



**Department of Veterans Affairs
Office of Inspector General**

Office of Healthcare Inspections

Report No. 15-00425-380

Healthcare Inspection

Medication Management Concerns South Texas Veterans Health Care System San Antonio, Texas

June 15, 2015

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by a complainant regarding the intravenous compounded sterile product (CSP) medication error rate, improper aseptic technique while mixing CSPs, and excessive CSP wastage at the South Texas Veterans Health Care System (system), San Antonio, TX. A CSP is a pharmaceutical preparation that has been made or modified using manufacturer labeled instructions in a controlled sterile environment.

We did not substantiate the allegation that the system's pharmacy compounding error rate was high. We also did not substantiate that pharmacy personnel did not observe aseptic technique while compounding sterile products. However, we did substantiate excessive waste of CSPs.

Because the stability of most compounded sterile products increases with refrigerated storage, we recommended that the System Director ensure that processes be developed to improve storage conditions of CSPs on patient units in an effort to reduce unnecessary waste.

Comments

The Acting Veterans Integrated Service Network and Acting Facility Directors concurred with our recommendation and provided an acceptable action plan. (See Appendixes A and B, pages 8–10 for the Directors' comments.) We will follow up on the planned actions until they are completed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by a complainant regarding the intravenous (IV) compounded sterile product¹ (CSP) medication error rate, improper aseptic technique while mixing CSPs, and excessive CSP wastage at the South Texas Veterans Health Care System (system), San Antonio, TX.

Background

The system is part of Veterans Integrated Service Network (VISN) 17 and serves an estimated patient population of 81,000 in South Texas. It comprises the Audie L. Murphy Memorial VA Hospital in San Antonio, the Kerrville Campus in Kerrville, and the Satellite Clinic Division. The 268-bed system provides primary, secondary, and tertiary health care in medicine, surgery, psychiatry, and rehabilitation medicine. It also supports a 90-bed Community Living Center; a 30-bed Spinal Cord Injury Center; an eight-bed Bone Marrow Transplant Unit; a Polytrauma Center; and a Geriatric Research, Education, and Clinical Center. Affiliated with the University of Texas Health Science Center at San Antonio, the system has an active ambulatory care program with satellite outpatient clinics in San Antonio and Victoria. Community based outpatient clinics are located in Alice, Beeville, New Braunfels, Seguin, and Uvalde, TX.

The system pharmacy operates 24 hours a day, 7 days a week and includes 154.3 full-time equivalent employees (FTEs) including clinical pharmacy specialists, staff pharmacists, pharmacy technicians, and other support staff. Veterans Health Administration (VHA) policy defines clinical pharmacy specialists as individuals with a Master or Doctor of Pharmacy degree who have completed accredited residencies, are board certified-pharmacists, or pharmacists with equivalent experience.²

According to VHA Handbook 1108.06, *Inpatient Pharmacy Services*, which provides specific directions on the handling and dispensing of all medications, the Chief of Pharmacy must institute a “planned and systematic monitoring program to evaluate, on an annual basis, the quality, and the appropriateness of pharmacy services in regard to the medication use process.”³ It also requires a licensed pharmacist to review all medication orders prior to administration except in emergencies.

A complainant contacted the OIG and alleged that the system's pharmacy service failed to discharge its obligations under VHA policy and general standards of pharmaceutical practice due to a high rate of errors in manufacturing CSPs. The complainant alleged that the following errors occurred in December 2013:

¹ A compounded sterile product is a pharmaceutical preparation that has been made or modified using manufacturer labeled instructions in a controlled sterile environment.

² VHA Directive 2009-014, *Establishing Medication Prescribing Authority for Clinical Pharmacy Specialists*, March 12, 2009. This Directive expired March 31, 2014 and has not yet been updated.

³ VHA Handbook 1108.06, *Inpatient Pharmacy Services*, June 27, 2006. This Handbook was scheduled for recertification in June 2011, which has not yet occurred.

- A pharmacy technician prepared a medication that was 1000 times the correct ordered strength for a patient.
- Pharmacy staff diluted two CSPs with incorrect solutions.
- Pharmacy staff prepared a CSP with the incorrect concentration of medication.

The complainant stated the errors had been identified during system safety checks prior to the medications being administered and had therefore caused no patient harm. Because the pharmacy safety procedures for checking CSPs prior to distribution and administration prevented the medications from reaching the intended patient(s), the errors would be considered near misses. A near miss is a potential medication or other error that is prevented from reaching a patient due to staff intervention.

The complainant also alleged that pharmacy staff did not follow aseptic technique in the IV-compounding clean room, and failed to reuse CSPs resulting in needless waste.

Scope and Methodology

The period of our review was October 2014 through February 2015. To determine the merit of the allegations, we interviewed the complainant and conducted a site visit from November 3–6, 2014. While on site, we reviewed quality data, and inspected areas where medications were prepared and dispensed. We interviewed clinical pharmacy specialists, licensed pharmacists, a pharmacy technician, the Chief of Staff, the Chief of Pharmacy, and the Chief of Quality Management.

We also interviewed clinical leaders involved in the tracking of medication errors to include the Chair of the Pharmacy and Therapeutics Committee and the Chair of the Clinical Executive Board.

We reviewed system and VHA policies and procedures, reports, committee meeting minutes and other relevant documents.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Issue 1: Alleged Medication Errors

We did not substantiate the allegation that medication errors occurred in or around December 2013. No documentation existed to support that the medication errors described by the complainant occurred during this timeframe, and no pharmacy employee we interviewed could recall the errors described in the complaint. However, VHA and system requirements did not necessitate reporting of these types of pharmacy incidents or that action be taken if reported.

The system has three primary mechanisms through which staff report pharmacy errors. Two are VHA-wide processes, and the third is a system-based reporting process. These mechanisms include the root cause analysis (RCA) mandated by the National Center for Patient Safety,⁴ the Adverse Drug Event Reporting System (ADERS) used by the National Pharmacy Benefits Management Office, and the system's electronic patient incident reporting (ePIR) process. The system did not have a policy requiring reporting through other mechanisms, nor did any system policy specify what staff should report through ePIR. None of these mechanisms would have explicitly required the system to report, track, or trend the near miss medication errors alleged in the complaint unless such errors had been viewed as severe or common.

When an incident, such as a medication error, is severe and has a high probability of recurrence, VHA policy may require a system management team to conduct an RCA to determine the reason(s) why events occurred in an effort to prevent future occurrences.⁵ System managers analyze incidents that result in patient harm, as well as near misses, based on severity and probability of recurrence using the safety assessment code (SAC). SAC scores, if high enough, can then prompt staff to generate an RCA. For problems that become common occurrences such as frequently occurring medication errors, falls, adverse drug events, actual or attempted suicides, and missing patients, aggregated RCAs (ARCAs) may be used so that data can be gathered over time and evaluated.⁶

System managers did not conduct an RCA or ARCA addressing issues in pharmacy CSP compounding or RCAs on similar incidents during FYs 2012–2014. During FY 2014, the system completed one unrelated ARCA.

Although patient safety personnel told us that they did not recall the cited medication related near misses as having occurred, even if they had occurred and been assigned a SAC score, the errors likely would not have resulted in a high enough SAC score to trigger an RCA or an ARCA.

⁴ VHA Handbook 1050.01, *VA National Patient Improvement Handbook*, March 4, 2011.

⁵ Ibid.

⁶ Facility managers aggregate similar incidents in order to analyze and identify common causes or contributing factors in an effort to prevent future incidents. The determination of common causes provides the opportunity to correct minor issues before they lead to serious adverse events.

Because the errors identified in the complaint did not result in patient harm, staff would not have reported them through the ADERS. This nationwide system allows staff to centrally track and trend pharmacy-related events but only includes those events resulting in patient injury.⁷

The third mechanism available to track pharmacy errors is a daily reporting process instituted by the system, known as the ePIR. This report, which includes near misses, is widely distributed to system leadership and nurse managers. The system has a medication aggregate team that consists of information technology specialists, a pharmacist, a physician, and a nursing representative. According to the Chief of Quality Management, the team determines whether there are trends in the ePIRs that warrant an RCA. The results of RCAs are reported to the Patient Safety Committee, which is responsible for overseeing the implementation of any resulting action plans.

System staff acknowledged that errors made in pharmacy, which do not reach the patient unit, might not appear in the ePIR. The system's ePIR system is an internal reporting mechanism available to all system employees. Patient safety staff compile daily ePIR entries and share the data with senior managers. No system policy at the time of our review specified what needed to be reported to the ePIR. Instead, staff we interviewed thought pharmacy related ePIR incidents were generated largely when staff identified near misses after a medication reached the patient unit, not when mistakes occurred but were corrected before medications left the pharmacy. For example, the ePIRs for the month of December 2013 identified three pharmacy related incidents. All three incidents were reported at the unit level prior to patient administration. The December report did not include instances of errors identified within pharmacy, before staff delivered medications to the patient unit.

While the system's ePIR system may not require reporting of near miss errors, it does appear to comply with VHA Handbook 1108.06, which requires only a planned and systematic monitoring mechanism.

Issue 2: Aseptic Technique

We did not substantiate that pharmacy staff failed to maintain aseptic technique while manufacturing CSPs in the pharmacy clean room. VHA requires that pharmacies adhere to relevant standards of the United States Pharmacopeia (USP) chapter <797> and the American Society of Health System Pharmacists (ASHP).⁸ Aseptic technique ensures that products prepared by compounding personnel are sterile for patient administration.

The compounding of medications is an essential part of patient care. Many types of medications are compounded or prepared from component ingredients including capsules or tablets; external products like creams and gels; and medications that are injected into the skin, muscle, or vein using a syringe or infusion. Because IV CSPs are

⁷ VHA Directive 1070, *Adverse Drug Event Reporting and Monitoring*, September 12, 2014.

⁸ VHA Handbook 1108.06, *Inpatient Pharmacy Services*, June 27, 2006.

injected or infused into a vein, the risks of infection are higher and they must be prepared following very strict quality standards established by the USP to ensure sterility.

Environment. ASHP guidelines require routine environmental monitoring of the pharmacy clean room to assure ongoing sterility and prevent contamination of CSPs.⁹ We reviewed the FY 2014 clean room environment quality control records to ensure that Pharmacy Service maintained a sterile environment. Cleaning logs; temperature control logs; air testing; microbial measures; and particle counts of surfaces, work areas, and equipment in the pharmacy clean room were complete and entries were within defined parameters.

The quality control records also included certificates of sterility testing of CSPs. Sterility tests measure whether there is microbial growth in a randomized sample of CSPs indicating poor aseptic technique. All CSPs tested for FY 2014 passed sterility testing.

Personnel. USP <797> requires that staff receive proper training and demonstrate competency prior to compounding CSPs. Staff should have an initial competency evaluation of aseptic technique and be reevaluated annually. The ASHP recommends staff evaluations include didactic training, a formal written exam, and practical evaluation of aseptic technique using gloved fingertip and growth media-fill sampling to detect the presence of microbial contamination.¹⁰

The system's Pharmacy Service tracks staff competency in gloved fingertip sampling and written exams utilizing Simplifi 797[®] software. Gloved fingertip sampling requires pressing the gloved fingertips of both hands on correspondingly labeled growth media-filled plates following proper hand hygiene and garbing. The plates are incubated and monitored for bacterial growth.¹¹ We reviewed the FY 2014 Simplifi 797[®] reports and found all pharmacy staff involved in the compounding of CSPs fulfilled both the written exam and the gloved fingertip sampling requirements.

Personnel competency in maintaining aseptic technique is assessed annually utilizing growth media-fill samples.¹² During preparation of media-fill tests, staff compound sample IV CSPs using microbiological growth medium in lieu of drug solutions.¹³ Any microbial growth present in the media-fill IV CSPs after incubation indicates poor technique and requires retesting of personnel.¹⁴ We reviewed Pharmacy Service documentation of growth media-fill validation and found personnel had passed all media-fill testing requirements.

⁹ Preparation and Handling Guidelines, ASHP Guidelines on Compounding Sterile Preparations, <http://www.ashp.org/DocLibrary/BestPractices/PrepGdlCSP.aspx> Accessed 12/8/2014.

¹⁰ Ibid

¹¹ 2015 USP Compounding Compendium <https://compounding.usp.org/cgb/pdf/download> Accessed 1/20/2015.

¹² Preparation and Handling Guidelines, ASHP Guidelines on Compounding Sterile Preparations, <http://www.ashp.org/DocLibrary/BestPractices/PrepGdlCSP.aspx> Accessed 12/8/2014.

¹³ 2015 USP Compounding Compendium <https://compounding.usp.org/cgb/pdf/download> Accessed 1/20/2015.

¹⁴ Preparation and Handling Guidelines, ASHP Guidelines on Compounding Sterile Preparations, <http://www.ashp.org/DocLibrary/BestPractices/PrepGdlCSP.aspx> Accessed 12/8/2014.

Additionally, ASHP guidelines require staff to demonstrate competency in proper aseptic technique including effective garbing procedures and hand hygiene. Proper garbing includes the donning of securely fastened gowns, shoe, hair, and beard covers, and a mask.¹⁵ Pharmacy staff we interviewed were well versed and knowledgeable in proper hand hygiene and garbing requirements. We observed staff compounding CSPs in the pharmacy clean room who were properly garbed and appeared to be utilizing proper aseptic technique. The pharmacy clean room appeared clean, orderly, and free from dust producing materials such as cardboard.

Central line associated blood stream infection (CLABSI) rates may be an indicator of improper aseptic technique in mixing CSPs. A central line is an IV line inserted into a large vein typically of the neck or heart. Blood stream infections occur due to improper central line insertion techniques and potentially through non-sterile medication administration through these lines. We reviewed the system's FY 2014 CLABSI rate data and found it to be consistently below the VHA national rate.

Issue 3: Excessive Pharmacy Waste

We substantiated that pharmacy personnel wasted a significant number of CSPs. Most CSPs are prepared in large volume (greater than 100 milliliter) bags or bottles for infusion at a consistent rate over a long period, or in smaller volume bags or bottles for infusion into an existing venous line over a shorter amount of time several times per day, for example IV antibiotics.

The beyond-use date applied to pharmacy generated CSP labels, often referred to as the expiration date, is the date after which a CSP should not be used and is determined by the date and/or time the CSP was mixed. The beyond use date of a given product is obtained from product labeling, appropriate literature resources, or direct testing and is dependent on adherence to the manufacturers compounding and storage guidance.

Extending the beyond use date of CSPs increases the length of time staff can use and reuse a previously manufactured CSP. In cases where patients' IV medication orders change for any reason, pharmacy can retrieve the previously manufactured CSP from the area of intended use and reuse the medication for another patient if proper manufacturing and storage requirements were met. The reuse of CSPs results in medication cost savings as well as increased staff efficiency.

Some medications have increased stability when stored at room temperature; however, the majority of manufactured CSPs are stable far longer under refrigeration.¹⁶ For example, the shelf life of a susceptible drug exposed to a 20-degree increase in temperature, such as storage at room temperature, could potentially decrease its shelf life by one-fourth to one-twentieth that compared to refrigerated storage.

¹⁵ Preparation and Handling Guidelines, ASHP Guidelines on Compounding Sterile Preparations, <http://www.ashp.org/DocLibrary/BestPractices/PrepGdlCSP.aspx> Accessed 12/8/2014.

¹⁶ 2015 USP Compounding Compendium, <https://compounding.usp.org/cgb/pdf/download> Accessed 1/20/2015.

We reviewed the system's IV drug cost report for FY 2014. The total cost of IV CSPs dispensed was \$2,483,977. Pharmacy personnel reused 7 percent of dispensed CSPs (5.2 percent of dispensed cost). However, pharmacy staff destroyed 6 percent of dispensed CSPs (4.6 percent of total dispensed cost), resulting in a total cost of destroyed CSPs of \$114,858.

Several staff members, including nursing and pharmacy staff, told us that patient units were not equipped with medication storage refrigerators. Refrigeration greatly increases the stability of commonly ordered CSPs and allows the pharmacy to reuse a larger percentage of CSPs and significantly decrease pharmacy CSP waste.

Conclusions

We did not substantiate the allegation that the system had a high rate of errors in CSPs. We reviewed the system's three primary error-tracking mechanisms and did not detect any of the alleged errors. We did note that VHA and system requirements did not require reporting and analyzing potential errors or near misses unless they were viewed as severe or common.

We did not substantiate that personnel did not use aseptic technique when manufacturing CSPs. We interviewed and observed CSP compounding staff. We reviewed validation records of staff written examinations, growth media-fill, and gloved fingertip testing data. We reviewed CSP sterility testing records in addition to records of the ASHP's mandated clean room environment tests. Observations and data supported that the staff were in adherence with USP <797> and ASHP guidelines as required by VHA.¹⁷

We substantiated excessive waste of CSPs. The lack of medication refrigerators on patient units decreases the extended stability of many CSPs, which decreases the length of time CSPs are available for reuse in cases where patient medication orders are changed.

Recommendation

1. We recommended that the System Director ensure that processes be developed to improve storage conditions of compounded sterile products on applicable patient units in an effort to reduce unnecessary waste.

¹⁷ VHA Handbook 1108.06, *Inpatient Pharmacy Services*, June 27, 2006.

Acting VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: May 5, 2015
From: Acting Director, Heart of Texas Health Care Network (10N17)
Subj: Healthcare Inspection—Medication Management Concerns, South Texas Health Care System, San Antonio, Texas
To: Director, Bedford Office of Healthcare Inspections (54BN)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

Thank you for allowing me to respond to this healthcare inspection of the South Texas Health Care System, San Antonio, Texas.

1. I concur with the recommendations and ensured that action plans with target dates for completion were developed.
2. If you have further questions, please contact Denise B. Elliot, VISN 17 Quality Management Officer at 917-385-3734.



Wendell Jones, MD
Acting Director

Acting System Director Comments

Department of Veterans Affairs

Memorandum

Date: May 4, 2015

From: Acting Director, South Texas Veterans Health Care System (671/00)

Subj: Healthcare Inspection—Medication Management Concerns, South Texas Veterans Health Care System, San Antonio, Texas

To: Director, Bedford Office of Healthcare Inspections (54BN)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. I concur with all of the findings and recommendations in the draft report. The South Texas Veterans Health Care System is proceeding with the completion of the following attached action plan.
2. If you have any questions, please contact Amjed Baghdadi, Chief Quality Management Officer at 210-617-5205.



Julianne Flynn, MD
Acting Director

Comments to OIG's Report

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

OIG Recommendations

Recommendation 1. We recommended that the System Director ensure that processes be developed to improve storage conditions of compounded sterile products on applicable patient units in an effort to reduce unnecessary waste.

Concur

Target date for completion: February 5, 2016

System response: To improve storage conditions of compounded sterile products (CSP) on applicable patient units in an effort to reduce unnecessary waste, the STVHCS established a Pharmacy/Nursing work group to develop and establish new processes for the management of CSP utilizing medication refrigerators on the nursing units. The team has identified the nursing units that currently do not have medication refrigerators and are identifying appropriate locations to place the medication refrigerators. The utilization of medication refrigerators on the nursing units will change the current pharmacy distribution process of CSP and the nurses' storage and administration procedures. The team will develop the new processes and educate nursing and pharmacy staff. The team will recommend procurement of the appropriate quality and sizes of medication refrigerators based on the units' layouts with minimal additional steps to the administration of these medications. Upon final acquisition of the requested medication refrigerators, the team will reinforce education and training to both pharmacy and nursing staff on the required process changes to include the new temperature monitoring system.

Office of Inspector General Contact and Staff Acknowledgments

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