders to complete concurrent reviews and investigations to evaluate potential and actual risk to patients, as well as discussion and resolution with staff and the patient's family.⁵⁷

Summary of Events

Nursing staff identified and verified the medication discrepancy (potential overdose) approximately two hours prior to the patient's death. An anonymous source contacted VA Police around eight hours after the death about a potential "overdose of pain medication (oxycodone solution) that may have caused the death." An hour later, VA Police documented they contacted the OIG OI, the Chief of Staff, and the Medical Center Director. The day after the patient's death, the ADPCS completed an Issue Brief titled "Medication Error," which indicated that an electronic incident report was entered and "administrative and criminal inquiry is in progress." VA Police and a nurse manager interviewed RN1, who allegedly administered the potential overdose, on the night shift the day after the identified patient's death to replicate the conditions of the event such as lighting. OIG OI staff and VA Police interviewed additional staff knowledgeable about the event two and four days after the patient's death. Three days after the death, blood was drawn to evaluate toxicology and the patient was released to the funeral home.

Patient Safety Processes

Clinical and Institutional Disclosures

The OIG determined the potential overdose was an adverse event that required consideration of disclosure, including a discussion with the patient's family. Facility leaders did not complete a clinical or institutional disclosure. A clinical disclosure must be initiated as soon as reasonably possible, generally within 24 hours of occurrence. According to VHA policy, a clinical disclosure was warranted for this patient because a possible medication error was known. Facility leaders did not adequately evaluate the circumstances to determine whether an

⁵⁷ VHA Directive 2010-025.

institutional disclosure was required. When indicated, an institutional disclosure must be initiated as soon as reasonably possible, generally within 72 hours.⁵⁸

Facility staff reported that the potential overdose was not discussed with the patient's family, who was present at the time of the patient's death. In addition, the VA Police "strongly suggested" the investigation be concluded before facility staff contacted the patient's family.

The OIG determined that the facility's decision to complete quality reviews and investigations prior to any type of disclosure was inconsistent with VHA policy. Facility staff voiced concern about the possibility that an adverse event occurred, although the cause of either potential overdose or diversion had not been determined. VHA and facility policy outline circumstances that warrant adverse event disclosure and include events that are "expected to have, a (clinical) effect on the patient that is perceptible to either the patient or the health care team, such as a mistakenly given dose of a medication."⁵⁹ A discussion with the patient's family members about the potential overdose would have allowed them to make informed decisions regarding the need for an autopsy and other rights and recourse.

RCA

The OIG determined that an RCA, or other quality or management review, of this event was not completed. Patient Safety staff did not advocate for, and facility leaders did not ensure completion of an RCA. Staff said they believed this event to be "a one off" or a medication error by one nurse. An RCA may have allowed the facility staff to determine why RN1 did not have the required syringe and did not follow the established process for administering the identified patient's medication.

VHA policy requires that unexpected occurrences are reviewed to determine if system or process issues contributed to the event.⁶⁰ Although the patient's death was possibly related to a terminal diagnosis, the potential overdose was an unexpected occurrence requiring further review.

Facility staff told the OIG that they believed the cause of this event was a medication error specific to RN1, who administered the potential overdose. An RCA could have provided clarification and additional information to identify the contributing causal factors associated with the adverse event.⁶¹

⁵⁸ VHA Handbook 1004.08, 2012; VHA Directive 1004.08 contains similar language regarding timeframes for disclosures.

⁵⁹ VHA Handbook 1004.08; VHA Directive 1004.08 contains the same language as VHA Handbook 1004.08 regarding perceptible events warranting disclosure; System Policy Memorandum 512-00/PS-003, *Disclosure of Adverse Events to Patients*, October 2016.

⁶⁰ VHA Handbook, 1050.01.

⁶¹ VHA Handbook, 1050.01.

Peer Review

The OIG determined facility staff did not complete a peer review. VHA policy requires screening of all facility deaths against criteria to determine the need for a peer review. According to VHA policy that was in effect at the time of the events discussed in this report, criteria specifically required peer review for deaths “related to a medication error or choice of medication.”⁶² A peer review was not initiated or completed. An initial peer review should be completed within 45 calendar days once the need for peer review is determined.⁶³ The OIG team was told by facility staff that a peer review was not conducted due to the ongoing criminal investigation.

ADE

The OIG determined that facility staff did not report the potential overdose as an ADE as required. VHA policy requires the reporting of “an injury resulting from the use of a drug” to the National Adverse Drug Event Reporting System as an ADE. The ADE may be reported even if the association of the drug to the adverse event has not been established.⁶⁴ The OIG team determined that an ADE assessment may have assisted the facility in determining the cause of the potential overdose and the continued medication risk.⁶⁵

Other Actions Impacting Patient Safety

Nurse Hiring, Competencies, and Orientation

The OIG determined facility nursing staff did not follow requirements when hiring RN1 and did not ensure RN1’s competency for administering the high-alert medication in the multi-step process used in the hospice unit.

When recruiting for a position, it is incumbent upon facility leaders to designate the duties of the position and the qualifications required. Once a person is hired into a position, this responsibility extends to orientation of the new person and development of a method to evaluate current and ongoing competency for the required work.

⁶² VHA Directive 2010-025, Attachment A outlined a list of clinical events, including those related to medication errors, that required a peer review. VHA Directive 1190, Appendix E outlined a list of clinical events, including those related to medication errors that “should be considered” for peer review.

⁶³ VHA Directive 2010-025; VHA Directive 1190 contains the same or similar language regarding the timeframe for the initial peer review.

⁶⁴ VHA Directive 1070, *Adverse Drug Event Reporting and Monitoring*, September 12, 2014.

⁶⁵ VHA Directive 1070.

Facility staff failed to

- Validate recent acute care experience for RN1,⁶⁶
- Establish orientation and competency for RN1's use of this high-alert medication as evidenced in the competency review, and⁶⁷
- Evaluate the care provided to other patients by RN1 to determine if other instances or trends of medication errors occurred.

RN1 was hired in 2015 and did not have recent documented acute care experience as required. Facility policy outlines basic requirements for appointment as two years of recent acute care, defined as medical/surgical, emergency, critical, geriatric long-term, or mental health. According to RN1's application, for seven consecutive years prior to being hired at the facility she was employed in administrative and non-acute nursing roles in a non-hospital environment. The work experience on the application contained a two-year gap in employment. The OIG determined that RN1 was employed at a hospital during that time as evidenced on RN1's resume, but it did not provide details of this position. Even if this employment was acute care, this would indicate the last acute care was seven years prior to hire.

The OIG determined that facility leaders did not provide safe medication practice for high-alert controlled substance through the nurse competency process. The Joint Commission requires VHA facilities to have a process for managing high-alert medications, as well as defining the competencies of staff. When asked, nurse managers could name only insulin as a high-risk medication at the facility. Although nurses were not specifically required to have competencies related to high-alert medications, it is reasonable to expect that a nurse would have the skill and ability to manage the risk, and safely administer these high-alert medications. The OIG was told by staff that the expectations were not outside of general nursing competencies.

RN1's medication competencies were general in scope and did not include competency for administering the high-alert medication in the multi-step process used in the hospice unit. RN1 was responsible for, and failed to ensure the "right dose" for medication administration. The facility competency checklist requires nurses to comply with the "six rights of medication safety" including right medication, dose, time, route, resident, and documentation (pain). Facility staff who interviewed RN1 following the identified patient's death stated RN1 admitted to giving an 11 mL dose of the medication.

⁶⁶ System Policy Memorandum 512-118-020, *Nursing Supplemental Staffing*, January 2016. RN1 was an intermittent nurse who did not have a routinely assigned schedule. An intermittent nurse, also known as a temporary nurse, can be called upon to work when staffing is needed to support patient care, and works without benefits.

⁶⁷ Competency is a skill or ability. <https://www.merriam-webster.com/dictionary/competency>. (The website was accessed on July 8, 2018.)

Position-specific competency forms were blank in key areas for RN1, including acting in accordance with VA directives, policies, and standard operating procedures “during high risk, problem prone or seldom performed activities” such as the multi-step process for the oxycodone solution.

RN1 was assigned to the hospice unit for the first time on the night shift when the potential overdose occurred. Staff reported that RN1 requested and received orientation to the hospice unit when beginning the shift and an experienced nurse on another unit was identified to be available for any questions. However, the OIG was told that unit-specific orientation takes between three and four days, which cannot reasonably be truncated to a briefing upon arrival to the unit.

Facility leaders reported, after the potential overdose, they did not evaluate the care provided to other patients by RN1 to determine if other instances, errors, or trends of practice issues occurred. Quality data for deaths and medication errors were trended and tracked by location. RN1 worked in a variety of care settings and units, which did not allow for the same competency oversight as other full-time permanent nurse positions. However, a facility leader reported the discovery of an additional medication error after the patient’s death that had not been reviewed further at the time of the OIG site visit.

Facility staff reported that RN1 resigned after this event. Concerns arise when clinical staff leave employment during an active investigation. For some clinicians, it is mandatory to report to oversight bodies when this occurs. The ADPCS reported that RN1 was not working and had plans to surrender the nursing license. As of January 22, 2019, RN1’s license remained active.

Medical Examiner Reporting

The OIG determined facility leaders did not ensure contact to the Medical Examiner as required once the potential medication overdose was identified. OIG OI staff discussed the need for Medical Examiner notification with the Chief of Police at the time of the identified patient’s death. The Facility Director did not recall any involvement in decisions regarding the identified patient’s death, including notification to the Medical Examiner.

Facility policy required facility staff to report the identified patient’s death to the Medical Examiner due to the possibility of a cause other than natural.⁶⁸ In addition, VHA policy required facility staff to consult with VA Regional Counsel⁶⁹ to determine whether the death should be reported to the Medical Examiner.⁷⁰ Facility policy also required that if remains are in the morgue for 72 hours, the Medical Examiner must be notified.⁷¹ The identified patient remained

⁶⁸ System Policy Memorandum 512-136/MAS-012, *Death, Autopsies, and Release of Remains*, October 2017.

⁶⁹ Currently known as Offices of Chief Counsel in the Districts. *Office of General Counsel*, U.S Department of Veterans Affairs, <https://www.va.gov/OGC/DistrictOffices.asp>. (This website was accessed on September 28, 2018.)

⁷⁰ VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, January 29, 2016.

⁷¹ System Policy Memorandum 512-136/MAS-012

in the facility morgue for approximately 81 hours before release to the funeral home to allow time for arrangements.

Facility leaders decided to have blood drawn for the identified patient three days after death. The serum blood results showed higher than normal values but as noted previously, the elapsed time between death and the procurement of a blood sample does not allow an accurate interpretation of the patient's blood level oxycodone concentrations.⁷²

Autopsy

The OIG determined that facility leaders did not follow VHA policy in reviewing the suspicious death to determine if an autopsy was required. According to VHA policy, when a death is suspected to have been the result of a crime, facility staff are required to inform Regional Counsel to assist in determining the need to obtain an autopsy.⁷³ The Facility Director stated to the OIG that according to policy, an autopsy should have been completed.

During the discussion regarding the notification to the Medical Examiner noted above, the OIG OI also discussed the need for an autopsy with the Chief of Police, who responded that the Facility Director did not determine it was necessary. The Facility Director did not recall any involvement in decisions regarding the identified patient's death, including obtaining an autopsy or approval of blood work.

Facility staff documented speaking with the patient's spouse and that "autopsy permission [was] denied/declined." VA policy and federal regulations required consent for autopsy by the surviving spouse.⁷⁴ However, as discussed previously, facility leaders did not disclose knowledge of the potential overdose prior to the patient's death to the patient's spouse, which would have allowed an informed decision regarding consideration of an autopsy.

⁷² Ferner, RE., October 2008.

⁷³ 38 CFR 17.170, Autopsies, July 1, 2001 edition

⁷⁴ VHA Handbook 1106.01; 38 CFR 17.170.

Conclusion

The patient may have received a potential overdose of 11 milliliters (mL) (220 milligrams) of oxycodone solution. Due to medication management issues, the OIG was unable to determine whether an overdose occurred or a potential overdose contributed to the patient's death. The OIG identified deficiencies in multiple facility medication management processes and facility leaders' actions taken after the patient's death.

The facility's lack of the most ready-to-administer dosage packaging (unit dose) oxycodone solution contributed to processes that increased risks in all phases of medication management. The facility's Pharmacy Service dispensing of 30 mL bulk bottles of oxycodone solution (20 mg/mL) to the ADC, instead of pre-packaged unit doses of oxycodone solution, contributed to the inventory discrepancies.

Facility leaders did not consider the loss of small amounts of medication as waste and, therefore, such losses were not controlled or evaluated for diversion. The OIG identified errors with the pharmacy inpatient medication order entry process. Pharmacists inconsistently processed orders for the same medication and strength.

The facility's established process for administering oxycodone solution contributed to additional risk for discrepancies in measurements. Nursing staff did not have the tools required to accurately measure and administer ordered doses from the bulk bottle of oxycodone solution and were required to estimate the amount. A combined interdisciplinary review of processes with nursing, medicine, and pharmacy would allow for evaluation of current processes and interventions.

Facility leaders and Patient Safety program staff failed to recognize the inherent risks in medication administration and did not evaluate the identified patient's potential medication overdose to determine the causes, facility or system issues, and continued risk. The medication discrepancy was identified prior to the patient's death, as either a potential overdose or diversion. However, the facility did not disclose the potential overdose to the patient's spouse or take steps to understand the outcome and reasons it occurred. RCA and peer review are well-established opportunities that facility leaders could have used to evaluate system processes and the care provided by the nurse, and to gain information to correct system and individual practices. More importantly, a comprehensive review of the identified patient's death may have led to other quality reviews to evaluate the medication process failures, or a management review related to any disciplinary actions or reporting to state licensing boards as needed.

The facility did not ensure recent acute care experience before hiring the nurse, assess the nurse's competency for administering this high-alert medication in the multi-step process, orient the nurse to the hospice unit complex medication administration process, or initiate a practice review of care provided to other patients. The nurse did not follow the process used on the hospice unit

for administration of the correct dose, possibly due to lack of familiarity with the syringes and dosing regimen for oxycodone solution.

Facility leaders did not ensure contact to the Medical Examiner as required once the potential medication overdose was identified and did not ensure the review of the suspicious death to determine if an autopsy was required. OIG OI staff discussed the need for Medical Examiner notification with the Chief of Police at the time of the identified patient's death. The Facility Director did not recall any involvement in decisions regarding the identified patient's death.

The OIG made eight recommendations.

Recommendations 1–8

1. The Veterans Integrated Service Network Director ensures evaluation of inaccuracies and risks involved with use of bulk bottles of controlled liquid solutions, takes actions as needed to reduce risks, and monitors effectiveness of actions taken.
2. The VA Maryland Health Care System Director ensures the interdisciplinary review of unit dose and multi-dose oxycodone solution dispensing and administration, takes actions as appropriate, and monitors effectiveness of actions.
3. The VA Maryland Health Care System Director consults with the Office of Chief Counsel regarding whether an institutional disclosure is appropriate for this patient's death and takes actions as needed.
4. The VA Maryland Health Care System Director conducts a quality review of the patient's death and takes actions as needed.
5. The VA Maryland Health Care System Director ensures that nursing staff follow facility policy in the hiring of nurses.
6. The VA Maryland Health Care System Director ensures evaluation and revision as needed of facility nurse competency processes on the hospice unit for high-alert medications and monitors effectiveness of actions taken.
7. The VA Maryland Health Care System Director evaluates the care provided to other patients by the nurse who administered the potential overdose for other possible practice issues.
8. The VA Maryland Health Care System Director ensures evaluation by nursing leaders to determine the need for reporting the nurse who administered the potential overdose to the State Licensing Board and takes steps as appropriate.

Appendix A: Process of Oxycodone Solution Administration

Nursing staff in the hospice unit used the following process to measure and administer oxycodone solution.

Step 1

The nurse removes the bulk bottle of oxycodone solution, which is fitted with an adapter cap, from the Omnicell®.



Figure 2. Bottle of oxycodone solution with manufacturer-calibrated syringe and adapter cap
Source: VA OIG; Perry Point, MD; May 2018.

Step 2

The nurse draws the prescribed patient dose into the manufacturer-calibrated oxycodone solution syringe.

Note: At the time of the event, facility staff were drawing medication directly from the bottle without using the adapter cap, resulting in crusty residue on the rim of the bottle, spills, and drips.

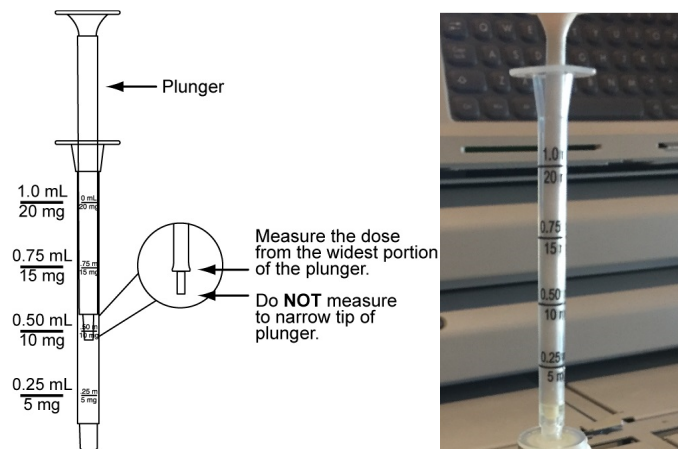


Figure 3. Manufacturer-calibrated oxycodone solution syringe
Source: USA Food & Drug Administration Medication Guide, May 2018.

Step 3

The nurse dispenses the prescribed patient dose into a medication cup and either administers the medication to the patient orally using the cup or proceeds to Step 4.



Figure 4. Sample of a medication cup.

Source: VA OIG example of medicine cup observed at the facility, May 2018.

Step 4

The nurse draws the prescribed patient dose from the medication cup into a zero-space safety syringe and administers it to the patient orally by dispensing it into the patient's vestibule (the area between the inside of the cheek and the teeth and gums).



Figure 5. The zero-space syringe used at the facility

Source: VA OIG; Perry Point, MD; May 2018.

Appendix B: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: January 15, 2019

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

Subj: Healthcare Inspection—Medication Management, Dispensing, and Administration
Deficiencies at the VA Maryland Health Care System, Perry Point, Maryland

To: Director, San Diego Office of Healthcare Inspections (54SD)
Director, Management Review Service (VHA 10E1D MRS Action)

1. I would like to express my appreciation to the Office of Inspector General (OIG) Healthcare Inspection Team for their professional and comprehensive review of Medication Management, Dispensing, and Administration at the VA Maryland Health Care System (VAMHCS), Perry Point, Maryland. I commend their professionalism and assistance to us in our continuing efforts to improve the care we provide to our Veterans.
2. I have reviewed the draft report, and concur with the report and conclusions rendered. Further, I have reviewed and concur with the VA Maryland Health Care System, Medical Center Director's response.
3. Please contact us if you should have any further questions.

(Original signed by:)

Raymond Chung, M.D.

Acting Director, VA Capitol Health Care Network, VISN 5

Comments to OIG's Report

Recommendation 1

The Veterans Integrated Service Network Director ensures evaluation of inaccuracies and risks involved with use of bulk bottles of controlled liquid solutions, takes actions as needed to reduce risks, and monitors effectiveness of actions taken.

Concur

Target date for completion: July 31, 2019

Director Comments

1. VISN 5 completed a virtual assessment of all VISN 5 facilities in relation to bulk oral controlled substance storage and dispensing practices within inpatient units in June 2018. Through this review it was identified that only one additional site (Martinsburg VA Medical Center) outside of VA Maryland Health Care System had these items marked for inpatient use. Further review was completed with the identified site and it was verified that bulk oral controlled substances were not stored on inpatient units, and pharmacy pre-packaged all needed doses within pharmacy prior to stocking on the inpatient unit. The process utilized was shared throughout VISN 5 as a strong practice should the need arise at another site to utilize these products.
 - a. Review of the storage and provision of bulk oral controlled substances on inpatient units will be reviewed annually through VISN Pharmacy Site visits.
2. VA Maryland Health Care System Specific Actions:

VA Maryland Health Care System has completed a physical assessment to ensure that oxycodone, morphine, and methadone are supplied to the inpatient areas in unit dose on the Loch Raven, Perry Point, and Baltimore campuses.

 - a. Provision of unit dosed bulk oral controlled substances
 - 1) VA Maryland Health Care System has elected to utilize a 3rd-party vendor (Atlantic Biologics) for primary preparation of unit-dosed bulk oral controlled substances for inpatient use and will include Oxycodone, Methadone, and Morphine. When commercially available products or products from the 3rd party vendor are not available, unit dose packaging will be prepared by pharmacy.
 - 2) Oxycodone oral syringes were purchased from Atlantic Biologics effective September 6, 2018 and are the only formulation of oral oxycodone available in clinic areas.
 - 3) Morphine and methadone oral syringes were ordered from the 3rd-party vendor the week of November 21, 2018 and will be utilized upon their receipt.
 - b. Order Sets and Standardization

- 1) Standardized order sets were developed and implemented for bulk oral oxycodone, methadone and morphine which reference both the strength and volume for available doses effective 10/15/2018.
- c. Non-controlled substance oral solutions:
- 1) The VAMHCS is assessing all drugs including non-controlled substances in bulk bottles to determine availability of commercial products. When not commercially available the oral dose will be prepared by pharmacy.
- d. Compliance Monitoring:
- 1) Pharmacy leadership will monitor and report the use / non-use of multi-dose (bulk) containers of Oxycodone, Methadone, and Morphine.
 - 2) No bulk bottles of Oxycodone, Methadone, or Morphine oral liquids will be purchased or stocked for the patient care areas which will be verified through review of automated dispensing cabinet (Omnicell) stock reports.
 - 3) Compliance with unit-dosed oral liquids will be reported to the monthly Executive Performance Improvement Committee (EPIC).
- e. Adverse Drug Event Reporting
- 1) The Joint Patient Safety Reporting(JPSR) is the mechanism for reporting adverse drug events, including medication errors, and the VAMHCS will reiterate and reinforce the reporting process throughout the organization. These reports are presented and discussed at Executive Performance Improvement Committee (EPIC) and the Pharmacy and Therapeutics Committee.

Appendix C: System Director Comments

Department of Veterans Affairs Memorandum

Date: January 15, 2019

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

Subj: Healthcare Inspection—Medication Management, Dispensing, and Administration
Deficiencies at the VA Maryland Health Care System, Perry Point, Maryland

To: Acting Director, VA Capitol Health Care Network (VISN 05)

1. I would like to express my appreciation to the Office of Inspector General Survey Team for their professional and comprehensive review conducted on May 15 – 17, 2018.
2. I have reviewed the draft report for the VA Maryland Health Care System, Baltimore, Maryland, survey and concur with the findings and recommendations.
3. Please express my gratitude to the survey team for their professional 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.
Medical Center Director

Comments to OIG's Report

Recommendation 2

The VA Maryland Health Care System Director ensures the interdisciplinary review of unit dose and multi-dose oxycodone solution dispensing and administration, takes actions as appropriate, and monitors effectiveness of actions.

Concur

Target date for completion: July 31, 2019

Director Comments

1. Two nurse verifications of Oxycodone, Methadone or Morphine liquids was implemented, effective immediately as of September 11, 2017.
2. Two nurse verifications required in the Bar Code Management System (BCMA), prior to the administration of Oxycodone, Methadone, or Morphine liquids to patients with the VA Maryland Health Care System were implemented August 2018.
3. The customized unit-dose packaging of Oxycodone oral liquid is currently procured from the VA pharmaceutical vendor, Atlantic Biologicals.
4. As of December 5, 2018, the unit-dosed product has been exclusively stocked in the automated dispensing cabinets (Omniceil) located within patient care areas at Baltimore, Loch Raven, and Perry Point.
5. Compliance of unit dosing will be monitored and reported monthly to EPIC as part of the management of controlled substance distribution and dispensing within the VA Maryland Health Care System.

Recommendation 3

The VA Maryland Health Care System Director consults with the Office of Chief Counsel regarding whether an institutional disclosure is appropriate for this patient's death and takes actions as needed.

Concur.

Target date for completion: Completed August 7, 2018

Director Comments

VAMHCS Legal Counsel was consulted about whether an institutional disclosure was appropriate for this patient's death. The institutional disclosure was conducted with the veteran's wife and children by the Associate Director of Patient Care Services, Geriatrics & Long Term Care Nurse Manager, Acting Chief of Staff, Director Patient Safety/Risk Management, and

additional Patient Safety staff on August 7, 2018. The family was informed that a medication error had occurred during the care of the veteran and that both internal and external quality reviews were conducted to evaluate this matter. The institutional disclosure documentation in the veteran's medical record documented that the veteran was administered a higher dose than prescribed of liquid oxycodone due to an error of transferring the medication from a multi-dose vial to an oral syringe. The spouse confirmed being present at the time, and that the patient required continued dosing of oxycodone for pain and restlessness. The patient expired approximately 6 hours after the medication was administered, with the family present at the bedside. Additionally, the Director, Patient Safety/Risk Management and an additional Patient Safety staff member met with the family and provided the family with information on benefits and the VHA tort claim process.

OIG Comment

Based on information provided and a review of the patient's electronic health record, the OIG considers this recommendation closed.

Recommendation 4

The VA Maryland Health Care System Director conducts a quality review of the patient's death and takes actions as needed.

Concur.

Target date for completion: July 31, 2019

Director Comments

A comprehensive quality review of the patient's death was conducted. System issues and process issues were identified. The VAMHCS implemented corrective actions and continues to monitor compliance to the new process established.

Recommendation 5

The VA Maryland Health Care System Director ensures that nursing staff follow facility policy in the hiring of nurses.

Concur.

Target date for completion: July 31, 2019

Director Comments

1. All current intermittent nurses who have been at the VAMHCS less than two years were audited to ensure compliance with policy (512-118-020). There were no nurses found to be out of compliance with the policy.
2. At the time of intermittent nurses' VetPro completion, a check will be made to ensure compliance of the policy. Any intermittent nurses found not to be in compliance with the policy will not be appointed.

Recommendation 6

The VA Maryland Health Care System Director ensures evaluation and revision as needed of facility nurse competency processes on the hospice unit for high-alert medications and monitors effectiveness of actions taken.

Concur.

Target date for completion: July 31, 2019

Director Comments

1. All current nurses who administer high-risk liquid medications were educated on the correct withdrawal and administration procedure of these medications.
 - Completed training for all hospice nurses on 8/2/18, including return demonstration.
2. High-Risk liquid medication training will be added to the nursing annual hospice competencies.
3. All new hire nurses will receive High-Risk liquid medication training as part of Nursing orientation.
4. All CLC [community living center] nurses will receive annual High-Risk liquid medication competency training for FY 2019.

Recommendation 7

The VA Maryland Health Care System Director evaluates the care provided to other patients by the nurse who administered the potential overdose for other possible practice issues.

Concur.

Target date for completion: July 31, 2019

Director Comments

1. At the time of the medication error, Nursing Service undertook multiple reviews of the care provided to other patients by the nurse who administered the potential overdose for other possible practice issues.
2. A review of all patient deaths during the periods of employment and of the identified nurse was undertaken and found no association between the presence of the identified nurse at work and the death of patients during this time.
3. A review of the medication administration practice of the identified nurse was undertaken by review of Bar Code Medication Administration (BCMA) records related to the care of this Veteran around the time of the patient's death. No other errors in medication administration by the identified nurse were found.
4. A review of an Omnicell report on the medications administered to this Veteran around the time of the patient's death found no other errors in medication administration by the identified nurse.
5. A review of a second Omnicell report on medications administered to this Veteran around the time of the patient's death found no other discrepancies other than the documented medication error for the identified nurse.
6. A review of Omnicell reports on medications administered to other patients by the identified nurse during the time(s) of the nurse's employment by the identified nurse found no other medication discrepancies.
7. In reviewing Patient Safety, Risk Management e-mails, NOD reports, emails through the Associate Director of Patient Care Services there were no complaints involving the identified nurse from Patient Advocates, Physicians, Nurse Managers, Patients or peers.
8. A review of VAMHCS Narcotic Discrepancy Reports during the time(s) of the nurse's employment was undertaken and found that the identified nurse had never had any other narcotic discrepancies found through narcotic inspections.
9. No additional incidents reports were discovered involving the nurse related to the potential medication error during her time of employment.

Recommendation 8

The VA Maryland Health Care System Director ensures evaluation by nursing leaders to determine the need for reporting the nurse who administered the potential overdose to the State Licensing Board and takes steps as appropriate.

Concur.

Target date for completion: Completed June 28, 2018

Director Comments

VAMHCS Nursing Leadership reported the nurse who administered the potential overdose to the Maryland State Licensing Board as of June 28, 2018.

OIG Comment

Based on information provided, the OIG considers this recommendation closed.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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