



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficiencies in Pharmacy
and Nursing Processes at
the Southeast Louisiana
Veterans Health Care
System in New Orleans



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate concerns that the failure to follow pharmacy and nursing policies and procedures may have contributed to the death of a patient at the Southeast Louisiana Veteran’s Health Care System (facility) in New Orleans.

In spring 2019, a patient with multiple known medical problems including diabetes mellitus, coronary artery bypass surgery, unintentional weight loss of 40–60 pounds in the preceding months, and chronic lymphocytic leukemia was transferred from one of the facility’s medical/surgical units to the intensive care unit (ICU) following a code blue.¹ The patient’s treatment in the ICU included the administration of intravenous (IV) fentanyl and IV norepinephrine.² After transfer to the ICU, the patient’s day shift nurse attempted to document the medications being administered to the patient, but was unable to scan the barcode label on the infusing IV fentanyl bag.³ An ICU nurse called for a new label. Pharmacy staff printed a duplicate label—for the IV norepinephrine—and sent the unattached label to the ICU. An ICU nurse incorrectly attached the new IV norepinephrine label to the IV fentanyl medication bag that

¹ Code blue is a medical emergency when medical personnel are attempting to resuscitate a patient after cardiac or respiratory arrest. Merriam-Webster, *Code Blue*, <https://www.merriam-webster.com/medical/code%20blue>. (The website was accessed on April 28, 2020.) Chronic lymphocytic leukemia is a “cancer of the body’s blood-forming tissues” such as the lymphatic system. “Lymphatic tissue makes up [the] immune system.” Mayo Clinic, *Leukemia*, <https://www.mayoclinic.org/diseases-conditions/leukemia/symptoms-causes/syc-20374373>. (The website was accessed on May 14, 2020.) Diabetes mellitus is a group of diseases that impact how the body utilizes glucose. Too much blood glucose can lead to serious health issues. Mayo Clinic, *Diabetes Mellitus*, <https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444>. (The website was accessed on May 14, 2020.) Coronary artery bypass surgery takes a “blood vessel from the leg, arm, or chest” and attaches it to a blocked artery in the heart to increase the blood flow. Mayo Clinic, *Coronary Bypass Surgery*, <https://www.mayoclinic.org/tests-procedures/coronary-bypass-surgery/about/pac-20384589>. (The website was accessed on May 14, 2020.)

² Administration is “the act of giving medication.” Merriam-Webster, *Definition of administration*, <https://www.merriam-webster.com>. (The website was accessed on May 12, 2020.) Fentanyl is a “synthetic opioid that is similar to morphine but 50 to 100 times stronger.” Fentanyl is a Schedule II controlled substance under the Controlled Substance Act, 21 United States Code § 802. National Institute of Health, National Institute on Drug, *Fentanyl*, <https://www.drugabuse.gov/drug-topics/fentanyl>. (The website was accessed February 7, 2020.) Fentanyl may be administered intravenously to maintain sedation for intensive care patients who are on a ventilator. Prescribers’ Digital Reference, *Fentanyl-Citrate*, <https://www.pdr.net/drug-summary/Fentanyl-Citrate>. (This website was accessed on February 2, 2020.) Norepinephrine, also known as levophed, is administered intravenously and is generally used to restore and maintain a patient’s blood pressure during cardiac resuscitation. Prescribers’ Digital Reference, <https://pdr.net/drug-summary/Levophed-norepinephrine-bitartrate-868>. (The website was accessed on June 8, 2020.)

³ According to an ICU nurse, the initial order for the dispensed bag of IV fentanyl was associated with the medical and surgical unit, became inactive upon the patient’s transfer to the ICU, and therefore would not scan.

was being administered to the patient.⁴ After another code blue later that morning, the patient's spouse decided against further resuscitation efforts, and the patient died that afternoon.

According to the OIG Office of Investigations, the facility VA Police alerted the OIG that there was a loss of a controlled substance following the patient's death.⁵ In late 2019, following the completion of an investigation by the Office of Investigations, the OIG opened a healthcare inspection to evaluate patient safety concerns related to the patient at issue. Specifically, the OIG reviewed the following concerns:

- The improper sending of a medication label and mislabeling of a medication
- The failure of ICU nursing staff to follow medication administration policies and procedures that resulted in a medication error and incomplete documentation⁶

During the course of the inspection, the OIG identified additional concerns with the securing of IV controlled substances and the facility's response to the medication error and patient's death.

The OIG concluded that the delivery of an unaffixed label did not comply with the intent of the Veterans Health Administration (VHA) or facility policy that states pharmacists are responsible for all labeling of dispensed compounded sterile preparations.⁷ In addition, ICU nursing staff failed to comply with facility policy by not verifying the "five rights" (right patient, right dose, right route, right time, and right medication) when improperly affixing the new IV norepinephrine label over the label on the IV fentanyl bag.⁸ For approximately three hours, the patient received IV fentanyl although the medication was labeled IV norepinephrine. The OIG determined that pharmacy staff improperly sent an unaffixed label through the pneumatic tube

⁴ National Center for Biotechnology Information, *Barcode Medication Administration: Lessons Learned from an Intensive Care Unit Implementation*. <https://www.ncbi.nlm.nih.gov/books/NBK20569>. (This website accessed April 23, 2020.) Only labels associated with active orders will scan into Bar Code Medication Administration (BCMA). BCMA is a software system used to improve accuracy of medication administration through validation of medications against active medication orders prior to administration.

⁵ Controlled substances are drugs in which the law regulates the use and possession. Merriam-Webster, *Definition of controlled substance*. <https://www.merriam-webster.com/dictionary/controlled%20substance>. (The website was accessed April 20, 2020.) VHA policy states in the event of a loss of a controlled substance, it must be reported to the OIG. VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock)*, November 16, 2010. The handbook was incorporated into VHA Directive 1108.01(1) *Controlled Substances Management*, May 1, 2019, amended December 2, 2019, and contains similar language related to VA police contacting OIG about missing controlled substances.

⁶ Merriam-Webster, *Definition of dispense*. <https://www.merriam-webster.com/dictionary/dispense> (The website was accessed April 16, 2020.) To dispense is to prepare and distribute a medication.

⁷ VHA Directive 1108.12, *Management and Monitoring of Pharmaceutical Compounded Sterile Preparations*, November 5, 2018. A compounded sterile preparation is made by combining commercially available drug products to make a final drug product intended to meet an individual patient's needs and minimize risk.

⁸ "Five Rights" of medication administration are right patient, right dose, right route, right time, and right medication. Agency for Healthcare Research and Quality, *Bar-coded Medication Administration*, <https://digital.ahrq.gov/ahrq-funded-projects/emerging-lessons/bar-coded-medication-administration>. (This website was accessed on April 23, 2020.)

system, and ICU nursing staff subsequently mislabeled a medication and failed to follow medication administration policies.

The OIG determined that ICU nursing staff failed to follow facility policies in administration of fentanyl and norepinephrine. The night shift nurse failed to follow the physician's orders by initiating the administration of IV fentanyl at a higher rate than was ordered, not adjusting the fentanyl infusion rate as indicated by the patient's assessed sedation scale, and not adjusting the norepinephrine infusion rate as ordered by the physician.

High-alert medications, such as fentanyl and norepinephrine, require "double-check" by two licensed personnel (verifiers) before the medication can be administered. In addition, fentanyl, which is a high-risk, controlled substance medication, requires a second verifier for rate changes and frequent documentation of a patient's response.⁹

The OIG found completed documentation for the initial administration and second verification for the norepinephrine. The OIG, however, did not find documentation of the initial administration of fentanyl, second verification for administration of fentanyl, second verification for each fentanyl rate change, or reassessment following rate change to either norepinephrine or fentanyl. The OIG concluded ICU nursing staff did not follow policy, and the lack of complete documentation did not ensure an accurate record of the medications administered.

In addition, the IV fentanyl bag was not securely attached to the IV pole as required by facility policy for controlled substances. At the time of the site visit, the Chief of Pharmacy informed the OIG that the secured boxes that had been ordered did not prevent possible diversion and that the facility was looking for other appropriate boxes for medications such as fentanyl. Securing the fentanyl in a locked box may have prevented the ICU nurse from placing the IV norepinephrine label over the IV fentanyl label.

The facility did not conduct a thorough evaluation of the mislabeling of the IV fentanyl that resulted in a medication error (adverse event).¹⁰ The OIG's inspection did not reveal that a Joint Patient Safety Report had been filed that specifically addressed the mislabeling of the fentanyl bag. ICU nurse leaders discovered the mislabeling of the IV fentanyl bag three days after the patient's death. The OIG concluded that facility staff failed to report the mislabeling of the IV fentanyl as a medication error, resulting in peer reviews excluding key clinical staff involved in the mislabeling of a medication.

⁹ High-alert medications are known to have a high percentage of medication errors and have a higher risk of significant harm to patients. Facility Memorandum 119-3, *Medication Management Policy*, June 30, 2017. Facility Memorandum 118-48, *Administration of Intravenous (IV) Fluids and IV Medications Via IV Piggy Back (IVPB) and IV Push (IVP)*, January 31, 2019.

¹⁰ Facility policy lists medication errors as reportable adverse events. Facility Memorandum 11-24, *Patient Safety Improvement Program*, September 29, 2016.

Although the patient had a very grave prognosis and the spouse had decided against resuscitation efforts following the second code blue, the facility failed to comply with VHA policy by not conducting an institutional disclosure for the adverse event of the patient receiving the incorrect dose of IV fentanyl.¹¹ The intent of institutional disclosure is to fully inform patients and their families about all clinically significant facts related to the harm caused by VA medical care and options to pursue potential compensation. When institutional disclosures are not completed as required, patients and their families may inadvertently be denied their rights.

The OIG made eight recommendations to the Facility Director related to unaffixed medication labels; medication administration, medication orders, and compliance with VHA and facility policies regarding high-alert and high-risk medications; security of controlled substances on the inpatient units; submitting Joint Patient Safety Reports; peer review; and institutional disclosure.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided an acceptable action plan (see appendixes A and B). The OIG considers all recommendations open and will follow up on the planned and recently implemented actions to allow time for the facility to submit documentation of actions taken to ensure they have been effective and sustained.



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¹¹ VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. Institutional disclosure is a formal process in which the facility leadership and respective clinician(s) inform the patient or representative about an adverse event.

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Abbreviations

BCMA	bar code medication administration
EHR	electronic health record
ICU	intensive care unit
IV	intravenous
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate concerns that the failure to follow pharmacy and nursing policies and procedures may have contributed to the death of a patient at the Southeast Louisiana Veterans Health Care System (facility) in New Orleans.

Background

The facility is part of Veterans Integrated Service Network (VISN) 16 and includes the New Orleans VA Medical Center and seven community-based outpatient clinics located in nearby parishes.¹ The facility is designated as Level 1b, high complexity, and provides acute care and outpatient services in medicine, primary care, mental health, and spinal cord injury.² From October 1, 2018, to September 30, 2019, the facility served 46,743 patients and had 116 hospital operating beds and 40 Community Living Center beds.

Bar Code Medication Administration

Medication errors can occur at every stage of medication use, including the [dispensing](#) and [administration](#) stages. Bar code medication administration (BCMA) is a software system used to improve accuracy of medication administration through validation of medications against active medication orders prior to administration. BCMA enables users to electronically document the administration of medications at various points of care, and to maintain compliance with the “five rights” of medication administration: right patient, right dose, right route, right time, and right medication.

Compounding and Labeling of Intravenous Medications

The Veterans Health Administration (VHA) states that a compounded sterile preparation is made by combining commercially available drug products to make a final drug product intended to meet an individual patient’s needs and to minimize risk.³ VHA states that compounded sterile

¹ The State of Louisiana refers to counties as parishes. LA HomeTown Locator®, <https://louisiana.hometownlocator.com/counties>. (The website was accessed on June 8, 2020.)

² VHA Office of Productivity, Efficiency, and Staffing. The VHA Facility Complexity Model categorizes medical facilities for purposes such as operational reporting, performance measurement, and research studies. Complexity levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered the most complex, and Level 3 facilities are the least complex. <http://opes.vssc.med.va.gov/Pages/Facility-Complexity-Model.aspx>. (The website is an internal website to VHA and was accessed on April 27, 2020.)

³ VHA Directive 1108.12, *Management and Monitoring of Pharmaceutical Compounded Sterile Preparations*, November 5, 2018.

preparations must be correctly prepared, packaged, labeled and dispensed in accordance with United States Pharmacopeia Chapter <797>.⁴ The final compounded sterile preparation label includes the patient's name; unit of location; date prepared; "identity and strength of additive(s) and diluent(s);" volume, route, and rate of administration; product expiration date; storage requirements; barcode; and identification of the staff that prepared and checked the product for accuracy, one of whom must be a clinical pharmacist.⁵ VHA requires pharmacy staff to "affix the CSP [compounded sterile preparation] label directly to the preparation" before delivering it to the patient care area.⁶ Pharmacy staff apply the unique label to the compounded sterile preparation and then nursing staff scan the barcode on the label into the BCMA system for validation prior to administration.⁷

Fentanyl

The National Institute on Drug Abuse defines fentanyl as a synthetic opioid, similar to morphine but 50 to 100 times stronger; it is considered a Schedule II [controlled substance](#).⁸ Fentanyl may be administered intravenously to maintain sedation for intensive care patients who are on a ventilator.

Norepinephrine

Norepinephrine, also known as levophed, is administered intravenously and is generally used to restore and maintain a patient's blood pressure.⁹

Request for Review and Related Concerns

The OIG conducted a healthcare inspection at the facility to review patient safety concerns identified following assistance provided during an OIG Office of Investigations inquiry into the loss of a controlled substance and a patient's death. According to the OIG Office of

⁴ VHA Directive 1108.06. *Inpatient Pharmacy Services*, February 8, 2017. United States Pharmacopeia is an independent, not-for-profit, nongovernmental organization of experts who "[set] quality, purity, strength, and identity standards for medicines, food ingredients, and dietary supplements." *What is US Pharmacopeia? Quality Matters?*, <https://qualitymatters.usp.org/what-us-pharmacopeia>. (The website was accessed May 5, 2020.) United States Pharmacopeia "develops standards for preparing compounded sterile medications to help ensure patient benefit and reduce risks such as contamination, infection or incorrect dosing." *General Chapter Pharmaceutical Compounding—Sterile Preparations*, <https://www.usp.org/compounding/general-chapter-797>. (The website was accessed April 23, 2020.)

⁵ VHA Directive 1108.06.

⁶ VHA Directive 1108.06.

⁷ VHA Directive 1108.06. Facility Memorandum 118-26, *Bar Code Medication Administration (BCMA)*, July 10, 2017.

⁸ National Institute of Health, National Institute on Drug Abuse, *Fentanyl*. www.drugabuse.gov/drugs-abuse/fentanyl. (The website was accessed February 7, 2020.)

⁹ Prescribers' Digital Reference. <https://pdr.net/drug-summary/Levophed-norepinephrine-bitartrate-868>. (The website was accessed on June 8, 2020.)

Investigations, the facility's VA Police, per VHA handbook, alerted the OIG that there was a loss of a controlled substance in spring 2019.¹⁰ In late 2019, following the completion of an investigation by the Office of Investigations, the OIG opened a healthcare inspection to evaluate safety concerns related to the patient at issue. Specifically, the OIG reviewed the following concerns:

- The improper sending of a medication label and subsequent mislabeling of a medication
- The failure of intensive care unit (ICU) nursing staff to follow high-risk medication administration policies and procedures that resulted in a medication error and incomplete documentation

During the course of the inspection, the OIG identified additional concerns with the securing of intravenous (IV) controlled substances and the facility's response to the adverse event.

Scope and Methodology

The OIG initiated an inspection in January 2020 and conducted a site visit the week of March 9, 2020.

The OIG interviewed the Facility Director; Associate Director of Patient Care Services; Chiefs of Staff, Pulmonary, Pharmacy, and Quality Management; the Assistant Nurse Executive; the Risk Manager; the Pharmacy Informatics and Pharmacoeconomic Program and Compounded Sterile Preparations Program managers; the Patient Safety Manager; the BCMA Coordinator; the inpatient pharmacy supervisor; the inpatient and ICU clinical pharmacists; an assistant nurse manager; and ICU nursing staff.

The OIG team reviewed relevant VHA and facility policies, Joint Commission standards, peer reviews, a root cause analysis, relevant staff trainings and competencies, relevant committee and staff meeting minutes, intravenous (IV) medication and BCMA communication logs, Picis and Alaris™ smart pump documentation, medication label reports, and the identified patient's electronic health record (EHR).¹¹

¹⁰ VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock)*, November 16, 2010. The handbook was incorporated into VHA Directive 1108.01(1) *Controlled Substances Management*, May 1, 2019, amended December 2, 2019, and contains similar language related to VA police contacting OIG about missing controlled substances.

¹¹ VA Technical Reference Model v20.1, *PICIS Critical Care Manager*. Picis is a software that "is used to identify and assess patterns and potential complications in ICU patients." The software collects the patient's vital signs and other data through connections with medical monitoring devices and IV pumps. <https://www.oit.va.gov/Services/TRM/ToolPage.aspx?tid=11507>. (The website was accessed on February 10, 2020.) BD, *BD Alaris™ Pump Module*. The BD Alaris™ smart pump is an infusion device that allows infusions to be delivered to patients continuously or intermittently. The pump is a single point of care unit that allows up to four IV infusion channels to be attached and administered to a patient. <https://www.bd.com/en-us/offering/capabilities/infusion-therapy/infusion-system-devices/>. (The website was accessed on February 10, 2020.)

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).

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, § 7, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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, in their early seventies, had multiple known medical problems including [chronic lymphocytic leukemia](#), [diabetes mellitus](#), [coronary artery bypass graft surgery](#), [hyperlipidemia](#), [chronic kidney disease](#), [atrial flutter](#) on [anticoagulant](#) medication, and an unintentional weight loss of 40–60 pounds in the preceding months.¹²

In spring 2019 (Day 1), the patient presented to the facility’s Emergency Department for dizziness, shortness of breath, and right-sided chest pain after falling at home and striking their right chest. The patient’s blood pressure on presentation was 94/53 and x-rays showed that the patient had four fractured ribs on the right chest. Laboratory studies revealed that they had worsening kidney function compared to their previous results.

The following day, the patient was admitted to the facility medicine unit for IV fluid therapy, pain control, and further monitoring. The patient received IV fluids to treat hypotension (low blood pressure). An [electrocardiogram](#) showed a new left [bundle branch block](#). The Cardiology Service evaluated the patient and recommended an [echocardiogram](#). The admitting physicians noted abnormal [liver function tests](#) and ordered blood tests to evaluate for [hepatitis](#). The admitting physicians attributed an elevated white blood cell count to the chronic lymphoid leukemia and noted plans for outpatient management by the patient’s hematologist.

The patient continued with intermittent episodes of hypotension on Days 3 and 4. [Blood cultures](#) were obtained to evaluate for [sepsis](#) as a cause of the hypotension. On Day 4, the cardiology consultant reviewed the echocardiogram and determined that there had not been a change from prior echocardiograms and that no further cardiac workup was indicated.

¹² The OIG uses the singular form of their (they) in this report for the purpose of patient privacy.

At 7:00 p.m. on Day 4, a medicine unit resident physician evaluated the patient who had become lethargic and diaphoretic (sweating heavily). Radiologic studies and laboratory tests were ordered. The radiologist reported the chest x-ray done at 7:22 p.m. demonstrated low [lung volumes](#) with airspace disease. At 9:36 p.m., the patient's blood tests showed an elevated [lactic acid](#) level and antibiotics were started.¹³ At approximately 10:00 p.m., a [computerized tomography scan](#) of the head demonstrated a left [sphenoid](#) sinus lesion; the radiologist recommended a consultation with an ears, nose, and throat specialist for a possible [fungus ball](#). Although the patient was on 100 percent oxygen by mask, the [blood gas](#) results showed that the patient was retaining carbon dioxide and had [acidosis](#). The patient's [hemoglobin](#) was unchanged from a laboratory test done earlier the same day.

On Day 5, at 5:14 a.m., the medicine unit nurse noted the patient had developed concerning signs and symptoms: "agonal respirations, diaphoretic and unresponsive to verbal stimuli." A [code blue](#) was immediately called and resuscitation efforts were initiated. [Epinephrine](#) was given, and a shock was administered with the return of spontaneous circulation. The patient's blood pressure was recorded as 193/80 at 5:27 a.m. The patient was intubated (a breathing tube inserted into the airway to assist breathing) at 5:31 a.m. Fentanyl was ordered at 5:45 a.m. for sedation, but the fentanyl was not administered until the patient was transferred to the ICU. According to the ICU assistant nurse manager, norepinephrine was prepared by nursing staff at the patient's bedside at the time of the code blue and administered by [titration](#). A chest x-ray obtained at 5:46 a.m. showed persistent findings of "congestive failure and potentially [an] underlying infiltrate." At 5:49 a.m., the patient was transferred to the ICU.

The events detailed below were after the code blue on the medicine unit and took place over a six-hour time span in the ICU.

At 6:03 a.m., an ICU resident physician ordered [vasopressin](#) and reordered fentanyl at 6:04 a.m., at the same dosage to be titrated for sedation while intubated.

The night shift nurse admitted the patient to the ICU and documented in a nursing progress note starting the patient on vasopressin at 0.04 micrograms per minute at 6:23 a.m., fentanyl at 50 micrograms per hour at 6:30 a.m., and norepinephrine at 0.1 micrograms per kilogram per minute at 6:45 a.m. The night shift nurse noted that the patient had a [junctional/nodal rhythm](#) and frequent ectopy (irregular heart rhythm). At 7:26 a.m., the ICU resident physician ordered norepinephrine 1 milligram per milliliter to be started at 0.05 micrograms per kilogram per minute to be titrated every five minutes to a maximum of 3 micrograms per kilogram per minute.

At 7:55 a.m., a day shift nurse was notified of a critical laboratory result that showed a low hemoglobin value, and another ICU resident physician ordered transfusions of two units of packed red blood cells.

¹³ The patient had a lactic acid level of 2.3 millimoles per liter, and a normal range is 0.5–2.2 millimoles per liter.

At 8:29 a.m., the ICU fellow physician placed a central venous catheter for IV access for medications. At 8:51 a.m., a day shift nurse received a critical laboratory test result for [troponin](#).

At 9:50 a.m., a second code blue was called when the patient was noted to be in [asystole](#); they were resuscitated with a return of spontaneous circulation at 10:04 a.m. According to BCMA, Picis, and the Alaris™ pump data, the patient continued to receive norepinephrine after the code. Although fentanyl had been ordered and the night shift nurse documented in the patient's EHR that fentanyl was started at 6:30 a.m., fentanyl does not appear on the patient's BCMA record.

At 10:19 a.m., the attending ICU physician discussed life-sustaining treatment with the patient's spouse. The spouse requested that staff continue current supportive efforts but not attempt resuscitation as per the patient's wishes. The ICU physician determined the patient likely had [septic shock](#).

At approximately 11:00 a.m., the patient's lactic acid levels increased from 6.1 millimoles per liter at 7:00 a.m. to 13.2 millimoles per liter.

At 11:14 a.m., although the patient was on a ventilator at 100 percent oxygen, a blood gas demonstrated worsening oxygenation with an oxygen level of 33 (normal range 80–105) and acidosis with a pH of 6.99 (normal range pH 7.35–7.41). The ICU attending physician documented that “the prognosis is very grave due to underlying medical comorbidities and multiorgan failures.”

The patient died at 12:00 p.m. on Day 5.

Inspection Results

1. Improper Sending of a Medication Label and Mislabeling of a Medication

Sending an Unaffixed Label

The OIG determined that pharmacy staff failed to follow the intent of VHA and facility policies for dispensing compounded sterile preparation medications by sending an unaffixed label through the [pneumatic tube system](#).

VHA policy states that pharmacy staff must affix labels, complete with identification of the pharmacy staff who prepared and checked the mixture, directly to all compounded sterile preparations.¹⁴ Facility policy states that pharmacists are responsible for the labeling of all medications they dispense.¹⁵ In addition, VHA and facility policies follow the United States

¹⁴ VHA Directive 1108.06, *Inpatient Pharmacy Services*, February 8, 2017.

¹⁵ Facility Memorandum 119-3, *Medication Management Policy*, June 30, 2017.

Pharmacopeia Chapter <797> standard for preparation and dispensing of compounded sterile preparations, which states all compounded sterile preparations are to be inspected for accuracy of ingredients, packaging, and labeling before they are dispensed.¹⁶

An order for the IV fentanyl was entered at 5:45 a.m. and dispensed with a label at 6:01 a.m. by the night shift pharmacist. A night shift ICU nurse told the OIG about receiving and signing for the IV fentanyl bag and the patient's night shift ICU nurse initiated the infusion at 6:30 a.m.¹⁷ ICU nursing staff informed the OIG that after shift change, the day shift nurse attempted to scan the IV fentanyl label into the BCMA system. Nursing staff told the OIG that an ICU nurse called the pharmacy and requested a new label. The OIG determined from the IV label log that pharmacy staff did not print a new IV fentanyl label, but noted that the pharmacy printed a new IV norepinephrine label at 7:37 a.m. The OIG found that sometime between 7:37 a.m. and 8:18 a.m., the duplicate IV norepinephrine label was sent via the pneumatic tube system to the ICU. An ICU nurse placed the IV norepinephrine label over the existing IV fentanyl label, and scanned the incorrect label into BCMA. From 8:18 a.m. until 11:45 a.m., the patient received IV fentanyl even though the medication was labeled IV norepinephrine.

During an interview with the OIG, the night shift pharmacist denied receiving a call from an ICU nurse requesting a new label or sending the unaffixed label through the pneumatic tube system. The OIG could not determine which nursing staff called pharmacy services for a new IV label or which pharmacy staff sent the new IV norepinephrine label.

The OIG concluded that the delivery of an unaffixed label did not comply with the intent of VHA or facility policy, which states pharmacists are responsible for labeling of dispensed compounded sterile preparations. The improper sending of an unaffixed label through the pneumatic tube system by pharmacy staff and subsequent mislabeling of a medication and failure to follow medication administration policies by ICU nursing staff resulted in a medication error.

Mislabeled an IV Medication

The OIG determined that facility ICU nursing staff failed to follow facility medication administration policies when labeling a medication that was being administered to the patient.

¹⁶ VHA Directive 1108.12. Facility Memorandum 119-3. *General Chapter, <797>Pharmaceutical Compounding – Sterile Preparations*, <https://www.usp.org/compounding/general-chapter-797>. (The website was accessed April 23, 2020.)

¹⁷ According to an ICU nurse, the dispensed IV fentanyl order was associated with the medical/surgical unit and became inactive upon the patient's transfer to the ICU. Only labels associated with active orders will scan into BCMA.

Facility policy states that nursing staff must adhere to the five rights to ensure the safe administration of medications.¹⁸ BCMA software is utilized for documenting medication administration.¹⁹

Nursing staff informed the OIG that on Day 5, following shift change, the patient's day shift ICU nurse was unable to scan the barcode on the IV fentanyl label into BCMA. The ICU assistant nurse manager instructed the day shift nurse to call the pharmacy to "get another drip" or "get a label." Nursing staff informed the OIG that when unable to scan a medication they can manually document the administration of the medication. Nursing staff told the OIG that it was common practice to request from pharmacy services a new label when a barcode would not scan into BCMA. Nursing staff reported that pharmacy staff sent a label with a new barcode through the pneumatic tube system to the ICU. The OIG confirmed that the incorrect label (IV norepinephrine) was placed on the IV fentanyl bag.

The OIG concluded that ICU nursing staff failed to comply with facility policy by not verifying the five rights when affixing the new incorrect norepinephrine label onto the IV fentanyl bag. The deficient practices by nursing staff led to the patient receiving a mislabeled medication at incorrect dosages.

2. High-Alert IV Medication Administration

Following Medication Orders

The OIG determined that ICU nursing staff failed to follow facility policies and physician's orders in administering two IV medication titration orders, fentanyl and norepinephrine.

Medications are generally administered by nurses in response to a medication order from a physician.²⁰ High-alert medications are known to have a high percentage of medication errors and have a higher risk of significant harm to patients.²¹ For medications requiring titration (increase or decrease), the physician's order should include "the initial or start rate of infusion (dose per minute), incremental units the rate can be increased or decreased, maximum rate (dose) of infusion, and the objective [clinical endpoint](#)."²²

¹⁸ Facility Memorandum 119-3. Facility Memorandum 118-45, *Administration of Medications*, June 30, 2017.

¹⁹ Facility Memorandum 118-26.

²⁰ Facility Memorandum 119-3

²¹ Facility Memorandum 119-3.

²² Facility Memorandum 118-48, *Administration of Intravenous (IV) Fluids and IV Medications Via IV Piggy Back (IVPB) and IV Push (IVP)*, January 31, 2019.

Fentanyl Administration

At 8:17 a.m., after the patient had been intubated, the ICU physician entered an order for IV fentanyl that was to be titrated to a Richmond Agitation-Sedation Scale ([RASS](#)) score of -1. The nursing staff did not follow the physician's order; rather the ICU day shift nurse documented that the patient's RASS score was at "-4 or -5" and the patient's mental status was "lethargic, comatose/unresponsive." Based on the documented RASS score, the patient was considered more sedated and should not have required additional sedation. The OIG determined that the night shift nurse initiated the administration of IV fentanyl at a higher rate than was ordered by the physician. At 8:02 a.m., the day shift nurse paused the medication for five minutes, readjusted the dose, and restarted the administration of the IV fentanyl rate to the ordered dose. At these two points of adjustment, the day shift nurse did not document the assessment associated with the rate change into the patient's EHR.

Norepinephrine Administration

The ICU physician entered an order for IV norepinephrine 8 milligrams in 250 milliliters to be titrated to maintain a [mean arterial pressure](#) (MAP) >65. The OIG determined that ICU nursing staff did not follow the physician's orders when titrating the norepinephrine dose to ensure a MAP of >65.

The OIG concluded that facility ICU nursing staff did not follow medication orders or the facility medication administration policy.

Documentation of Medication Administration

The OIG did not find documentation on Day 5, of initial administration of fentanyl, second verification of the fentanyl administration, reassessment following rate change to medications, or second verification with each fentanyl rate change. Documentation was completed for the initial administration of norepinephrine and a second verification was completed.

Facility policy states that a nurse completes an assessment of the patient's response to the medications administered and notifies the physician of any adverse changes in the patient's condition.²³ Facility policies require ICU nursing staff to document medication infusions in Picis and BCMA.²⁴ Fentanyl and norepinephrine are considered high-alert medications and require a "double-check" by two licensed personnel (verifiers) before the medication can be administered. In addition, as a controlled substance, fentanyl infusions also require a second verifier for rate changes.²⁵ For controlled substances, nursing staff are required to document the patient's

²³ Facility Memoranda 119-3. Facility Memorandum 118-48.

²⁴ Facility Memorandum 118-26. Facility Memorandum 118-4, *Documentation of Nursing Care*, June 30, 2017.

²⁵ Facility Memorandum 118-48. Facility Memorandum 119-3.

“respiratory rate, sedation level, pain level,” medication “dosage for the shift, and any increases or decreases in the infusion rate” once an hour for four hours and then every four hours for the duration of the infusion. Nursing staff monitor for side effects of the medication and document any treatments pursued in the EHR.²⁶

The OIG determined that nursing staff did not consistently document the initial administration or assessment of the patient’s responses when administering fentanyl. Nursing staff also did not consistently document rate changes or assessments when administering norepinephrine (see table 1). The lack of complete documentation did not ensure an accurate record of the medications administered.

Table 1. Administration and Assessment of High-Alert Medications

Documentation	Fentanyl	Norepinephrine
Initial Administration	No	Yes
2nd Verifier of Initial Administration	No	Yes
Rate Change Administration	No	No
2nd Verifier of Rate Change Administration	No	N/A*
Initial Assessment and Patient’s Response	No	No
Rate Change Assessment and Patient’s Response	No	No

*Source: OIG analysis of documentation of the administration and assessment of a patient.
N/A—not applicable*

3. Additional Finding: Securing Controlled Substances

The OIG determined that the facility did not follow policy by ensuring that IV controlled substances were secured while being infused. Facility policy requires that continuous opioid (controlled substance) infusions be “securely attached to the IV pole” when administered in the ICU.²⁷

The ICU assistant nurse manager told the OIG that the ICU did not have a way to securely attach the IV fentanyl bag to the IV pole while infusing the medication. At the time of the site visit, the Chief of Pharmacy informed the OIG that they had ordered secured boxes, but the boxes did not prevent possible diversion. The Chief of Pharmacy stated they were looking for appropriate locked boxes to secure IV opioids (fentanyl) to an IV pole. In addition to securing the controlled substance in a locked box to prevent diversion, the locked box would have added an extra

²⁶ Facility Memorandum 118-48.

²⁷ Facility Memorandum 118-48.

checkpoint for nursing staff to confirm the unaffixed label against the medication being administered.

The OIG concluded that the IV fentanyl bag was not secured to the IV pole in a locked box as required.

4. Additional Finding: Facility Response

Quality Management Reviews

The OIG determined that the facility did not conduct a thorough evaluation of the mislabeling of a medication that resulted in an adverse event.

VHA and facility policies identify several actions that are required to be completed following an adverse event. These actions are intended to promote a “culture of safety” that encourages a nonpunitive environment to address concerns related to systems of care and to improve patient outcomes.²⁸ The actions may include submitting a Joint Patient Safety Report, chartering a root cause analysis, coordinating peer reviews, and conducting an institutional disclosure.

The OIG determined that the facility completed a root cause analysis but found that the facility did not file a Joint Patient Safety Report that addressed the mislabeling of a medication. This lack of information led to an inability of the facility to identify potential staff to be peer reviewed per the facility’s Risk Manager and no institutional disclosure per the facility’s Chief of Staff.

Joint Patient Safety Report

The OIG’s inspection did not reveal that a Joint Patient Safety Report had been filed that specifically addressed the mislabeling of the fentanyl bag.

VHA requires staff to identify and report adverse events through the electronic reporting system.²⁹ Facility policy identifies medication errors as an adverse event that should be entered into the Joint Patient Safety Report system.³⁰ Once reported, the designated nurse manager and associate nurse executive review and address with staff the medication error.³¹

On Day 5 between 7:37 a.m. and 8:18 a.m., pharmacy sent an unaffixed IV norepinephrine label to the ICU and a nurse affixed that label to an IV fentanyl bag that was being administered to the patient. ICU nurse leaders told the OIG that the mislabeling of the IV fentanyl bag was discovered on Day 8.

²⁸ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. Facility Memorandum 11-24, *Patient Safety Improvement Program*, September 29, 2016.

²⁹ VHA Handbook 1050.01.

³⁰ Facility Memorandum 11-24.

³¹ Facility Memorandum 118-45.

The OIG concluded that facility staff failed to report the mislabeling of the IV fentanyl bag as a medication error.

Peer Review

The OIG determined that the facility did not conduct a peer review on key clinical staff involved in the mislabeling of a medication.

VHA and facility policies define peer review for quality management as a confidential and nonpunitive review of individual clinical decisions and actions with a primary goal of overall improvement in patient care.³² Facility policy identifies one of the risk manager's responsibilities is to coordinate peer review. In addition, the facility risk manager and patient safety manager are to collaborate on the review of processes and systems with appropriate recommendations and actions to improve patient safety and good clinical outcomes.³³

The OIG concluded that because the Risk Manager was unaware of the mislabeling of a medication, the facility did not conduct peer reviews on all relevant clinical staff.

Institutional Disclosure

The OIG determined that the facility did not conduct an institutional disclosure of the mislabeling of a medication that resulted in an adverse event.

VHA and facility policy requires disclosure of injury related to an adverse event to patients or their personal representatives.³⁴ VHA and the facility define institutional disclosure as a formal process in which facility leadership and respective clinician(s) inform the patient or representative about the adverse event.³⁵ Facility policy lists medication error as a reportable adverse event.³⁶ The intent of institutional disclosure is to fully inform patients and their families about all clinically significant facts related to the harm caused by VA medical care and options to pursue potential compensation.³⁷ When institutional disclosures are not completed as required, patients and their families may inadvertently be denied their rights.

³² VHA Directive 1190, *Peer Review*, November 21, 2018. Facility Memorandum 11Q-8, *Peer Review for Quality Management*, March 31, 2018.

³³ Facility Memorandum 11-36, *Risk Management Program*, July 7, 2016. This facility memorandum was rescinded and replaced by Facility Memorandum 11Q-17, *Risk Management Program*, November 30, 2019. Both memorandums contain similar language related to the collaboration between the risk manager and the patient safety manager to improve patient safety. Facility Memorandum 11-24.

³⁴ VHA Directive 1050.01. Facility Memorandum 11-15.

³⁵ VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. Facility Memorandum 11Q-17.

³⁶ Facility Memorandum 11-24.

³⁷ VHA Directive 1004.08. Facility Memorandum 11-15.

The patient's ICU physician told the OIG that the patient had a very grave prognosis from the beginning and that following the second code blue the family decided against resuscitation efforts. The Chief of Staff told the OIG about becoming aware of the medication error, the mislabeling of a medication, through an internal review, and decided not to conduct an institutional disclosure because of the patient's medical history, the two recent episodes of sudden cardiac death, and the family's decision against further resuscitation efforts.

The OIG concluded that although the patient had a very grave prognosis and the spouse decided against further resuscitation efforts, the facility failed to comply with policy by not conducting an institutional disclosure for the mislabeling of a medication, which was a medication error.

Conclusion

Pharmacy staff failed to follow the intent of the VHA and facility dispensing policies and procedures. When the barcode would not scan into BCMA on a dispensed and labeled IV fentanyl bag, pharmacy staff sent an unaffixed label (for IV norepinephrine) through the pneumatic tube system to the ICU. The improper sending of an unaffixed label through the pneumatic tube system by pharmacy staff, the subsequent mislabeling of a medication, and the failure to follow medication administration policies by ICU nursing staff resulted in a medication error.

Nursing staff failed to follow facility medication administration policies and procedures by affixing a label, sent by pharmacy, to a medication without verifying the five rights; not following medication orders or facility policy in the administration of medications; and not documenting the assessment, reassessments, initial administration, and second verifiers when administering IV medications. The failures resulted in incomplete and inaccurate records of medication administration.

The OIG determined that the IV fentanyl bag was not securely attached to the IV pole as required. Securing the fentanyl in a locked box may have prevented the ICU nurse from placing the IV norepinephrine label over the IV fentanyl label.

The facility failed to follow VHA and facility policy in their response to the identification of mislabeling the IV fentanyl as IV norepinephrine. The facility did not address the mislabeling of the medication in a Joint Patient Safety Report. This lack of information led to an incomplete peer review process by failing to identify staff directly involved in the mislabeling.

Although the patient had a grave prognosis, the facility failed to comply with policy by not conducting an institutional disclosure for the mislabeling of a medication.

Recommendations 1–8

1. The Southeast Louisiana Veterans Health Care System Director educates pharmacy staff on the Veterans Health Administration and Southeast Louisiana Veterans Health Care System policies related to unaffixed medication labels, and monitors compliance.
2. The Southeast Louisiana Veterans Health Care System Director ensures that the intensive care unit nursing staff comply with the five rights of medication administration prior to administering medications.
3. The Southeast Louisiana Veterans Health Care System Director ensures that the intensive care unit nursing staff administer medications in accordance with physician orders as required by Veterans Health Administration and Southeast Louisiana Veterans Health Care System policies.
4. The Southeast Louisiana Veterans Health Care System Director confirms that the intensive care unit nursing staff comply with the Southeast Louisiana Veterans Health Care System policy for high-alert and high-risk medications.
5. The Southeast Louisiana Veterans Health Care System Director validates compliance with obtaining locked boxes to secure controlled substances for intravenous medications administered on the inpatient units.
6. The Southeast Louisiana Veterans Health Care System Director verifies that facility staff are aware of how to submit Joint Patient Safety Reports that contain complete and accurate information.
7. The Southeast Louisiana Veterans Health Care System Director evaluates the circumstances surrounding the death of the patient and determines if peer reviews of relevant clinical staff are warranted.
8. The Southeast Louisiana Veterans Health Care System Director evaluates the circumstances surrounding the death of the patient and determines if an institutional disclosure is warranted.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: September 18, 2020

From: Director, South Central VA Health Care Network (10N16)

Subj: Healthcare Inspection—Deficiencies in Pharmacy and Nursing Processes at the Southeast Louisiana Health Care System in New Orleans

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

1. The South Central VA Health Care Network (VISN 16) has reviewed and concur the findings and recommendations in the OIG draft report—Deficiencies in Pharmacy and Nursing Processes at the Southeast Louisiana Veterans Health Care System, New Orleans, LA.

(Original signed by:)

Skye McDougall, PhD
Network Director

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: September 16, 2020

From: Director, Southeast Louisiana Health Care System (629/00)

Subj: Healthcare Inspection—Deficiencies in Pharmacy and Nursing Processes at the Southeast Louisiana Health Care System in New Orleans

To: Director, South Central VA Health Care Network (10N16)

1. Southeast Louisiana Veterans Health Care System acknowledges receipt of the draft report and submits the attached comments in a separate Microsoft Word Document.
2. If you should have any questions please contact Ms. MaryBeth Cooper, Performance Improvement Coordinator.

(Original signed by:)

Fernando O Rivera, FACHE
Medical Center Director

Facility Director Response

Recommendation 1

The Southeast Louisiana Veterans Health Care System Director educates pharmacy staff on the Veterans Health Administration and Southeast Louisiana Veterans Health Care System policies related to unaffixed medication labels and monitors compliance.

Concur.

Target date for completion: December 31, 2020

Director Comments

Southeast Louisiana Veterans Health Care System recognizes the importance of the medication administration process to patient safety. To ensure the safety of our Veterans, all Pharmacy staff completed re-training on the Veterans Health Administration (VHA) and Southeast Louisiana Veterans Health Care System (SLVHCS) policies related to unaffixed medication labels by June 230, 2019. The following policies and Standard Operating Procedures (SOP) were re-trained: Numbered Memorandum 119-03 Medication Management, VHA Directive 1108.06 Inpatient Pharmacy Services, SLVHCS Numbered Memorandum 118-26 Barcode Medication Administration (BCMA) Policy, SLVHCS Numbered Memorandum 119-04 Sterile Compounding Policy, SOP for Medications That Do Not Scan process, and the expectation that unaffixed medication labels are not sent from the pharmacy.

Pharmacy supervisors will observe for appropriate labeling procedures and tracers will be performed by Pharmacy staff monthly.

Recommendation 2

The Southeast Louisiana Veterans Health Care System Director ensures that the intensive care unit nursing staff comply with the five rights of medication administration prior to administering medications.

Concur.

Target date for completion: December 31, 2020

Director Comments

Recognizing the primary function of nursing medication administration as a key factor in assuring the safety of our Veterans, 100% of ICU nursing staff are participating in refresher training on Administration of Medication SOP 118-45 5 Rights of Medication Administration including competency validation that will be completed by September 30, 2020. Training and competency validation in compliance with the five rights of medication administration is

scheduled to occur annually and has been added to the Nursing New Employee Orientation curriculum.

Nursing will perform daily audits of barcode scanning until a consistent goal of 100% compliance has been achieved for three consecutive months. Audit results will be reported monthly at the Nursing Quality Safety Council.

Recommendation 3

The Southeast Louisiana Veterans Health Care System Director ensures that the intensive care unit nursing staff administer medications in accordance with physician orders as required by Veterans Health Administration and Southeast Louisiana Veterans Health Care System policies.

Concur.

Target date for completion: December 31, 2020

Director Comments

Recognizing the primary function of nursing medication administration in accordance with physician orders as a key factor in assuring the safety of our Veterans, 100% of Intensive Care nursing staff are receiving refresher training on the Southeast Louisiana Health Care System policy NM11-45 Medication Administration Policy, in accordance with physician orders as required by Veterans Health Administration and Southeast Louisiana Veterans Health Care System. Nursing will perform weekly chart audits to confirm 100% compliance for three consecutive months with medication being administered in accordance with physician orders. Audit results will be reported monthly at the Nursing Quality and Safety Council.

Recommendation 4

The Southeast Louisiana Veterans Health Care System Director confirms that the intensive care unit nursing staff comply with the Southeast Louisiana Veterans Health Care System policy for high-alert and high-risk medications.

Concur.

Target date for completion: December 31, 2020

Director Comments

Nursing is auditing 100% of all high-risk and high-alert medications that have been administered in the ICU for validation of second verification process in BCMA. Compliance with the verification process will be monitored until 100% is achieved for three consecutive months. Audit results will be reported monthly at the Nursing Quality and Safety Council.

Recommendation 5

The Southeast Louisiana Veterans Health Care System Director validates compliance with obtaining locked boxes to secure controlled substances for intravenous medications administered on the inpatient units.

Concur.

Target date for completion: October 1, 2020

Director Comments

Locked boxes were originally purchased August 2019 by the Inpatient Pharmacy Supervisor. The locked boxes received lacked optimal design to prevent diversion or to connect safely to facility IV polies. An alternate locked box design was located that would work for the system in place and was purchased July 13, 2020. A new SOP was developed for pharmacy staff to place all controlled substances in the locked boxes during dispensing and will be delivered to the floor already locked in box. Training for 100% of Inpatient Pharmacy staff and Nursing staff is to be completed by September 30, 2020 and the new process will be implemented October 1, 2020.

Recommendation 6

The Southeast Louisiana Veterans Health Care System Director verifies that facility staff are aware of how to submit Joint Patient Safety Reports that contain complete and accurate information.

Concur.

Target date for completion: December 31, 2020

Director Comments

All facility staff will receive refresher training for submitting a complete and accurate Joint Patient Safety Report (JPSR). New employees are required to complete the training tutorial within 90 days of New Employee Orientation. Monitoring of completed training will be performed by the Patient Safety Office until 95% compliance with training for three consecutive months is demonstrated. Audit compliance will be reported to the Quality, Safety, and Value Committee and Executive Leadership Council.

Recommendation 7

The Southeast Louisiana Veterans Health Care System Director evaluates the circumstances surrounding the death of the patient and determines if a peer review of relevant clinical staff is warranted.

Concur.

Target date for completion: October 21, 2020

Director Comments

The electronic medical record documentation of the patient's care was reviewed by Risk Management through the usual process of Peer Review for Quality Management that is performed on all inpatient deaths and two physicians, one each from Medicine and Critical Care Medicine Services were peer reviewed. The initial reviewers in both cases assigned level one ratings to the reviews indicating most experienced, competent clinicians would have managed the case in a similar manner. The Peer Review Committee agreed with both level one ratings. After further information was received including additional details of the patient's care that were not documented in the medical record, Risk Management also assigned peer reviews for the nursing and pharmacy staff involved in the case; these are underway with a target completion date of 10/21/2020. An Administrative Inquiry was conducted by nursing shortly after the patient's death and inquiry recommendations did not include peer review. The Southeast Louisiana Veterans Health Care System will continue to conduct peer reviews and follow the guidance outlined VHA Directive 1190 Peer Review for Quality Management.

Recommendation 8

The Southeast Louisiana Veterans Health Care System Director evaluates the circumstances surrounding the death of the patient and determines if an institutional disclosure is warranted.

Concur.

Target date for completion: October 21, 2020

Director Comments

At the time of the event, the Chief of Staff reviewed the case and did not believe an Institutional Disclosure was warranted as the medication error was not thought to have caused the patient's death in the medical opinion of the treating team. However, for additional thoroughness, a pre-disclosure meeting was held on September 11, 2020 to determine if an institutional disclosure was warranted. It was determined that a disclosure will be done as it is believed the potential was there to cause harm to the patient. A private meeting will be scheduled with the family member, pending availability, to empathetically discuss the adverse events and inform the family member of their rights, including the right to file a tort claim. The expected completion date 10/21/2020. The Southeast Louisiana Veterans Health Care System will continue to follow the guidance outlines in VHA Directive 1004.08 Disclosure of Adverse Events to Patients.

Glossary

acidosis. The condition of “too much acid in the body fluids.” “Metabolic acidosis develops when too much acid is produced in the body.”¹

administration. The act of giving a medication.²

anticoagulant. A medication or substance that prevents blood from clotting.³

asystole. “Also known as flatline. It is a state of cardiac standstill with no cardiac output and no ventricular [movement] depolarization.”⁴

atrial flutter. A heart condition in which the upper chambers of the heart beat too fast; the rhythm is regular.⁵

blood cultures. Laboratory tests to identify which microorganisms, such as bacteria or fungus, are causing an infection.⁶

blood gas. A test that measures the pressures and concentration of oxygen and carbon dioxide in the blood.⁷

bundle branch block. A heart condition that causes delays or blockages in the transmission of the electrical impulses that allow the heart to beat. These delays can occur in the left or right bottom chambers of the heart.⁸

chronic kidney disease. “describes the gradual loss of kidney function” that causes elevated “levels of fluid, electrolytes and waste to build up in [the] body.”⁹

¹ MedlinePlus Medical Encyclopedia, *Acidosis*, <https://medlineplus.gov/ency/article/000335.htm>. (The website was accessed on May 15, 2020.)

² Merriam-Webster, *Definition of administration*. <https://www.merriam-webster.com/dictionary/administration>. (The website was accessed on May 12, 2020.)

³ Merriam-Webster, *Definition of anticoagulant*. <https://www.merriam-webster.com/dictionary/anticoagulant>. (This website was accessed May 19, 2020.)

⁴ Sandy N. Shah, *Asystole*. <https://emedicine.medscape.com/article/757257-overview>. (This website accessed May 1, 2020.)

⁵ Mayo Clinic, *Atrial Flutter*, <https://www.mayoclinic.org/diseases-conditions/atrial-flutter/symptoms-causes/syc-20352586>. (The website was accessed on May 14, 2020.)

⁶ National Cancer Institute, *Blood Culture*, <https://www.cancer.gov/publications/dictionaries/cancer-terms>. (This website was accessed on May 14, 2020.)

⁷ Merriam-Webster, *Blood Gas*, <https://www.merriam-webster.com/medical/blood%20gas>. (The website was accessed May 15, 2020.)

⁸ Mayo Clinic, *Bundle Branch Block*. <https://www.mayoclinic.org/diseases-conditions/bundle-branch-block/symptoms-causes/syc-20370514>. (The website was accessed on May 14, 2020.)

⁹ Mayo Clinic, *Chronic Kidney Disease*, <https://www.mayoclinic.org/diseases-conditions/chronic-kidney-disease/symptoms-causes/syc-20354521>. (The website was accessed on May 14, 2020.)

chronic lymphocytic leukemia. A “cancer of the body’s blood-forming tissues” such as the lymphatic system. “Lymphatic tissue makes up [the] immune system.”¹⁰

clinical endpoint. A measured outcome that can objectively determine if an intervention achieves the desired action in a patient’s condition.¹¹

code blue. A medical emergency when medical personnel are attempting to resuscitate a patient after cardiac or respiratory arrest.¹²

computerized tomography (CT) scan. “Combines a series of x-ray images taken from different angles around [the] body and uses computer processing to create cross-sectional images (slices) of the bones, blood vessels and soft tissues.”¹³

controlled substance. Drugs and medications in which the law regulates the use and possession.¹⁴

coronary artery bypass surgery. The removal of a “blood vessel from the leg, arm, or chest” that is used to bypass a blocked artery in the heart to increase the blood flow.¹⁵

diabetes mellitus. A group of diseases that impact how the body utilizes glucose. Too much blood glucose can lead to serious health issues.¹⁶

dispense. To prepare and distribute a medication.¹⁷

¹⁰ Mayo Clinic, *Leukemia*, <https://www.mayoclinic.org/diseases-conditions/leukemia/symptoms-causes/syc-20374373>. (The website was accessed on May 14, 2020.)

¹¹ The National Library of Medicine, National Institute for Health, National Information Center on Health Services Research and Health Care Technology, <https://www.nlm.nih.gov/nichsr/hta101/ta101013.html>. (The website accessed on May 13, 2020.)

¹² Merriam-Webster, *Code Blue*, <https://www.merriam-webster.com/medical/code%20blue>. (The website was accessed on April 28, 2020.)

¹³ Mayo Clinic, *CT scan*, <https://mayoclinic.org/tests-procedures>. (This website accessed on May 15, 2020.)

¹⁴ Merriam-Webster, *Definition of controlled substance*. <https://www.merriam-webster.com/dictionary/controlled%20substance>. (The website was accessed April 20, 2020.)

Controlled substances are in some manner regulated under federal law. They are listed into one of five schedules, “based upon the substance’s medical use, potential for abuse, and safety or dependence liability.” Drug Enforcement Agency, *Controlled Substances Act*, <https://www.dea.gov/controlled-substances-act>. (This website was accessed May 20, 2020.)

¹⁵ Mayo Clinic, *Coronary Bypass Surgery*, <https://www.mayoclinic.org/tests-procedures/coronary-bypass-surgery/about/pac-20384589>. (The website was accessed on May 14, 2020)

¹⁶ Mayo Clinic, *Diabetes Mellitus*, <https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444>. (The website was accessed on May 14, 2020.)

¹⁷ Merriam-Webster, *Definition of dispense*. <https://www.merriam-webster.com/dictionary/dispense>. (The website was accessed April 16, 2020.)

echocardiogram. A study that produces images of the heart by using sound waves. It is used to determine how the heart is pumping blood and if the patient has heart disease.¹⁸

electrocardiogram (EKG). The recording of the electrical signal in the heart to monitor and detect heart problems.¹⁹

epinephrine. A blood pressure raising hormone that is used to stimulate the heart during severe allergic reactions and cardiac arrests.²⁰

fungus ball. A ball of fungal debris located in the sinuses.²¹

hemoglobin. “A protein in [the] red blood cell that carries oxygen to [the] body’s organs and tissues and transports carbon dioxide from [the] organs and tissues.”²²

hepatitis. An infection in the liver.²³

hyperlipidemia. A condition in which cholesterol and triglycerides (or a combination of both) are abnormally elevated in the blood.²⁴

junctional rhythm. A type of rhythm “where the heartbeat originates from the atrioventricular node or His Bundle, which lies within the tissue at the junction of the atria and the ventricle.”²⁵

lactic acid. A laboratory test that measures lactate in the blood. One common cause of elevated lactate is shock.²⁶

¹⁸ Mayo Clinic, *Echocardiogram*, <https://www.mayoclinic.org/tests-procedures/echocardiogram/about/pac-20393856?p=1>. (This website was accessed May 15, 2020.)

¹⁹ Mayo Clinic, *Electrocardiogram*, <https://www.mayoclinic.org/tests-procedures/ekg/about/pac-20384983>. (The website was accessed on May 14, 2020.)

²⁰ Merriam-Webster, *Epinephrine*, <https://www.merriam-webster.com/dictionary/epinephrines>. (This website was accessed on May 15, 2020.)

²¹ Cleveland Clinic, *Fungus Ball*, <https://my.clevelandclinic.org/health/diseases/17012-fungal-rhinosinusitis>. (This website was accessed on May 15, 2020.)

²² Mayo Clinic, *Hemoglobin Test*, <https://www.mayoclinic.org/tests-procedures/hemoglobin-test/about/pac-20385075>. (This website was accessed on May 15, 2020.)

²³ National Institute of Diabetes and Digestive and Kidney Diseases, *Viral Hepatitis*, <https://www.niddk.nih.gov/health-information/liver-disease/viral-hepatitis>. (This website was accessed May 15, 2020.)

²⁴ Johns Hopkins All Children’s Hospital, *Nutritional Services for Pediatric Gastrointestinal Conditions*, <https://www.hopkinsallchildrens.org/Services/Nutrition/Pediatric-Gastrointestinal-Conditions>. (The website was accessed on May 14, 2020.)

²⁵ Hafeez, Y, Grossman, S, *Junctional Rhythm*. (StatPearls Publishing 2019): 1-9. <https://www.ncbi.nlm.nih.gov/books/NBK507715/#!po=94.4444>. (The website was accessed on May 18, 2020.)

²⁶ Mayo Clinic. <https://www.mayocliniclabs.com/test-catalog/Clinical+and+Interpretive/601685>. (This website was accessed May 15, 2020.)

liver function tests. Tests used to “measure how well the liver is performing” and “help diagnose and monitor liver function.”²⁷

lung volume. A measurement that “can be used to differentiate obstructive from restrictive pulmonary disorders.”²⁸

mean arterial pressure. “The average arterial pressure throughout one cardiac cycle.”²⁹

pneumatic tube system. A system of tubes that allows the sending of items through the use of air pressure.³⁰

RASS. The Richmond Agitation-Sedation Scale (RASS) is for neurological assessment for ICU patients. The 10-point scale (+4 to -5) with +4 to +1 rates the level of agitation, 0 is used for calm and alert patients, and -1 to -5 shows, with -5 being considered a higher rate of sedation.³¹

sepsis. “The body’s response to an infection.” It is “potentially life-threatening” and may result in death if it progresses into septic shock (a dramatic drop in blood pressure.)³²

septic shock. A life-threatening form of sepsis that is characterized by decreased blood flow to organs and tissue, impaired mental status and multisystem organ failure.³³

titration. The gradual increase or decrease of a medication.³⁴

troponins. “A group of proteins found in skeletal and heart (cardiac) muscle fibers that regulate muscular contraction. Troponin tests measure the level of cardiac-specific troponin in the blood

²⁷ Mayo Clinic, *Liver function tests*, <https://www.mayoclinic.org/tests-procedures/liver-function-tests/about/pac-20394595>. (This website was accessed May 15, 2020.)

²⁸ Merck Manual Professional Version, Airflow, Lung Volumes, and Flow-Volume Loop, Wood, K., <https://www.merckmanuals.com/professional/pulmonary-disorders/tests-of-pulmonary-function-pft/airflow,-lung-volumes,-and-flow-volume-loop>. (The website was accessed on May 19, 2020.)

²⁹ Daniel DeMers and Daliah Wachs, *Physiology, Mean Arterial Pressure*. (StatPearls Publishing 2020): <https://www.ncbi.nlm.nih.gov/books/NBK538226/>. (This website was accessed on April 30, 2020.)

³⁰ Merriam-Webster, *Definition of pneumatic*. <https://www.merriam-webster.com/dictionary/pneumatic>. (This website was accessed April 17, 2020.)

³¹ Vrinda Trivedi and Vivek N. Iyer, *Journal of Thoracic Disease*, v. 8(5), May 2016, *Utility of the Richmond Agitation-Sedation Scale in Evaluation of Acute Neurologic Dysfunction in the Intensive Care Unit*. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4842812/>. (The website accessed on April 30, 2020.)

³² Mayo Clinic, *Sepsis*, <https://www.mayoclinic.org/diseases-conditions>. (This website was accessed May 14, 2020.)

³³ Merriam-Webster, *Septic Shock*, <https://www.merriam-webster.com/dictionary/septic%20shock>. (This website was accessed May 15, 2020.)

³⁴ The Joint Commission, *Medication Administration—Titration Orders*, <https://www.jointcommission.org/standards/standard-faqs/hospital-and-hospital-clinics/medication-management-mm/000002114/>. (This website was accessed April 29, 2020.)

to help detect heart injury.” “When there is damage to the heart muscle, troponin is released into the blood.” Elevated troponin levels are used to determine if a patient has had a heart attack.³⁵

vasopressin. A medication that is administered intravenously “used to increase blood pressure in adults with vascular dilation from shock.”³⁶

³⁵ American Association for Clinical Chemistry, *Troponin*. <https://labtestsonline.org/tests/troponin>. (This website was accessed on May 18, 2020.)

³⁶ Mayo Clinic, *Vasopressin*. <https://www.mayoclinic.org/drugs-supplements/vasopressin-injection-route/description/drg-20066681>. (This website was accessed May 1, 2020.)

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