DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficiencies in Leaders' Responses to Lapses in Reusable Medical Equipment Reprocessing at the Chillicothe VA Medical Center in Ohio

HEALTHCARE INSPECTION | REPORT #20-02265-100 | MAY 6, 2021

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess facility leaders' responses to a Sterile Processing Services (SPS) employee's failure to follow endoscope reprocessing procedures at the Chillicothe VA Medical Center (facility) in Ohio.[1] As part of its response, the facility notified Veterans Health Administration (VHA) leaders that a lapse in reusable medical equipment reprocessing may have affected multiple patients.[2] During its review of the facility's response, the OIG identified additional concerns related to actions taken by VHA leaders in response to the situation.

From November 1, 2019, through February 28, 2020, the OIG received three similar complaints concerning a facility SPS employee (employee) who allegedly reprocessed endoscopes improperly in the gastrointestinal (GI) laboratory, placing patients at risk (event). Per the OIG's request, facility leaders responded to the original allegation and provided the following information regarding SPS procedures, staff compliance, corrective actions taken, and whether there were reports of patient harm:

- The facility became aware of the allegation in October 2019 and temporarily detailed the employee outside of SPS while conducting an investigation.
- The facility's Chief and Assistant Chief of SPS (SPS leaders) conducted an audit of endoscope reprocessing supplies; the findings of the audit did not correlate with the supply use documented by the employee.
- The facility and Veterans Integrated Service Network (VISN) investigations substantiated that the employee did not adhere to facility standard operating procedures when reprocessing endoscopes and had falsely documented compliance with the procedure.

[1] Merriam-Webster, *Definition of endoscope*. An endoscope is an illuminated usually fiber-optic flexible or rigid tubular instrument for visualizing the interior of a hollow organ or part (such as the bladder or esophagus) for diagnostic or therapeutic purposes that typically has one or more channels to enable passage of instruments (such as forceps or scissors). https://www.merriam-webster.com/dictionary/endoscope. (The website was accessed on August 4, 2020.)

[2] VHA Directive 1116(2), *Sterile Processing Services*, March 23, 2016. Reusable medical equipment refers to equipment (instrument, device, or item) "intended for repeated use on different patients with appropriate decontamination and other processing between uses." Centers for Disease Control and Prevention, Sterilization "describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods." Decontamination "removes pathogenic microorganisms from objects so they are safe to handle, use, or discard." https://www.cdc.gov/infectioncontrol/guidelines/disinfection/. (The website was accessed on April 8, 2020.)

- The facility and VISN notified VHA's Clinical Episode Review Team (CERT) through VA Central Office for the potential of an adverse event.[3]
- The facility initiated a preliminary review of patients potentially at risk, but suspended the review pending the CERT's direction.
- The Facility Director reinstated the employee to SPS with a corrective action plan of retraining and reassessing SPS competencies despite a recommendation from the Chief of SPS to remove the employee.

After reviewing responses from facility leaders and the CERT, the OIG identified concerns regarding oversight of the employee's performance, the review of potentially impacted patients, and patient disclosure. These concerns were the focus of this review.

The OIG found that despite concerns regarding the employee's integrity and a recommendation from the Chief of SPS for the employee's removal, the Facility Director reinstated the employee with a reprimand. The Facility Director's decision to reinstate the employee was based, in part, on the assertion made by the employee and one additional employee that former SPS managers had given the employee permission to modify work. The Facility Director recommended that the employee return to SPS to be retrained with oversight.

The OIG determined that the Facility Director did not develop and implement an adequate plan to monitor the employee's compliance with SPS procedures following reinstatement to SPS duty, particularly given concerns raised by facility and VISN leaders and the CERT regarding the employee's integrity and compliance. The Facility Director planned to conduct regular audits of supplies that the employee used during endoscope reprocessing as an oversight measure. The former Assistant Chief of SPS reported to the OIG that supply audits were time-intensive, not practical, and did not indicate compliance with policy. One supply audit was completed between January and April 2020. When interviewed, the Chief of SPS attributed the lack of audits to the reduction of SPS reprocessing during the COVID-19 pandemic and stated that audits would resume when surgical services returned to 50 percent capacity. The OIG found supply audits to be an insufficient measure of employee compliance.

Facility and VISN leaders followed VHA's policy requiring the escalation of potential adverse events that may have affected multiple patients to the CERT through VA Central Office for

[3] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The Clinical Episode Review Team is "the team that serves as the Deputy Under Secretary for Health for Operations and Management's coordinated triage process for review of each potential adverse event that may require large-scale disclosure." VHA considers an adverse event to be harm or potential harm either caused by or directly associated with care delivered by VHA providers, including exposure to bloodborne pathogens and infectious entities. In the context of this report, the OIG refers to VA Central Office as the Under Secretary for Health, Principal Deputy Under Secretary for Health, Deputy Under Secretary for Health for Operations and Management, or their delegated authorities.

review and disposition.[4] The CERT convened a VHA subject matter expert review panel that included the Director of Infectious Diseases, Director of the National Program Office for Sterile Processing, the Director of Public Health Surveillance and Research, and the VA Central Office Health Care Ethicist to review the event. Although the CERT and the subject matter expert review panel concluded that the facility's SPS event resulted in minimal risk to patients and that a large-scale disclosure was not warranted, the OIG found that the CERT's determination may have been based partly on an inaccurate understanding of automated endoscope reprocessor operations. When verifying technical information with the manufacturer's representatives for the automated endoscope reprocessor biomedical equipment, the OIG was given information that contradicted the CERT and subject matter expert panel's understanding of the equipment's capabilities to measure the concentration of a chemical used in the high-level disinfection process. The OIG notified the CERT of the conflicting information on July 30, 2020.[5]

The OIG made one recommendation to the Under Secretary for Health regarding the CERT's review of the OIG-provided manufacturer's information to determine if the information alters its determination of the potential risk to patients or the need for a large-scale disclosure.

The OIG made one recommendation to the Facility Director related to the oversight of the employee's performance.

[4] VHA Directive 1004.08. VHA's Principal Deputy Under Secretary for Health makes decisions regarding large-scale disclosure of adverse events following a multistep process beginning with a coordinated triage process by CERT. The process is to ensure that all required disclosures are based on a thorough investigation, careful assessment of the risks, and the development of a plan to best perform the disclosure. When VHA determines the risk of harm to patients is negligible or clinically insignificant, a large-scale disclosure is not warranted.

[5] VHA Directive 1116(2), *Sterile Processing Services*, March 23, 2016. VHA defines automated endoscope reprocessor (AER) as "an automated machine designed to clean, disinfect, and rinse flexible endoscopes."

Comments

The Executive in Charge, Office of the Under Secretary for Health, and the VISN and Facility Directors concurred with the recommendations and provided acceptable action plans (see appendixes A, B, and C).[6] Based on information provided, the OIG considers the recommendation directed to the Under Secretary for Health closed. The OIG considers the recommendation to the Facility Director open and will follow up on the planned actions until they are completed.

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Assistant Inspector General
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[6] The recommendation directed to the Under Secretary for Health was submitted to the Executive in Charge, who had the authority to perform the Under Secretary's functions and duties. Effective January 20, 2021, he was appointed to acting Under Secretary for Health with the continued authority to perform the functions and duties of the Under Secretary.

Contents

Abbreviations

AER	automated endoscope reprocessor
CERT	Clinical Episode Review Team
GI	gastrointestinal
NPOSP	National Program Office for Sterile Processing
OIG	Office of Inspector General
SOP	standard operating procedure
SPS	Sterile Processing Services
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted an inspection to review concerns regarding facility leaders' responses to a Sterile Processing Services (SPS) employee's failure to follow endoscope reprocessing procedures at the Chillicothe VA Medical Center (facility) in Ohio.[1]

Background

The facility, part of Veterans Integrated Service Network (VISN) 10, consists of a medical center in Chillicothe, five community-based outpatient clinics in Athens, Cambridge, Lancaster, Marietta, and Portsmouth, and one outreach clinic in Wilmington, Ohio. The facility provides comprehensive healthcare services including acute and chronic mental health, primary and specialty medical, women's health, and extended and nursing home care. The Veterans Health Administration (VHA) classifies the facility as a Level 1c (high-complexity facility).[2] From October 1, 2018, through September 30, 2019, the facility served 22,483 patients and had a total of 295 operating beds, including 55 inpatient beds, 78 domiciliary beds, and 162 community living center beds.

Sterile Processing Services

SPS "has the primary responsibility in facilities to decontaminate, high-level disinfect, and/or sterilize…reusable medical equipment and instruments."[3] The Centers for Disease Control and Prevention guidelines emphasize that the high-level disinfection or sterilization of medical

[1] Merriam-Webster, *Definition of endoscope*. An endoscope is an illuminated usually fiber-optic flexible or rigid tubular instrument for visualizing the interior of a hollow organ or part (such as the bladder or esophagus) for diagnostic or therapeutic purposes that typically has one or more channels to enable passage of instruments (such as forceps or scissors). https://www.merriam-webster.com/dictionary/endoscope. (The website was accessed on August 4, 2020.)

[2] The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity levels include 1a, 1b, 1c, 2, or 3, with level 1a facilities being the most complex and level 3 facilities being the least complex. VHA Office of Productivity, Efficiency and Staffing. http://opes.vssc.med.va.gov/Pages/Facility-Complexity-Model.aspx. (The website was accessed March 26, 2020, and is an internal VA website not publicly accessible.)

[3] VHA Directive 1116(2), *Sterile Processing Services*, March 23, 2016. Reusable medical equipment refers to equipment (instrument, device, or item) "intended for repeated use on different patients with appropriate decontamination and other processing between uses." High-level disinfection "is a process that uses a sterilant for a shorter contact time than that used for sterilization and that kills all microbial organisms but not necessarily large numbers of bacterial spores." Centers for Disease Control and Prevention, Sterilization "describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods." Decontamination "removes pathogenic microorganisms from objects so they are safe to handle, use, or discard." https://www.cdc.gov/infectioncontrol/guidelines/disinfection/. (The website was accessed on April 8, 2020.)

instruments is essential in preventing the transmission of infectious pathogens to patients; similarly, failure to properly disinfect or sterilize equipment carries significant risk for person-to-person transmission of infectious diseases.[4] Reprocessing is a term used to describe all of the steps involved in making a contaminated item reusable, including cleaning, testing, disinfection, or sterilization. For each piece of reusable medical equipment, a medical facility develops standard operating procedures (SOPs) for reprocessing according to the biomedical equipment manufacturer's instructions for use. Personnel responsible for reprocessing reusable medical equipment must be trained according to device-specific SOPs and establish competency by demonstrating the proper reprocessing procedure for each item.[5]

The VHA National Program Office for Sterile Processing (NPOSP) is organizationally aligned under the Deputy Under Secretary for Health for Operations and Management. The Director of the NPOSP is responsible for the "development and oversight of national policy pertaining to the standardization and reprocessing" of reusable medical equipment.[6]

Disclosure of Adverse Events

VHA's policy is to notify patients of adverse events. VHA considers an adverse event to be harm or potential harm caused by or directly associated with care delivered by VHA providers, including exposure to bloodborne pathogens and infectious entities. When a definite exposure cannot be determined, but an increased risk of exposure is known or thought to exist, the decision about disclosure should be based on both the risk and benefit of disclosure.[7]

Large-Scale Disclosure

When an adverse event may have affected multiple patients, VHA evaluates the appropriateness of a large-scale disclosure. A large-scale disclosure is a formal process by which VHA officials inform multiple patients that they have been or may have been affected by an adverse event involving actual or potential harm deemed clinically significant. A large-scale disclosure is not required when VHA determines the risk of harm to patients is negligible or clinically insignificant.[8]

VHA's Principal Deputy Under Secretary for Health makes decisions regarding large-scale disclosure of adverse events following a multi-step process that begins with the VHA Deputy

[4] Centers for Disease Control and Prevention, *Guideline for Disinfection and Sterilization in Healthcare Facilities,* 2008. Last updated May 2019. https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf. (The website was accessed on April 8, 2020.)

[5] VHA Directive 1116(2).

[6] VHA Directive 1116(2).

[7] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. Decision makers should consider risk within the context of the probability of serious future health consequences.

[8] VHA Directive 1004.08.

Under Secretary for Health for Operations and Management's coordinated triage process. The triage process involves the VHA Clinical Episode Review Team's (CERT) analysis of each adverse event potentially affecting multiple patients. This process "is designed to ensure that all required disclosures are based on a thorough investigation of the facts, a careful assessment of the risks involved, and the development of a plan for the best way to perform the disclosure."[9]

The facility, VISN, or a program office initiates the triage process once they discover that a harmful or potentially harmful adverse event occurred and submits an issue brief to the CERT through the Deputy Under Secretary for Health for Operations and Management. Once received, the CERT chairperson convenes relevant facility, VISN, and program office leaders, and subject matter experts to review and discuss the issue and make a recommendation regarding the disclosure.[10] The CERT can make one of the following recommendations:

- Close the event if a large-scale disclosure is not warranted.
- Convene a subject matter expert review panel or Clinical Review Board to conduct a more detailed review.[11]
- Proceed with a large-scale disclosure.

When a large-scale disclosure is warranted, the Deputy Under Secretary for Health for Operations and Management is responsible for "facilitating any required look-back activities and epidemiologic investigations."[12]

OIG Concerns

The OIG received three separate complaints concerning a facility SPS employee (employee) who allegedly reprocessed endoscopes improperly in the gastrointestinal (GI) laboratory, placing patients at risk. The OIG received the first complaint on November 1, 2019, and tasked facility leaders to provide information regarding relevant SPS policies and procedures, staff compliance, corrective actions taken, and reports of patient harm. Prior to the facility's response, the OIG received a second and third complaint with similar concerns on February 20 and February 28, 2020.

[9] VHA Directive 1004.08.

[10] VHA Directive 1004.08.

[11] VHA Directive 1004.08. The Clinical Review Board is "a multi-disciplinary board convened at the request of the Principal Deputy Under Secretary for Health in response to adverse events that may pose a clinically significant risk of harm to multiple patients or members of patients' families, but the probability of harm and/or the severity of the potential harm cannot be determined."

[12] VHA Directive 1004.08. An epidemiologic investigation as "a study of potentially affected populations to ascertain whether there is a linkage between health effects." A look-back as "an organized process for identifying patients or staff with exposure to potential risk incurred through past clinical activities, with the explicit intent to notify them and offer care and recourse, as appropriate."

According to the facility's response received on March 12, 2020, the facility's Chief of SPS conducted an internal investigation in October 2019 and substantiated that the employee did not adhere to facility SOPs for the reprocessing of endoscopes. The VISN SPS Lead (VISN Lead) found that the employee omitted several required process and quality assurance steps when reprocessing endoscopes and falsely documented compliance with the procedure. The employee, who had been temporarily detailed outside of SPS, received a reprimand, was re-educated on endoscope SOPs and "the importance of adhering to said guidelines," and returned to SPS in January 2020.

Facility leaders initiated a preliminary review of patients who may have had an endoscopy procedure with an endoscope reprocessed by the employee; however, the review was suspended after the event was elevated to VHA leaders and the CERT. On February 21, 2020, facility and VISN leaders discussed and agreed with the CERT and subject matter experts' determination that the event posed minimal risk to patients and that patient disclosure was not warranted.

As noted above, the facility substantiated the original allegations. When reviewing facility leaders' response and the CERT actions, the OIG identified additional concerns that became the focus of this review:

- Performance oversight of the reinstated employee
- Patient review and nondisclosure

Scope and Methodology

The OIG initiated the inspection on April 6, 2020, and conducted a virtual site visit between June 1 and 11, 2020.

The OIG interviewed the Facility Director; Acting Chief of Staff; Associate Director for Patient Care Services; Chief and former Assistant Chief of SPS; a biomedical technician; and staff from infection control, quality improvement, and SPS. Other interviewees included the CERT members, NPOSP leaders, the VISN Lead, and automated endoscope reprocessor (AER) biomedical equipment manufacturer representatives.[13]

The OIG reviewed VHA policies and handbooks, facility reusable medical equipment SOPs, organizational charts, personnel documents, and VHA's response to the OIG. The OIG also reviewed email correspondence between the facility, VISN, NPOSP, and CERT; the CERT meeting minutes between November 2019 and February 2020; and an AER biomedical equipment manufacturer's manual.

[13] VHA Directive 1116(2). VHA defines automated endoscope reprocessor (AER) as "an automated machine designed to clean, disinfect, and rinse flexible endoscopes."

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

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

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, 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.

Timeline of Key Events

On October 7, 2019, the former Assistant Chief of SPS was notified that an inadequate amount of endoscope reprocessing supplies was used in the GI laboratory during the employee's shift, leading to concerns that endoscopes were improperly reprocessed (event).

From October 7 through 24, 2019, the Chief and former Assistant Chief of SPS (SPS leaders) conducted an internal review that included staff interviews and an unannounced audit of endoscope reprocessing supplies (endoscope supply audit) in the GI laboratory. During the endoscope supply audit, SPS leaders counted the amount of supplies (the volume of CIDEX OPA and number of CIDEX OPA test strips, and Rapicide test strips) present in the GI laboratory before and after the employee's shift and found the number was unchanged.[14] Although the employee documented having used these supplies and completing quality assurance checks, the findings of the audit did not correlate with the supply use documented by the employee. The employee was detailed out of the SPS department, pending the results of the facility and VISN investigations.

On October 25, 2019, facility leaders notified the VISN Lead of the event and requested assistance. Between October 28 and 30, 2019, the VISN Lead and facility SPS leaders conducted a fact-finding investigation.

The fact-finding investigation found that the employee was competent in the operation of the AER. The facility substantiated that the employee deliberately deviated from endoscope SOPs, and falsely documented completing the required quality assurance steps. The fact-finding investigation concluded the SPS employee did not follow SOPs when reprocessing endoscopes.

According to the Facility Director, SPS leaders, and the VISN Lead, although the employee did not perform all steps required in the SOP, the employee signed quality assurance documents verifying completion. The employee denied skipping steps, despite supply audits showing unused test strips associated with the employee's work shift. In a memorandum to the facility dated October 30, 2019, the VISN Lead summarized the results of the fact-finding investigation and documented concerns regarding the employee's integrity, "to me this is a huge integrity/credibility issue" and "I would not want [the employee] to work in my department."

The Chief of SPS recommended removal of the employee at the conclusion of the fact-finding investigation, but the Facility Director chose to reinstate the employee to SPS with a reprimand

[14] John Hopkins Medicine, *CIDEX® ortho-Phthalaldehyde (OPA) solution, Instructions for Use*, updated 2006. The facility used CIDEX OPA solution in the manual cleaning of endoscopes. CIDEX OPA is a high-level disinfectant for reprocessing heat sensitive reusable medical devices. https://www.hopkinsmedicine.org/hse/forms/cidexopa/opainstruction.pdf. (The website was accessed on July 23, 2020.) Medivators, *Rapicide® PA test strips*, updated 2018. The facility used Rapicide PA test strips, which test the concentration of Rapicide PA high-level disinfectant. http://www.medivators.com/sites/default/files/pdf/50097-532%20Rev%20D.pdf. (The website was accessed on August 6, 2020.)

and a corrective action plan of retraining and reassessing of competencies. Additionally, the Facility Director's response to the OIG's initial query noted regular endoscope supply audits were conducted in the GI laboratory as an additional corrective action measure.

Inspection Results

1. Inadequate Performance Oversight of the Reinstated Employee

The OIG determined that the Facility Director did not develop and implement an adequate plan to monitor the employee's compliance with procedures after reinstatement to SPS duty. The OIG noted there was no oversight plan to address the integrity and compliance concerns regarding the employee identified by facility and VISN leaders and the CERT.[15]

Integrity—one of VA's five core values in addition to **C**ommitment, **A**dvocacy, **R**espect, and **E**xcellence, known as "I CARE"—is essential to VA's mission. These core values provide a baseline for the standards of behavior expected of all VA employees.[16] VHA's Code of Integrity centers around VA's I CARE values and emphasizes VHA's common culture of integrity and its responsibility to operate with the highest principles in the provision of health care and provides guidance on how employees serve in government.[17]

Facility, VISN, NPOSP, and CERT leaders described the employee as experienced, competent, and knowledgeable about SPS processes, but expressed concerns regarding the employee's integrity after the fact-finding investigation found that the employee deviated from endoscope SOPs and falsified quality assurance documentation. The Acting Director of NPOSP told the OIG that the employee chose not to follow the SOPs and expressed concern about the employee's integrity, further defining integrity as, "doing the right things even though no one is looking." In an interview the VA Central Office Health Care Ethicist, a CERT member, stated that integrity concerns regarding the "quality of the evidence" were discussed during the CERT meetings, specifically how to trust the employee's account of what occurred. The Facility Director expressed challenges with trusting the employee's future adherence to SOPs.

Despite concerns regarding the employee's integrity and a recommendation from the Chief of SPS for the employee's removal, the Facility Director reinstated the employee with a reprimand. According to the Facility Director, the decision to reinstate the employee was based, in part, on the assertion made by the employee and one additional employee that former SPS management had given the employee permission to modify work. The Facility Director recommended that the employee return to SPS to be retrained with oversight.

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[15] In the context of this report, the employee's deviation from SOPs and falsification of quality assurance documents will be referred to as integrity concerns.

[16] VA. Veterans Health Administration. *Code of Integrity*. 2019. https://www.va.gov/HEALTHCAREEXCELLENCE/docs/VHA-Code-of-Integrity-March-2019-FINAL.pdf. (The website was accessed on August 13, 2020.); U.S. Department of Veterans Affairs, I CARE Leadership.

[17] VA. Veterans Health Administration. *Code of Integrity*. 2019. https://www.va.gov/HEALTHCAREEXCELLENCE/docs/VHA-Code-of-Integrity-March-2019-FINAL.pdf. (The website was accessed on August 13, 2020.)

Although the employee previously demonstrated competency in endoscope SOPs, the implemented corrective action plan for the employee's reinstatement included retraining of the endoscope SOPs. The plan did not include monitoring the employee's compliance to address integrity concerns. The facility's response to the OIG stated that regular supply audits were being conducted in the GI laboratory.

The OIG found supply audits to be an insufficient measure of employee compliance. After the employee's reinstatement, only one audit had been completed between January and April 2020. In April 2020, the employee was temporarily detailed to another service due to a reduction of surgical procedures, until July 2020, when the employee returned to SPS. The Chief of SPS attributed the lack of audits to the reduction of SPS processing related to the COVID-19 pandemic and stated that audits would resume when surgical services returned to 50 percent capacity.[18] Although the Chief of SPS told the OIG that audits were the only planned oversight of the employee, the former Assistant Chief of SPS reported the audits were time-intensive, not practical, and did not indicate compliance with policy. The Chief of SPS stated that the employee could simply dispose of supplies without using them, forge quality assurance records, and could likely do so undetected.

During interviews, SPS leaders expressed concerns about the ability to adequately supervise and monitor the employee upon returning to SPS. SPS leaders explained that the GI laboratory was located in a separate building apart from SPS and the small space often required employees that reprocessed endoscopes to work alone and independently. Notably, the Facility Director did not know that the employee worked alone in the GI laboratory and reported to the OIG team being unaware that SPS leaders planned to leave the employee alone and unmonitored.

SPS leaders informed the OIG team that they reported concerns about the employee's reinstatement to facility leaders; however, SPS leaders described a lack of authority to make decisions about the employee's disposition. When questioned how facility leaders responded to these concerns, the Chief of SPS reported, "The Director made a decision, and that's what the decision is." The Chief of SPS further stated that the Associate Director of Patient Care Services said that facility leaders understood the concerns but the decision to reinstate the employee was made.[19] The OIG noted that at the time of the event, the Chief of SPS was new to the position and department.

[18] World Health Organization, "Naming the coronavirus disease (COVID-19) and the virus that causes it." https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it. (The website was accessed on August 31, 2020.) COVID-19 is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

[19] The Chief of SPS is administratively aligned under the direct supervision of the Associate Director of Patient Care Services.

The OIG determined that despite concerns regarding the employee's integrity and compliance, the Facility Director did not develop an oversight plan or mechanism to monitor the employee's performance.

2. Patient Review and Nondisclosure

The OIG determined that facility and VISN leaders followed VHA policy by escalating the event to the CERT for review and determination. The CERT concluded that the event resulted in minimal risk to patients and that a large-scale disclosure and patient review was not warranted. However, the OIG found that the CERT's understanding of technical information related to the AER capabilities that contributed to their conclusion, conflicted with information the OIG obtained from the AER biomedical equipment manufacturers' representatives.

VHA policy requires that when facility, VISN, or program office (such as the NPOSP) leaders discover that a harmful or potentially harmful adverse event occurred that may have affected multiple patients, leaders elevate the event to VA Central Office, which designates the CERT to review the event and determine whether disclosure is warranted.[20] If the adverse event is recognized after the episode of care, it is appropriate for the facility "to wait until the required VA Central Office coordination process for large-scale disclosure is completed before making either a large-scale or institutional disclosure to an individual patient," unless the delay negatively affects patients' health or well-being.[21] When a large-scale disclosure is warranted, the Deputy Under Secretary for Health for Operations and Management facilitates any look-back activities and investigations to study potentially affected populations. When the risk of harm to patients is negligible or clinically insignificant, a large-scale disclosure is not required.[22]

During the week of October 20, 2019, facility leaders initiated a review of patients who may have had an endoscopy procedure with an endoscope reprocessed by the employee. On October 28, 2019, the facility outlined the event in a VHA issue brief and elevated the event to the CERT through VA Central Office. Following the CERT's initial meeting on November 4, 2019, the facility's Acting Chief of Staff halted the facility's patient reviews pending the CERT's review and disclosure determination.

The CERT met five times between November 4, 2019, and February 21, 2020, to assess the event, and included facility, VISN, and NPOSP leaders. The CERT convened a subject matter expert review panel consisting of the VHA Director of Infectious Disease, VHA Director of NPOSP, VHA Director of Public Health Surveillance and Research, and the VA Central Office

[20] In the context of this report, the OIG refers to VA Central Office as the Under Secretary for Health, Principal Deputy Under Secretary for Health, Deputy Under Secretary for Health for Operations and Management, or their delegated authorities.

[21] VHA Directive 1004.08.

[22] VHA Directive 1004.08.

Health Care Ethicist. The panel reviewed the facility's gap analysis and determined that there was minimal risk to patients and disclosure was not warranted.[23]

The OIG found that the CERT's recommendation not to initiate a large-scale disclosure relied heavily on information provided by the Director of NPOSP. During an interview with the OIG, the Director of NPOSP reported that when assessing the potential risk of harm to patients, the CERT and subject matter expert panel conducted a thorough assessment, including the review of

- The steps the employee omitted from the endoscope SOP,
- The micro-organisms and bioburden that might have been left on the endoscopes,
- The facility's infection rate related to GI endoscope processes that found no incidents of infections,
- The facility's endoscope SOPs and biomedical equipment manufacturer's instructions for use, and
- The verification that the AER had been functioning properly.[24]

Although the employee omitted the endoscope SOP step of using a test strip to verify the necessary high-level disinfectant concentration, the Director of NPOSP, who reported conferring with the manufacturer's representatives, explained that the AER would abort or fail if the Rapicide disinfectant did not meet the minimum required concentration.[25]

However, when verifying this information with AER biomedical equipment manufacturer's representatives, the OIG was given information that contradicted the CERT and subject matter expert panel's understanding of the AER capabilities.[26] The OIG provided the updated information to VHA leaders to determine whether the conclusion regarding disclosure and patient risk is sustained. The CERT Chair reported that the subject matter experts were closely reviewing the information provided by the OIG.

[23] The facility's gap analysis identified the gaps between the required reprocessing steps outlined in the facility's endoscope SOPs (paired with the manufacturer's instructions for use) and the actual steps the employee completed.

[24] VHA Directive 1116(2). "Bioburden is the number of microorganisms on a contaminated object."

[25] Medivators*, Safety, Efficacy and Microbiological Considerations,* updated 2012. Rapicide PA is used for "High-Level Disinfection of semi-critical clean, heat sensitive endoscopes and related accessories" in AERs. https://www.medivators.com/sites/default/files/minntech/documents/50096-959%20REV%20D.pdf. (The website was accessed on August 10, 2020.)

[26] The OIG learned that the AER does not have the capability to verify the presence or concentration of the Rapicide disinfectant but rather relies upon the operator (SPS technician) to manually measure the minimum recommended concentration using a Rapicide test strip.

Conclusion

The OIG determined that the Facility Director did not develop and implement an adequate plan to monitor the employee's performance after reinstatement to SPS duty, despite concerns regarding the employee's integrity and compliance.

Based on VHA's policy requiring the escalation of adverse events that may have affected multiple patients to the CERT through VA Central Office for review and disposition, the facility's actions were appropriate. The OIG determined that some of the technical information the CERT considered when assessing risk to patients in making the nondisclosure determination was inconsistent with the information the OIG obtained from the AER biomedical manufacturer's representatives. The OIG provided the updated information to VHA leaders for awareness and consideration to determine whether the conclusion regarding disclosure and patient risk is sustained; the CERT Chair and subject matter experts were reviewing the information.

Recommendations 1–2

1. The Chillicothe VA Medical Center Director develops an oversight plan to address concerns regarding the employee's compliance with Sterile Processing Services' procedures as identified by facility and Veterans Integrated Services Network leaders and the Clinical Episode Review Team and confirms effective resolution.

2. The Under Secretary for Health ensures that the Clinical Episode Review Team reviews the OIG-provided biomedical equipment manufacturer's information for the automated endoscope reprocessor to determine if the information alters their determination regarding the potential risk to patients or the need for a large-scale disclosure and takes action as necessary.[27]

[27] The recommendation directed to the Under Secretary for Health was submitted to the Executive in Charge, who had the authority to perform the Under Secretary's functions and duties. Effective January 20, 2021, he was appointed to acting Under Secretary for Health with the continued authority to perform the functions and duties of the Under Secretary.

Appendix A: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: January 12, 2021

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: Healthcare Inspection—Deficiencies in Leaders' Responses to Lapses in Reusable Medical Equipment Reprocessing at the Chillicothe VA Medical Center in Ohio

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report Veterans Health Administration: Deficiencies in Leaders' Responses to Lapses in Reusable Medical Equipment Reprocessing at the Chillicothe VA Medical Center in Ohio.

2. The Veterans Health Administration (VHA) embraces a system of transparency that leads to a safe psychological environment and chartered an interdisciplinary Clinical Episode Review Team (CERT) to review, evaluate and make recommendations based on the evidence. Additionally, the vendor's senior executive provided thorough insight into the expected operational capabilities of the automated endoscope reprocessor.

3. After extensive review of clinical evidence and ethical values, the CERT concluded that appropriate steps were identified and completed, no additional actions were recommended.

4. I concur with OIG's recommendation to the Office of the Under Secretary for Health. VHA has fully implemented the action plan for this recommendation and asks OIG to consider closure.

5. Comments and action plans for recommendation 1 are provided by the Medical Center Director for Chillicothe VA Medical Center.

6. Comments regarding the contents of this memorandum can be directed to Director, GAO/OIG Accountability Liaison Office at VHA10BGOALAction@va.gov.

(*Original signed by*:)

Richard A. Stone, M.D.
Executive in Charge, Office of the Under Secretary for Health

Executive in Charge Response

Recommendation 2

The Under Secretary for Health ensures that the Clinical Episode Review Team reviews the OIG-provided biomedical equipment manufacturer's information for the automated endoscope reprocessor to determine if the information alters their determination regarding the potential risk to patients or the need for a large-scale disclosure and takes action as necessary.

Concur.

Target date for completion: [Request for closure]

Executive in Charge Comments

VHA is committed to ensure safety and best practices for our Veteran population. VHA's Clinical Episode Review Team (CERT) chartered a subject matter expert board to provide expert review and opinions regarding the biomedical equipment manufacturer's information for the Automated Endoscope Reprocessor (AER). The goal of this team was to review all evidence presented including interviews and documentation to identify any potential risk for patients. The team reviewed the overall evidence to include extensive review of information pertaining to the outcome of the root cause analysis, information provided by the Veterans Integrated Service Network Sterile Processing Service Lead, the National Program Office for Sterile Processing and expertise from a senior executive at Cantel Medical (manufacturer for the AER). Technical, ethical, and clinical considerations were discussed to identify any potential concerns. The Clinical Review Board was tasked to determine whether disclosure was warranted in this case. Based on all clinical evidence provided, the Clinical Review Board determined that no disclosure would be required or warranted. VHA considers actions on this recommendation complete and asks OIG to consider closure.

OIG Comment

Based on the response submitted by the Executive in Charge which outlined the actions taken and review conducted, the OIG considers this recommendation closed.

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: January 13, 2021

From: Director, VA Healthcare VISN 10, Cincinnati, Ohio (10N10)

Subj: Healthcare Inspection— Deficiencies in Leaders' Responses to Lapses in Reusable Medical Equipment Reprocessing at the Chillicothe VA Medical Center in Ohio

To: Executive in Charge, Office of the Under Secretary for Health (10)
Director, Office of Healthcare Inspections, (54HL04)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. I have reviewed the draft report for the Healthcare Inspection— Deficiencies in Leaders' Responses to Lapses in Reusable Medical Equipment Reprocessing at the Chillicothe VA Medical Center in Ohio.

2. I concur with the response and action plans submitted by the Chillicothe VA Medical Center Director.

3. Thank you for the opportunity to respond to this report.

(*Original signed by:*)

RimaAnn O. Nelson
Network Director

Appendix C: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: January 7, 2021

From: Medical Center Director, Chillicothe VA Medical Center (538/00)

Subj: Healthcare Inspection— Deficiencies in Leaders' Responses to Lapses in Reusable Medical Equipment Reprocessing at the Chillicothe VA Medical Center in Ohio

To: Director, VA Healthcare- VISN 10, Cincinnati, Ohio (10N10)

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Deficiencies in Leaders' Responses to Lapses in Reusable Medical Equipment Reprocessing at the Chillicothe VA Medical Center in Ohio.
2. I have reviewed and concur with Recommendation 1 with details contained within the accompanying Facility Director Response.
3. I have the following concerns with this report.
    a. The OIG missed an opportunity to conduct interviews with key players including Human Resources and did not include clarifying information provided by the Associate Director of Patient Care Services who oversees the Sterile Processing Services (SPS) Department.
    b. The report does not appear to consider that there were multiple concerns about the validity of the fact finding, which was subsequently reviewed by the Medical Center Director in consultation with both Human Resources and Office of General Counsel representatives. It was determined that the flawed fact finding failed to adequately support a significant adverse disciplinary action despite the documented recommendation for removal. There was additional information presented by the employee and the labor partner during the employee's response, which was also taken under consideration. For this reason, the proposed removal was not upheld.
    c. As noted within the report, the employee was provided retraining and competency verification upon return to the SPS department January 2020. The period of retraining and competency verification occurred between January 2020 and March 2020. It should be noted that the volume of equipment processed through SPS was markedly decreased as a result of COVID related discontinuation of non-urgent procedures between March 2020 and June 2020. The employee was detailed out of the SPS department for three months to administrative duties to support COVID operations and on leave for two weeks during the summer. Thus, no audits of the employee's work were indicated during those periods.
4. The leadership team at the Chillicothe VA Medical Center is committed to the principles of High Reliability and will diligently pursue all measures to ensure safe, high-quality care for the Veterans whom we serve.

(*Original signed by*:)

Kathy W. Berger
Medical Center Director

Facility Director Response

Recommendation 1

The Chillicothe VA Medical Center Director develops an oversight plan to address concerns regarding the employee's compliance with Sterile Processing Services' procedures as identified by facility and Veterans Integrated Services Network leaders and the Clinical Episode Review Team and confirms effective resolution.

Concur.

Target date for completion: April 30, 2021

Facility Director Comments

As noted within the report, the employee was provided retraining and competency verification between January 23, 2020 and April 3, 2020.

The following plan for oversight of the employee has been developed with input from the Sterile Processing Services (SPS) Service Chief:

1. Weekly audits of the automated SPS quality control system (CensiTrac) by the SPS service chief.
2. Bi-monthly direct observation performed randomly by the SPS Chief, while performing SPS procedures.
3. Annual competency reassessment with re-education and competency verification to be performed more frequently if indicated.

The above described oversight plan will remain in place until 100% compliance is documented for a period of three consecutive months. The direct oversight of this plan will be provided by the SPS Chief with further report to the Associated Director of Patient Care Services (ADPCS). If the desired compliance is achieved, the employee's oversight plan will be aligned with the standard oversight plan for other SPS employees. If the desired compliance is not achieved, appropriate actions will be taken.

OIG Contact and Staff Acknowledgments

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