



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

Office of Healthcare Inspections

Report No. 16-03150-277

**Healthcare Inspection
Alleged Unreported Surgical
Incidents and Deaths
VA Caribbean Healthcare System
San Juan, Puerto Rico**

June 27, 2017

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General conducted a healthcare inspection in 2016 in response to complaints about the VA Caribbean Healthcare System, San Juan, Puerto Rico. An anonymous complainant alleged that surgical incidents and deaths were unreported because of a conflict of interest between a quality management employee and a senior leader.

During interviews, we did not find evidence of a conflict of interest. We reviewed the validity of the allegation regarding the reporting of surgical incidents and deaths.

We did not substantiate that surgical incidents or deaths were unreported. We compared information regarding surgical deaths extracted from the Corporate Data Warehouse with the facility morbidity and mortality committee minutes and found the data to be congruent with information in patients' Electronic Health Records.

We distributed a bilingual survey (English and Spanish) to 128 VA Caribbean Healthcare System Quality Management, operating room (OR), and Post-Operative Care Unit staff as well as surgeons. We asked the following survey questions:

- Do you have any concerns about the reporting of incidents in surgery?
- Are incidents in surgery being reported as required?

We had an 11 percent response rate to the survey; no employees reported concerns about incidents in surgery on the survey. For purposes of this review, we used the terms incident, adverse event, and occurrence interchangeably.

Surgical Service staff completed a Critical Incident Tracking Notification report when incidents occurred including deaths in the OR, incorrect surgery (wrong patient, wrong procedure, wrong side/site, wrong implant), retained surgical item, OR fire, and OR burn. This information was aggregated and included in the quarterly National Surgery Office Report and reconciled with records from the National Patient Safety Office. In addition to the Critical Incident Tracking Notification system, we found the facility had an electronic system for reporting incidents. The Patient Safety Officer informed us the first person who sees an incident is responsible for initiating a report. The facility Patient Safety Improvement Program described a "culture of safety" which includes identification and reporting of incidents, review of incidents to determine underlying causes, and implementation of changes to reduce the likelihood of recurrence. The Patient Safety Officer provided us a copy of the incident reporting presentation given to all employees during facility orientation.

We made no recommendations.

Comments: The Acting Veterans Integrated Service Network and System Directors concurred with our findings. (See Appendixes A and B, pages 7–8 for the full text of the Directors' comments.) No further action is required.

A handwritten signature in black ink that reads "John D. Daigh, Jr., M.D." The signature is written in a cursive style.

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

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to allegations about the VA Caribbean Healthcare System (system), San Juan, Puerto Rico. An anonymous complainant alleged that surgical incidents and deaths were unreported because of a conflict of interest between a quality management employee and a senior leader. During interviews, we did not find evidence of a conflict of interest. We reviewed the validity of the allegations as to whether surgical incidents and deaths were reported.

Background

The system is comprised of a medical center (facility) in San Juan, Puerto Rico, a community living center, and nine community based outpatient clinics located in Puerto Rico and the United States Virgin Islands. The community clinics are located in Arecibo, Comerio, Guayama, Mayaguez, Utuado, Ponce, Vieques, St. Croix, and St. Thomas.¹ The system provides medical, surgical, and mental health services to 63,879 unique veterans. The facility is a 1a, high-complexity facility with 280 inpatient and 122 community living center beds.²

Surgical Services

The system is designated as a complex Veterans Health Administration (VHA) surgical program. VA assigned each of its inpatient medical centers an "operative complexity" level of standard, intermediate, or complex. The designations are based on complexity and/or capacity of facilities, equipment, workload, and staffing.³

The National Surgery Office (NSO) is organizationally situated within the Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM). The NSO provides VHA surgical programs with clinical oversight and analysis of surgical outcomes. The NSO publishes a quarterly report that provides analyses of surgical processes, structures, and outcomes through integration of surgical and other data. One section of the NSO is the critical incident tracking notification (CITN) report. The CITN report displays counts of surgical incidents including deaths in the operating room (OR), incorrect surgery (wrong patient, wrong procedure, wrong side/site, wrong implant), retained surgical item, OR fire, and OR burn.⁴ NSO reports enable Veterans Integrated Service Network (VISN) and VHA Facility Surgical Work Groups and the Veterans Affairs Surgical Quality Improvement Program (VASQIP) Executive Board to

¹VA Caribbean Healthcare System website. <http://www.caribbean.va.gov/locations/index.asp>. Accessed May 13, 2016.

² The National Leadership Board established VHA facility complexity in August 2005. Characteristics of a 1a facility include: those with the largest volume of patients, including high-risk patients, medical education and research programs, the largest number and breadth of physician specialties, and those with at least 5 intensive care units. <http://vaww.bdc.med.va.gov/vapublic/detailcom.htm>. Accessed May 13, 2016.

³ VHA Directive, 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*. May 6, 2010. This Directive expired May 31, 2015 and has not yet been updated.

⁴National Surgery Office/National Center for Patient Safety Critical Event Definitions.

<https://vaww.nso.med.va.gov/apps/VASQIP/SitePages/CITNInfo.aspx>. Accessed August 4, 2016.

fulfill their assigned duties by providing validated clinical data with ongoing summaries, long-term trending, and national comparisons. Some NSO reports are confidential and privileged under the provisions of 38 U.S.C. §5705.

Patient Safety

VHA requires facility directors to designate a patient safety manager (PSM), and backup.⁵ The VA National Center for Patient Safety (NCPS) is responsible for developing and implementing VHA's patient safety programs. In 1999, the Institute of Medicine published the "To Err is Human" report, which brought national attention to the problem of incidents in health care. VHA has implemented an approach to improving patient safety which includes:

- Understanding the health care continuum as a system and exploring system vulnerabilities that can result in patient harm.
- Reporting of incidents and close calls.
- Emphasizing prevention rather than punishment.

These three steps can be implemented at the local and national levels to effectively prevent system vulnerabilities that can lead to patient harm.⁶

Allegations

In 2016, we received an anonymous complaint alleging surgical incidents and deaths were unreported because of a conflict of interest involving a quality management employee and a senior leader. During interviews, we did not find evidence of a conflict of interest. We reviewed the validity of the allegation regarding the reporting of surgical incidents and deaths.

Scope and Methodology

We conducted our work from May through August 2016. We reviewed VHA and system policies and procedures and relevant VHA data that were collected from October 1, 2014 through December 31, 2015. We reviewed meeting minutes from Peer Review, Morbidity and Mortality, Surgical Work Group, Quality Management, Executive Leadership, and Patient Safety Committees. We interviewed executive leadership, the Chief of Surgery, the Chief of Quality Management, the Patient Safety Officer, Quality Management Staff, the VA Surgical Quality Nurse (VASQIP), OR Manager, Surgical Services Staff, and the Chief of Human Resources. We offered and conducted some of our interviews in Spanish.

⁵ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This VHA Handbook was scheduled for recertification on or before March 2016 and has not yet been updated.

⁶ VHA Handbook 1050.01.

We took the following steps to identify unreported surgical incidents:

- We compared information regarding surgical deaths extracted from the Corporate Data Warehouse (CDW) with facility morbidity and mortality (M&M) committee minutes from October 1, 2014 through December 31, 2015.⁷⁸⁹¹⁰
- We reviewed Electronic Health Records (EHR) to confirm documentation of the reported surgical deaths.
- We reviewed the quarterly NSO reports from October 1, 2014 through December 31, 2015.
- We reviewed the CITN section of the quarterly NSO reports.¹¹
- We distributed a bilingual survey (English and Spanish) to Healthcare System Quality Management, OR, and Post-Operative Care Unit staff as well as surgeons.
- We asked the following survey questions:
 - Do you have any concerns about the reporting of incidents in surgery?
 - Are incidents in surgery being reported as required?

The survey initially opened June 22, 2016 and closed July 1, 2016 at midnight eastern standard time. We reopened and redistributed the survey on July 8 with a notification that the survey was extended to July 15. We officially closed the survey on July 18th at 9 a.m. eastern standard time.

When we distributed the survey we provided the following instructions, “For the purposes of our survey we define incidents as an occurrence or event such as patients waiting a long time in the operating room before a surgical procedure is performed, or patients dying from surgical complications.”

We used the terms incident, adverse event, and occurrence interchangeably throughout this report.

Two VHA policies cited in the report were beyond the recertification date or expired and had not been updated:

⁷ Morbidity and mortality conferences historically have been the core meeting for education, quality, assurance, and training of surgical residents. <http://www.sciencedirect.com/science/article/pii/S0002961006000687>. Accessed September 22, 2016.

⁸ The Veterans Health Administration Corporate Data Warehouse is a national repository of data from VHA clinical and administrative systems. <http://vaww.virec.research.va.gov/CDW/Overview.htm>. Accessed September 22, 2016.

⁹ Mortality is the number of deaths that occur in a particular time or place. <http://www.merriam-webster.com/dictionary/mortality>. Accessed September 22, 2016.

¹⁰ Morbidity is a complication or undesirable side effect following surgery or medical treatment. <http://www.merriam-webster.com/dictionary/morbidity>. Accessed September 22, 2016.

¹¹ The NSO reports enable VISN and VHA Facility Surgical Work Groups and the VASQIP Executive Board to fulfill their assigned duties by providing validated clinical data with ongoing summaries, long-term trending, and national comparisons. <https://vaww.nso.med.va.gov/apps/VASQIP/Default.aspx>. Accessed September 22, 2016.

1. VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011 (recertification due date March 31, 2016)
2. VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010 (expired May 31, 2015)

We considered the policies to be in effect as they had not been superseded by more recent policy or guidance. In a June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),¹² the VA Under Secretary for Health (USH) mandated the "...continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."¹³ The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "...the timely rescission or recertification of policy documents over which their program offices have primary responsibility."¹⁴

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

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.

¹² VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 11, 2017.

¹³ VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.

¹⁴ *Ibid.*

Inspection Results

Alleged Unreported Surgical Incidents and Deaths

We did not substantiate that surgical incidents and deaths were unreported. According to the Chief of Staff, and Director, patient/facility incidents were discussed daily during the facility morning report. We had an 11 percent response rate to our survey and no employees reported concerns about incidents in surgery on the survey. We compared information relating to surgical deaths extracted from the CDW with facility morbidity and mortality (M&M) committee minutes and found the data to be congruent with information in patients' EHRs.¹⁵¹⁶¹⁷

As required by VHA, when indicated, Surgical Service staff completed a CITN report.¹⁸ This information was aggregated and included in the CITN section of the quarterly NSO report.¹⁹ We were told during our interviews that staff on duty knew how to complete a CITN report, and that surgical incidents were reported to the Chief of Surgery.

In addition to the CITN, the Patient Safety Officer informed us the facility had an electronic system for reporting incidents.²⁰ Incidents reported in the CITN were reconciled with records from the NCPS. The Patient Safety Officer informed us the first person who sees an incident is responsible for initiating a report. In addition, staff and leadership are mindful of reporting incidents brought to their attention in committees, or any other venue where patient care is discussed. This included a discussion of patient/facility incidents during morning report. The Chief of Surgery advises the Patient Safety Office when incidents occur in surgery.

During our interview with the Patient Safety Officer, we were told that incident reports may be filed on paper or electronically, and all employees were trained on incident reporting during facility orientation. In addition, we were told the Patient Safety Committee sends out frequent information about incident reporting and patient safety tips via email, and a Patient Safety SharePoint site was accessible to all employees and included information and a power point presentation.

¹⁵ Morbidity and mortality conferences historically have been the core meeting for education, quality, assurance, and training of surgical residents. <http://www.sciencedirect.com/science/article/pii/S0002961006000687>. Accessed September 22, 2016.

¹⁶ The Veterans Health Administration Corporate Data Warehouse is a national repository of data from VHA clinical and administrative systems. <http://vaww.virec.research.va.gov/CDW/Overview.htm>. Accessed September 22, 2016.

¹⁷ Mortality is the number of deaths that occur in a particular time or place. <http://www.merriam-webster.com/dictionary/mortality>; Morbidity is a complication or undesirable side effect following surgery or medical treatment. <http://www.merriam-webster.com/dictionary/morbidity>. Accessed September 22, 2016.

¹⁸ VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013.

¹⁹ Ibid.

²⁰ See VA Caribbean Healthcare System Center Memorandum No. 00-13-70 *Patient Safety Improvement Program*, January 2013 that was in effect at the time of the events discussed in this report. The 2013 policy was rescinded and replaced by VA Caribbean Healthcare System Center Memorandum No. 00-16-70 *Patient Safety Improvement Program* March 2016 which contains the same or similar language regarding the reporting of incidents.

The facility Patient Safety Improvement Program described a “culture of safety” which included identification and reporting of incidents, review of incidents to determine underlying causes, and implementation of changes to reduce the likelihood of recurrence.²¹

We did not substantiate that surgical incidents or deaths were unreported.

Conclusions

We did not substantiate that surgical incidents and deaths were unreported. We found CITN reports were submitted to the NSO. These incidents were reconciled with records from the NCPS. Patient/facility incidents were discussed daily during the facility morning report. The Chief of Surgery advised the Patient Safety Officer when incidents occurred in surgery. The Patient Safety Officer informed us that during facility orientation, all employees were trained on incident reporting.

We had an 11 percent response rate to our survey, and no employees reported concerns about incidents in surgery on the survey.

We compared information regarding surgical deaths extracted from the CDW with facility morbidity and mortality committee minutes and found the data to be congruent with information in patients’ EHRs.

We made no recommendations.

²¹ VA Caribbean Healthcare System Center Memorandum No. 00-13-70 *Patient Safety Improvement Program*, January 2013 was in effect at the time of the events discussed in this report; it was rescinded and replaced by VA Caribbean Healthcare System Center Memorandum No. 00-16-70 *Patient Safety Improvement Program*, March 2016, which contains the same or similar language regarding a culture of safety.

Acting VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 21, 2017

From: Acting Director, VA Sunshine Healthcare Network (10N8)

Subj: Healthcare Inspection—Alleged Unreported Surgical Incidents and Deaths, San Juan, Puerto Rico

To: Director, Denver Office of Healthcare Inspections (54DV)
Director, Management Review Service (VHA 10E1D MRS Action)

I have reviewed the response to the alleged unreported surgical incidents and deaths at San Juan VA Medical Center and concur with the conclusion presented by the Office of Inspector General.

(original signed by:)

Timothy W. Liezert
Acting Network Director, VISN 8

System Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 14, 2017

From: Acting Director, VA Caribbean Healthcare System (672/00)

Subj: Healthcare Inspection—Alleged Unreported Surgical Incidents and Deaths, San Juan, Puerto Rico

To: Director, VA Sunshine Healthcare Network (10N8)

1. We thank you for the opportunity to collaborate on this investigation and submit a response on behalf of the VA Caribbean Healthcare System.
2. We concur with the conclusion presented by the Office of the Inspector General. We will continue to strengthen our reporting mechanisms.

(original signed by:)

Antonio Sanchez, MD, MHSA, FAPA, FACHE

OIG Contact and Staff Acknowledgments

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