US DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficiencies in Facility Leaders' Response to Critical Surgical Events at the Michael E. DeBakey VA Medical Center in Houston, Texas

Healthcare Inspection | **23-00080-227** | **October 4, 2023**

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Michael E. DeBakey VA Medical Center (facility) in Houston, Texas, to evaluate Veterans Integrated Service Network (VISN) and facility leaders' response to critical surgical events from 2018 through 2021 and assess actions to prevent reoccurrence.[1] The OIG found that facility leaders, in consultation with VISN leaders, took progressive actions to address a provider's surgical practices and completed root cause analyses (RCAs) for each critical surgical event. However, the OIG identified failures in reporting to state licensing boards (SLBs) and the national practitioner data bank (NPDB) as well as deficiencies in RCAs' timeliness, measurability, and sustainability. Facility leaders and staff could not explain the reasons for the failures in reporting or the deficiencies in the RCAs. The OIG determined that three critical surgical events may have been prevented in the absence of the RCA deficiencies.

During a Comprehensive Healthcare Inspection Program site visit in August 2022, the OIG learned that the facility had multiple instances of wrong-site surgeries and retained surgical items in 2018, and additional instances in fiscal years 2020 and 2021.[2] On September 28, 2022, the OIG opened a hotline inspection to assess VISN and facility leaders' administrative actions and quality reviews to address and prevent reoccurrence of the critical surgical events. For this inspection, the OIG found that the facility reported eight critical surgical events within Surgery Service from 2018 through October 2022.[3] Of these eight events, five wrong-site surgeries

[1] VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013, was in effect at the time of the events discussed in this report until it was rescinded and replaced by VHA Directive 1102.01(2), *National Surgery Office*, April 24, 2019, amended April 19, 2022. The two policies contain the same or similar language related to critical surgical events. The focus of this report was wrong-site surgeries and retained surgical items; The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

[2] Wrong-site surgery is a procedure performed by a surgeon on the wrong side or site of the body. "Wrong-Site, Wrong-Procedure, and Wrong-Patient Surgery" (web page), Agency for Healthcare Research and Quality (AHRQ), accessed October 5, 2022, https://psnet.ahrq.gov/primer/wrong-site-wrong-procedure-and-wrong-patient-surgery#. Retained surgical items are instruments or materials used to perform an operative procedure that are unintentionally left in a patient's body and found "after the patient has been taken from the operating room."; VHA Directive 1103(1), *Prevention of Retained Surgical Items*, March 5, 2016, amended October 19, 2020. It was rescinded and replaced by VHA Directive 1103, *Prevention of Unintended Retained Foreign Items in the Operating Room*, April 26, 2023. Unless otherwise specified, the 2023 directive contains the same or similar language regarding retained surgical items as the 2016 directive; "Budget of the U.S. Government" (web page), usa.gov, accessed January 27, 2023, https://www.usa.gov/budget#:%60:text=The%20federal%20government%27s%20fiscal%20year,September%2030%20of%the%20next. Fiscal years for federal agencies include an annual period of "October 1 of one calendar year through September 30 of the next."

[3] The Comprehensive Healthcare Inspection Program team identified critical surgical events through a review of institutional disclosures and sentinel events. For this hotline inspection, the OIG reviewed the facility's list of critical surgical events, institutional disclosures, clinical disclosures, critical incident tracking notification data, and adverse event reports, and identified the eight critical surgical events in this report.

occurred at the facility from 2018 through 2021, and three instances of a retained surgical item occurred at the facility from 2019 through 2020.

Wrong-Site Surgeries

The OIG found that one neurosurgery attending physician (provider) performed three of the wrong-site surgeries.[4] In response, facility leaders, in consultation with VISN leaders, took progressive actions including peer reviews, counseling, a focused professional practice evaluation (FPPE) for cause, and termination to address the provider's surgical practices.[5] However, the OIG identified deficiencies with the implementation and quality of the FPPE for cause and in reporting the provider to SLBs and the NPDB.

An FPPE for cause is a management review where "medical staff leadership assesses the provider's professional performance to determine if any action should be taken on the provider's privileges."[6] Following the provider's second wrong-site surgery, Surgery Service leaders conducted an FPPE for cause to monitor and review the provider's localization of spinal levels. The OIG found that the initiating FPPE for cause document was incomplete and lacked required objective criteria such as the total number of spinal surgery cases, benchmarks for successful completion, and the final outcome of the evaluation. The current credentialing and privileging manager was unable to provide the OIG with the final completed version because the document was not maintained in the provider profile as required. Further, although the provider was due to be recredentialed, the current credentialing and privileging manager told the OIG that the Clinical Executive Board meeting minutes did not capture a discussion of the FPPE for cause.[7] Therefore, the OIG is concerned that the information contained within the FPPE for cause may not have been considered as required when determining whether to recredential the provider.

Following the provider's third wrong-site surgery, facility leaders summarily suspended the provider's privileges and initiated a focused clinical care review of spine surgeries performed

[4] The provider performed a wrong-site surgery at the facility in early 2018, and a second wrong-site surgery approximately three months later. The provider performed a third wrong-site surgery approximately seven months after the second wrong-site surgery.

[5] The provider's care for Patients A and B was peer reviewed. A protected peer review is an evaluation of a provider's specific episode of care to identify opportunities for improvement. US Office of Personnel Management defines counseling as meeting with an employee "to review and clarify expectations, and discuss performance problems." "Addressing and Resolving Poor Performance: A Guide for Supervisors," Office of Personnel Management, accessed March 29, 2023, https://www.opm.gov/policy-data-oversight/employee-relations/employee-rights-appeals/performance-based-actions/toolkit.pdf. While peer reviews were conducted in compliance with VHA policy, these protected quality improvement reviews are not discussed further in the report.

[6] VHA Medical Staff Affairs Quality, Safety, and Value, "Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance," Revision 3, January 2018.

[7] The current and former credentialing and privileging managers were unable to recall why the Clinical Executive Board minutes did not capture the discussion or why the FPPE for cause was not maintained in the provider's practitioner profile.

that confirmed the provider did not meet standard of care for the three wrong-site surgeries. Facility leaders revoked the provider's privileges and terminated the provider's employment.[8] However, following the provider's termination, facility leaders delayed reporting the provider to the Pennsylvania SLB, and failed to report the provider to the Texas SLB and NPDB in accordance with Veterans Health Administration (VHA) policy.[9] The Facility Director, Chief of Staff, and current and former credentialing and privileging managers were unable to provide an explanation to the OIG for the delay in reporting the provider to the Pennsylvania SLB, while the current credentialing and privileging manager told the OIG the facility did not have records to identify that the provider was licensed in Texas.[10] The current and former credentialing and privileging managers were unable to recall the reason for lack of reporting the provider to the NPDB.

VHA policy states that sentinel events, including wrong-site surgeries and retained surgical items, indicate a need for an RCA or other type of immediate investigation. RCAs must "identify at least one root cause with a corresponding action and outcome measure."[11] The OIG identified deficiencies with RCAs from 2018 that may have contributed to reoccurrence of wrong-site surgeries. The OIG found the RCA action plans for three of four patients in 2018 were either not mandated or measurable, or not measured for sustainability with complete audits. Additionally, the OIG found the RCA for one patient's wrong-site surgery significantly exceeded VHA's time requirement for completion.[12] In the absence of these deficiencies, two wrong-site surgeries may have been prevented. The OIG found, however, that the action plans associated with the wrong-site surgery in 2021 were implemented, monitored, and sustained.

The OIG found that facility leaders either changed processes or took additional actions to address wrong-site surgeries. No additional wrong-site surgeries occurred from 2021 through the time of this inspection.

[8] The OIG reviewed the Provider Profile Management System and confirmed the provider was deactivated from the system in early spring 2019, preventing the provider from rendering care within the VA Community Care Program or a VA Network.

[9] The provider was licensed in both Pennsylvania and Texas while employed at the facility.

[10] The credentialing and privileging manager reported being unaware of the process utilized to detect provider licenses during the time of the provider's employment. The current Credentialing and Privileging Manager was not in this role at the time of the events.

[11] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This handbook was in place during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1050.01, *VHA Quality and Patient Safety Program*, March 24, 2023. The two policies contain similar language related to RCAs.

[12] The RCA exceeded VHA's time requirement by 221 days.

Retained Surgical Items

The OIG found facility leaders ensured the completion of RCAs that included action plans to address each occurrence of a retained surgical item. The OIG reviewed the audits and facility documents related to the associated actions and found that action plans were implemented, monitored, and sustained for the three instances of retained surgical items. However, the OIG identified a deficiency with one patient's RCA related to timeliness. The OIG determined that had the RCA been completed within the required time frame, a subsequent instance of retained surgical item may have been prevented.

The OIG found that facility leaders either changed processes or took additional actions to address instances of retained surgical items. No additional instance of retained surgical items from late 2020 through the time of this inspection.

VISN Oversight

The OIG determined that VISN leaders provided consultation and oversight for the facility's critical surgical events. The VISN Chief Surgical Consultant was aware that the provider was responsible for three of the wrong-site surgeries. The VISN Chief Surgical Consultant told the OIG that facility leaders took progressive actions to address the provider's wrong-site surgeries. The VISN Chief Surgical Consultant reported recommending termination after learning of the provider's third wrong-site surgery, and facility leaders agreed with that course of action.

The OIG found the former VISN Patient Safety Officer's annual evaluations of the facility's patient safety program included documentation of deficiencies with the facility's RCAs related to due dates, actions, and outcome measures.[13] The former VISN Patient Safety Officer reported sharing the analysis of the quality of the RCAs, which included instructions for facility leaders and staff to address the deficiencies and provide updates, with the VISN Quality Management Officer who presented the information to the Facility Director. The Facility Director attributed some of the deficiencies to lack of an effective tracking system and reported that a new system was put in place in August 2021, which captures a summary of the event, awareness and closure dates, and the number of days to complete an RCA.

The OIG made three recommendations to the Facility Director related to conducting and documenting FPPEs for cause, reporting providers to SLBs and the NPDB, and conducting RCAs.

[13] The former VISN Patient Safety Officer confirmed the compliance and timeliness deficiencies contained in the annual evaluations were related to the RCAs referenced in this report.

VA Comments and OIG Response

The Veterans Integrated Network and Facility Directors concurred with the findings and recommendations and provided acceptable action plans (see appendixes B and C). The OIG will follow up on the planned actions until they are completed.

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Assistant Inspector General
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Contents

Abbreviations

EMG	electromyography
FPPE	focused professional practice evaluation
MRI	magnetic resonance imaging
NPDB	National Practitioner Data Bank
OIG	Office of Inspector General
PACU	post anesthesia care unit
RCA	root cause analysis
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Michael E. DeBakey VA Medical Center (facility) in Houston, Texas, to evaluate Veterans Integrated Service Network (VISN) and facility leaders' response to critical surgical events from 2018 through 2021 and assess actions to prevent reoccurrence.[1]

Background

The facility, part of VISN 16, consists of a medical center in Houston, Texas, and 11 community-based outpatient clinics.[2] The Veterans Health Administration (VHA) classifies the facility as a 1a, highest complexity level.[3] From October 1, 2021, through September 30, 2022, the facility served 122,509 unique patients and had a total of 517 operating beds, including 392 inpatient beds and 125 community living center beds. The facility has the nation's largest and most complex surgical program, and is affiliated with academic institutions in Texas.

Wrong-Site Surgery

Wrong-site surgery is a procedure performed by a surgeon on the wrong side or site of the body.[4] VHA notes that wrong-site surgeries "are uncommon adverse events in health care but are potentially devastating when they occur."[5] The Joint Commission considers wrong-site surgery to be a sentinel event and a "preventable medical error if certain steps are taken and standardized procedures are implemented in the perioperative setting."[6]

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[1] VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013, was in effect at the time of the events discussed in this report until it was rescinded and replaced by VHA Directive 1102.01(2), *National Surgery Office*, April 24, 2019, amended April 19, 2022. The two policies contain the same or similar language related to critical surgical events. The focus of this report was wrong-site surgeries and retained surgical items; The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

[2] The 11 outpatient clinics are located in Beaumont, Sugarland, Humble, Conroe, Galveston, Lufkin, Richmond, Texas City, Tomball, Katy, and Lake Jackson, Texas.

[3] VHA Office of Productivity, Efficiency, and Staffing (OPES), "Fact Sheet: Facility Complexity Model." The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and complexity. Level 1a facilities are considered the most complex.

[4] "Wrong-Site, Wrong-Procedure, and Wrong-Patient Surgery" (web page), Agency for Healthcare Research and Quality (AHRQ), accessed October 5, 2022, https://psnet.ahrq.gov/primer/wrong-site-wrong-procedure-and-wrong-patient-surgery#.

[5] VHA Directive 1039(3), Ensuring Correct Surgery and Invasive Procedures In and Out of the Operating Room, November 28, 2018, amended April 22, 2022.

[6] Deborah F. Mulloy and Ronda G. Hughes, "Wrong-Site Surgery: A Preventable Medical Error," chap. 36 in *Patient Safety and Quality: An Evidence-Based Handbook for Nurses,* ed. Ronda G. Hughes (Rockville: Agency for Healthcare Research and Quality, 2008), https://www.ncbi.nlm.nih.gov/books/NBK2678/.

Wrong-level spinal surgery is a specific type of wrong-site surgery that occurs when a surgeon performs a procedure on the unintended or incorrect vertebrae.[7] According to the Cleveland Clinic, "when you expose the spine at almost any level, except at the very top or very bottom of the spinal column, the vertebrae look essentially the same," which can lead to wrong-level spinal surgery.[8] Additionally, certain patient characteristics such as obesity, osteoporosis, scoliosis, and complications from previous spinal surgery increase the risk for this type of error.[9] Researchers have found that implementation of actions such as enhanced communication between operating room staff, consistent staff surgeon presence, intraoperative imaging, increased involvement of a radiologist, and strategies to verify marking the correct vertebrae have contributed to improvement in wrong-level spinal surgery rates.[10] Research also advises the use of mindful timeouts and use of the universal protocol "to work toward eliminating incorrect surgical adverse events."[11]

Retained Surgical Items

Retained surgical items are instruments or materials used to perform an operative procedure that are unintentionally left in a patient's body and found "after the patient has been taken from the operating room."[12] Contributing factors for retained surgical items include incorrect surgical item counts, inadequate staff training or staffing levels, noncompliance with policies or procedures,

[7] Mark A. Palumbo, Aaron J. Bianco, Sean Esmende, and Alan H. Daniels, "Wrong-site Spine Surgery," *Journal of the American Academy of Orthopaedic Surgeons*, no. 21 (May 2013): 312-320, https://journals.lww.com/jaaos/Fulltext/2013/05000/Wrong_site_Spine_Surgery.8.aspx. For the purpose of this report, the OIG used the umbrella term of "wrong-site surgery" when addressing wrong-level surgeries.

[8] "Road Map to a Successful Protocol for Reducing Wrong-Level Spinal Surgeries" (web page), Cleveland Clinic, accessed December 28, 2022, https://consultqd.clevelandclinic.org/road-map-to-a-successful-protocol-for-reducing-wrong-level-spinal-surgeries/.

[9] Shaarada Srivatsa, Shaleen Vira, Jean Schils, Steven Shook, Amanjit Gill and Ajit A. Krishnaney, "Reducing Wrong-level Spinal Surgeries Through Root Cause Analyses," *Spine Surgery* 46, no. 11, (June 2021): E648-E654, https://doi.org/10.1097/BRS.0000000000003864; "Road Map to a Successful Protocol for Reducing Wrong-Level Spinal Surgeries," (web page), Cleveland Clinic.

[10] Srivatsa, Vira, Schils, Shook, Gill, and Krishnaney, "Reducing Wrong-level Spinal Surgeries Through Root Cause Analyses;" "Road Map to a Successful Protocol for Reducing Wrong-Level Spinal Surgeries," (web page) Cleveland Clinic.

[11] Julia Neily, Christina Soncrant, Peter D. Mills, Douglas E. Paull, Lisa Mazzia, Yinong Young-Xu, William Nylander, Marilyn M. Lynn, William Gunnar, "Assessment of Incorrect Surgical Procedures Within and Outside the Operating Room: A Follow-up Study from US Veterans Health Administration Medical Centers," *JAMA Network Open.*1, no.7 (November 21, 2018), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2715615.

[12] VHA Directive 1103(1), *Prevention of Retained Surgical Items*, March 5, 2016, amended October 19, 2020. It was rescinded and replaced by VHA Directive 1103, *Prevention of Unintended Retained Foreign Items in the Operating Room*, April 26, 2023. Unless otherwise specified, the 2023 directive contains the same or similar language regarding retained surgical items as the 2016 directive.

and communication deficiencies between operating room staff.[13] The Joint Commission identified retained surgical items as the most frequently reported surgical sentinel event.[14] Research-identified recommendations to mitigate the risk for retained surgical items include tools to verify surgical counts, technology that detects surgical items after a procedure, audits to confirm adherence with policies and procedures, and verbal acknowledgment of the removal of items from the surgical area.[15]

Prior OIG Reports

In August 2021, the OIG published a report, *Deficiencies in COVID-19 Screening and Facility Response for a Patient Who Died at the Michael E. DeBakey VA Medical Center in Houston, TX*, that identified concerns related to facility leaders' failure to perform timely quality reviews for an adverse event. The OIG made nine recommendations that have been closed.[16]

Concerns

During a Comprehensive Healthcare Inspection Program site visit in August 2022, the OIG learned that the facility had multiple instances of wrong-site surgeries and retained surgical items in 2018, and additional instances in fiscal years 2020 and 2021.[17] On September 28, 2022, the OIG opened a hotline inspection to assess VISN and facility leaders' administrative actions and quality reviews to address and prevent reoccurrence of the critical surgical events.

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[13] Victoria M. Steelman, Clarissa Shaw, Laurel Shine, and Abbey J. Hardy-Fairbanks, "Unintentionally Retained Foreign Objects: A Descriptive Study of 308 Sentinel Events and Contributing Factors," *The Joint Commission Journal on Quality and Patient Safety* 45, no. 4, (April 2019): 249-258, https://doi.org/10.1016/j.jcjq.2018.09.001; Surgery staff count all items used during a procedure such as instruments, sponges, and sharps to ensure that nothing has been left within a patient. Eduardo T. Gomes, Mayana C. B. Galvao, Gilceria T. Shimoda, Larissa B. de. Oliveira, and Valanice A. de. Araujo Puschel, "Surgical counts in open abdominal and pelvic surgeries in a university hospital: a best practice implementation project," *JBI Evidence Implementation*, no. 19 (March 2021): 84-93, https://pubmed.ncbi.nlm.nih.gov/33570336/.

[14] Steelman, Shaw, Shine, and Hardy-Fairbanks, "Unintentionally Retained Foreign Objects: A Descriptive Study of 308 Sentinel Events and Contributing Factors."

[15] Steelman, Shaw, Shine, and Hardy-Fairbanks, "Unintentionally Retained Foreign Objects: A Descriptive Study of 308 Sentinel Events and Contributing Factors;" Robert R. Cima and James S. Newman, "A historical perspective on the problem of the retained surgical sponge: Have we really come that far?," *Surgery* Volume 170, Issue 1, (July, 1, 2021): 146-152, https://doi.org/10.1016/j.surg.2021.01.035.

[16] VA OIG, *Deficiencies in COVID-19 Screening and Facility Response for a Patient Who Died at the Michael E. DeBakey VA Medical Center in Houston, Texas*, Report No. 20-03635-217, August 18, 2021.

[17] VA OIG, *Comprehensive Healthcare Inspection of the Michael E. DeBakey VA Medical Center in Houston, Texas*, Report No. 22-00238-213, September 22, 2023; "Budget of the U.S. Government" (web page), usa.gov, accessed January 27, 2023, https://www.usa.gov/budget#:%60:text=The%20federal%20government%27s%20fiscal%20year,September%2030%20of%the%20next. Fiscal years for federal agencies include an annual period of "October 1 of one calendar year through September 30 of the next."

Scope and Methodology

The OIG initiated the inspection on September 29, 2022, and conducted a site visit November 7 through 9, 2022. Additionally, the OIG conducted interviews virtually prior to, during, and after the site visit.

The OIG interviewed the National Surgery Office Director, VISN leaders, facility leaders, service chiefs and supervisory staff, quality management staff, a current and former credentialing and privileging manager, and surgery nursing staff.[18]

The OIG reviewed VHA and facility policies, external standards, and literature reviews; VHA notification documents and email correspondence; human resource and personnel documents; patient electronic health records; quality management documents; and VISN and National Surgery Office reports.

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, as amended, 5 U.S.C. §§ 401–424. The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. 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.

[18] VISN leaders included the VISN Director, former VISN Patient Safety Officer, VISN Chief Surgical Consultant, and the VISN Lead Surgical Nurse. Facility leaders included the Facility Director and Chief of Staff.

Synopsis of Critical Surgical Events

The OIG found that the facility reported eight critical surgical events within Surgery Service from 2018 through October 2022—five wrong-site surgeries and three instances of a retained surgical item.[19] (See appendix A for patient case summaries.)

Wrong-Site Surgeries

Five wrong-site surgeries occurred at the facility from 2018 through 2021: four in 2018 and one in 2021. The OIG found that one neurosurgery attending physician (provider) performed the surgeries for Patients A, B, and C in 2018.[20]

- Patient A: Surgery at the C6 spinal level of the neck instead of the scheduled C5 and C6 levels. (See figure 1 for spinal levels of the neck.)
- Patient B: Surgery at the C4 through C6 spinal levels instead of the scheduled C3 through C5 levels.
- Patient C: Surgery at C5 through C6 spinal levels instead of the scheduled C6 through C7 levels.
- Patient D: Left ring finger instead of the scheduled left middle finger.
- Patient E: Surgery at the C4 through C5 spinal levels instead of the scheduled C5 through C6 levels.

[19] The Comprehensive Healthcare Inspection Program team identified critical surgical events through a review of institutional disclosures and sentinel events. For this hotline inspection, the OIG reviewed the facility's list of critical surgical events, institutional disclosures, clinical disclosures, critical incident tracking notification data, and adverse event reports, and identified the eight critical surgical events in this report.

[20] The provider performed a wrong-site surgery at the facility in early 2018, and a second wrong-site surgery approximately three months later. The provider performed a third wrong-site surgery approximately seven months after the second wrong-site surgery.

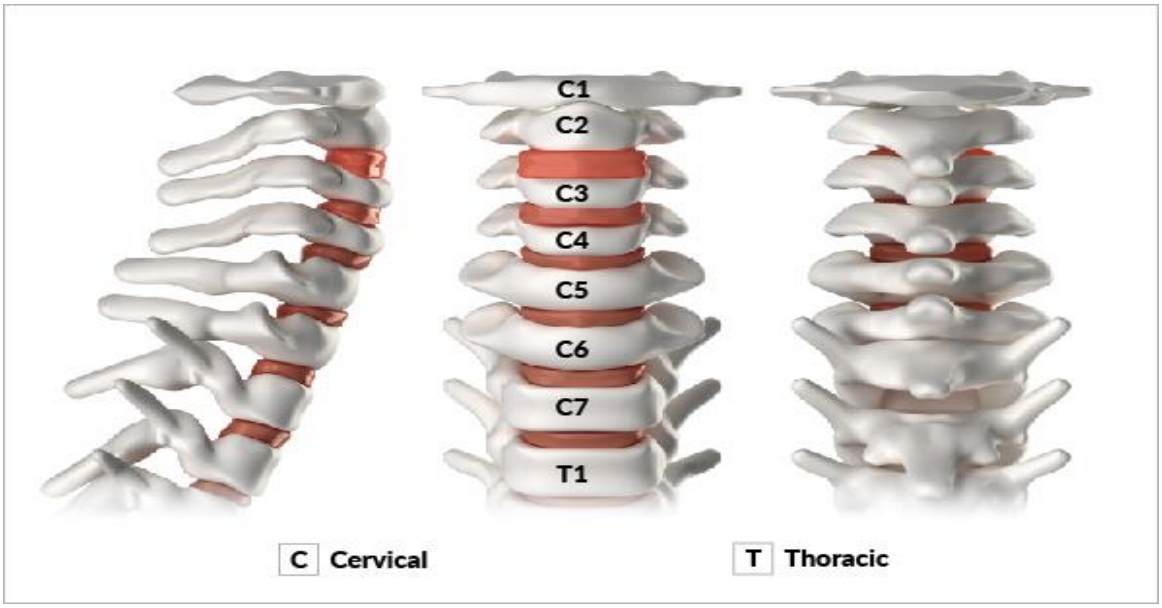

Figure 1. *Cervical spine anatomy of the neck.*
Source: OIG analysis/Adobe Stock

Retained Surgical Items

Three instances of a retained surgical item occurred at the facility from 2019 through 2020:

- Patient F: Surgery on the right knee with a retained piece of an impactor handle.
- Patient G: Surgery on the right hip with a retained piece of a drill tip.
- Patient H: Surgery on the right shoulder with a retained surgical sponge.

Inspection Results

The OIG reviewed the following information to determine how the facility addressed the critical surgical events and if subsequent provider or process errors could have been prevented:

- actions taken to address the wrong-site surgeries from 2018 through 2021,
- actions taken to address retained surgical items from 2019 through 2020, and
- VISN oversight.

1. Facility Response to Critical Surgical Events

The OIG found that facility leaders took administrative actions and conducted quality reviews in response to the critical surgical events. Although the efforts of facility leaders ultimately reduced the number of wrong-site surgeries and retained surgical items, the OIG identified that some facility leaders' responses were deficient or delayed.

Wrong-Site Surgeries

The OIG determined that facility leaders took progressive actions including peer reviews, counseling, a focused professional practice evaluation (FPPE) for cause, and termination to address the surgical practices of the provider that led to three of the five wrong-site surgeries.[21] (See figure 2 for a summary of progressive actions.) The OIG identified deficiencies with the implementation and quality of the FPPE for cause and identified deficiencies in reporting the provider to the state licensing board (SLB) and the national practitioner data bank (NPDB). Surgery Service leaders counseled providers involved in the two other wrong-site surgeries. In addition to taking actions focused on the providers, facility leaders ensured root cause analyses (RCAs) were completed and process changes made, which were aimed at preventing recurrences. The OIG found deficiencies in RCAs that were performed in response to three of the five wrong-site surgeries.

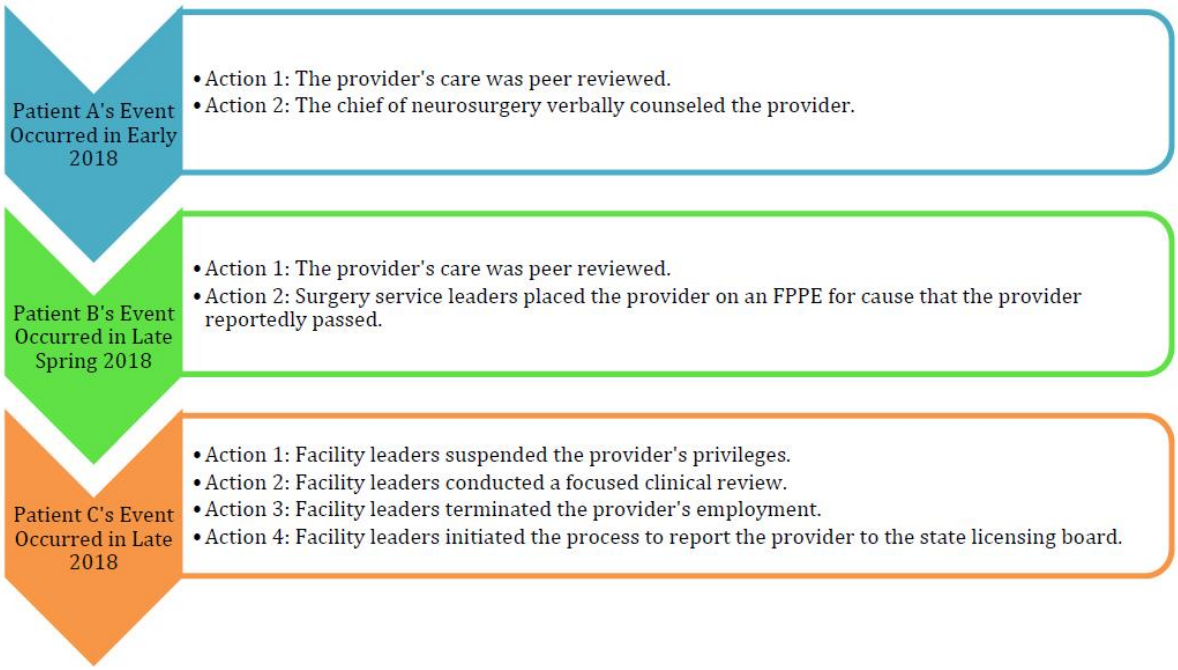

Figure 2. *Summary of actions to address the provider's care after each wrong-site surgery.*
Source: OIG analysis of peer reviews, FPPE for cause, and facility letters.

[21] The provider's care for Patients A and B was peer reviewed. A protected peer review is an evaluation of a provider's specific episode of care to identify opportunities for improvement. US Office of Personnel Management defines counseling as meeting with an employee "to review and clarify expectations, and discuss performance problems." "Addressing and Resolving Poor Performance: A Guide for Supervisors," Office of Personnel Management, accessed March 29, 2023, https://www.opm.gov/policy-data-oversight/employee-relations/employee-rights-appeals/performance-based-actions/toolkit.pdf. While peer reviews were conducted in compliance with VHA policy, these protected quality improvement reviews are not discussed further in the report.

Deficiencies in FPPE for Cause

The OIG identified concerns related to the FPPE for cause.

An FPPE for cause is a management review where "medical staff leadership assesses the provider's professional performance to determine if any action should be taken on the provider's privileges."[22] The criteria for the FPPE for cause is to be defined in advance using objective criteria recommended by the service chief and Executive Committee of the Medical staff (Clinical Executive Board).[23] The FPPE for cause must be documented in the provider profile and results must be reported to the Clinical Executive Board for consideration in recommending privileges.

The OIG learned that, following the provider's second wrong-site surgery, Surgery Service leaders conducted an FPPE for cause from June 4, 2018, through September 3, 2018, to monitor and review the provider's localization of spinal levels. The OIG reviewed the initiating FPPE for cause document and found the document was incomplete. Additionally, the document lacked required objective criteria such as the total number of spinal surgery cases, benchmarks for successful completion, and the final outcome of the evaluation. Although the Facility Director, chief of surgery, and the chief of neurosurgery stated the provider successfully completed the FPPE for cause after Patient B's wrong-site surgery, the current credentialing and privileging manager was unable to provide the final version of the document to the OIG indicating successful completion.

The OIG learned in an interview with the current credentialing and privileging manager that the Clinical Executive Board meeting on October 2, 2018, should have included a discussion of the results from the FPPE for cause because the provider was due to be recredentialed. The current credentialing and privileging manager reported that the Clinical Executive Board meeting minutes did not capture the discussion, and the FPPE for cause was not maintained in the provider profile as required per policy.[24] Therefore, the OIG is concerned that information

[22] VHA Medical Staff Affairs Quality, Safety, and Value, "Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance," Revision 3, January 2018.

[23] VHA Handbook 1100.19, *Credentialing and Privileging,* October 15, 2012. This handbook was in place during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1100.20 *Credentialing of Health Care Providers*, September 15, 2021. Both contain the same or similar language related to focused professional practice evaluation. The Chief of Staff chairs the Executive Committee of Medical Staff and must consider all information available, including the service chief's recommendation prior to making a recommendation to the Director for the granting of privileges. This deliberation must be clearly documented in the minutes. The facility uses the title Clinical Executive Board in the place of Executive Committee of the Medical Staff.

[24] The current and former credentialing and privileging managers were unable to recall why the Clinical Executive Board minutes did not capture the discussion or why the FPPE for cause was not maintained in the provider's profile.

contained within the FPPE for cause may not have been considered when determining whether to recredential the provider.

Deficiencies in Reporting to SLBs and NPDB

The OIG identified concerns related to reporting the provider to SLBs and the NPDB.

A provider's clinical privileges may be summarily suspended when a risk for imminent danger to patients' health is suspected. A comprehensive review of the reason for suspension should be completed within 30 days, and recommendations provided to facility directors on whether to move forward with formal procedures for reduction or revocation of clinical privileges.[25]

It is VA policy to report separated VHA-licensed healthcare professionals to each SLB where the professional holds a license when substantial evidence indicates that the professional's clinical practice significantly failed to meet generally accepted standards.[26] The SLB reporting processes should typically be completed within 100 days after the initial review stage begins.[27] VHA policy requires facility directors to report providers whose privileges have been revoked and employment terminated to the national NPDB within 15 calendar days of the date the action is made final by signature of the facility director.[28]

Following Patient C's surgery, facility leaders initiated a summary suspension of the provider's privileges in late 2018 due to the clinical care concerns. The OIG found that a focused clinical care review was conducted of the spine surgeries performed by the provider from early 2018 through late 2018 to determine whether the provider met the standard of care. In early 2019, reviewers submitted a completed focused clinical care review to the Chief of Staff that confirmed the provider did not meet the standard of care in the three wrong-site surgery cases.[29] As a result, the Facility Director revoked the provider's privileges and terminated the provider's employment a few weeks later. The OIG reviewed the Provider Profile Management System and confirmed the provider was deactivated from the system in early spring 2019, preventing the provider from rendering care within the VA Community Care Program or a VA Network.[30]

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[25] VHA Handbook 1100.19.

[26] VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards,* December 22, 2005. This handbook was in place during the time of the events discussed in this report until it was rescinded and replaced by VHA Directive 1100.18 *Reporting and Responding to State Licensing Boards,* January 28, 2021. Both contain the same or similar language related to the process for state licensing board reporting.

[27] VHA Handbook 1100.18; VHA Directive 1100.18. "The initial review begins within seven calendar days from the date a licensed health care professional leaves VA employment or information is received suggesting that a current employee's clinical practice has met the reporting standard."

[28] VHA Handbook 1100.17, *National Practitioner Data Bank (NPDB) Reports*, December 28, 2009; VHA Handbook 1100.19; VHA Directive 1100.20.

[29] Of the 104 total cases reviewed, reviewers found the standard of care was not met in 3 cases: Patients A, B, and C.

[30] In the context of this report, VA Community Care refers to any care paid for by the VA. The OIG does not have knowledge of the provider being responsible for additional critical surgical events subsequent to VHA employment.

The OIG reviewed documents and found the provider was licensed in Pennsylvania and Texas. Although the Facility Director sent a letter in early 2019 to alert the Pennsylvania SLB of an investigation involving the provider, the investigation's results were not disclosed to the SLB until early fall 2019, over seven months after the provider's termination.[31] The Facility Director, Chief of Staff, and current and former credentialing and privileging managers were unable to provide an explanation to the OIG for the delay in reporting the provider to the Pennsylvania SLB. According to the current credentialing and privileging manager, the provider was not reported to the Texas SLB because the facility did not have records to identify that the provider was licensed in Texas. The current credentialing and privileging manager reported being unaware of the process utilized to detect provider licenses during the time of the provider's employment.[32]

Additionally, the facility was unable to provide evidence that the provider was reported to the NPDB. The current credentialing and privileging manager told the OIG that documentation for reporting providers to the NPDB is stored in an electronic system called VetPro.[33] The credentialing and privileging manager reported that VetPro did not display an NPDB disclosure for adverse actions following the provider's termination. The current and former credentialing and privileging managers were unable to recall the reason for lack of reporting.

The OIG concluded that while facility and surgery leaders took progressive actions and ultimately terminated the provider's employment, staff did not maintain documentation in the provider's profile. Additionally, facility leaders failed to report the provider to the Texas SLB and NPDB, and delayed reporting the provider to the Pennsylvania SLB. Delays or failure to report clinicians to SLBs and the NPDB may result in organizations hiring providers who do not meet generally accepted standards of clinical practice creating a concern for patient safety.

Root Cause Analyses

The OIG determined that facility leaders ensured the completion of an RCA for each wrong-site surgery. However, the OIG identified deficiencies with RCAs that may have contributed to reoccurrence of wrong-site surgeries.

VHA policy states that sentinel events, including wrong-site surgeries and retained surgical items, indicate a need for an RCA or other type of immediate investigation. RCAs assist facility leaders in identifying the root cause of an adverse event that could subsequently help the facility

[31] Because the focused clinical care review concluded in early 2019 that the provider did not meet the standard of care, the initial SLB reporting stage should have begun no later than one week later, according to VHA policy. Therefore, reporting would typically have occurred by mid-spring 2019. VHA Handbook 1100.18.

[32] The current credentialing and privileging manager was not in this role at the time of the events.

[33] VHA Handbook 1100.19; VHA Directive 1100.20. VetPro is an electronic "data bank for the credentialing of VHA health care practitioners that facilitates completion of a uniform, accurate, and complete credentials file." Credentialing is VHA's process to screen and evaluate a provider's qualifications.

with identifying system vulnerabilities.[34] An RCA "focuses primarily on systems and processes rather than individual performance" and "must be completed, signed by the facility Director, and submitted to the National Center for Patient Safety within 45 days of the facility becoming aware that an RCA is required." RCAs must "identify at least one root cause with a corresponding action and outcome measure."[35]

Deficiencies in RCAs in 2018

For each of the wrong-site spinal level surgeries, the RCA team identified similar action plans to prevent subsequent wrong-site surgeries in 2018. These action plans included consideration of or an expectation for surgery staff to implement process improvement changes to address this matter.

The OIG reviewed the associated action plans and found that the action plans for one patient's wrong-site surgery were implemented, monitored, and sustained. However, the action plans for the other three patients were either not mandated or measurable, or not measured for sustainability with complete audits.

Additionally, the OIG found the RCA completion for one patient's wrong-site surgery significantly exceeded VHA's time requirement by 221 days. While the Deputy Director told the OIG an RCA should have been chartered sooner because the wrong-site surgery was a sentinel event, and that the former patient safety manager should have communicated the need for an RCA to facility leaders, "the exact cause of the RCA delay was unknown." The OIG analyzed the RCAs and found that in the absence of these noted deficiencies, two wrong-site surgeries may have been prevented.

Effective RCA for 2021 Wrong-Site Surgery

The OIG determined that implementation or sustainment of action plans from prior RCAs would likely not have prevented Patient E's wrong-site surgery. In fact, the OIG found that the sustained prior action plans assisted with the discovery and correction of Patient E's wrong-site surgery prior to leaving the operating room.

The RCA team identified action plans to prevent similar subsequent wrong-site surgeries. The OIG reviewed facility documents related to the associated action plans and found that the actions were implemented, monitored, and sustained.

The implementation and sustainment of the RCA action plans related to Patient E were effective and no additional wrong-site surgeries occurred from 2021 through the time of this inspection.

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[34] VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, March 4, 2011. This handbook was in place during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1050.01, *VHA Quality and Patient Safety Program*, March 24, 2023. The two policies contain similar language related to RCAs.

[35] VHA Handbook 1050.01; VHA Directive 1050.01

Process Changes and Other Actions

The chief of surgery told the OIG that after Patient A's wrong-site surgery, Surgery Service leaders reviewed the event to "identify what could have been done differently in the operating room." According to the chief of neurosurgery, the patient's complex anatomy contributed to the provider miscounting spinal levels, and the provider was educated on ways to improve surgical site confirmation.

Patient B experienced a wrong-site surgery although surgery staff completed an intraoperative x-ray to verify the site. After the wrong-site surgery, the chief of surgery reported mandating that two attending surgeons confirm the surgical site.

Patient C experienced a wrong-site surgery despite precautionary actions taken that included proper localization with intraoperative x-rays. Due to the repeated wrong-site surgeries, the provider was placed on a focused clinical review that resulted in termination.

The issue brief associated with Patient D's wrong-site surgery noted the involved surgeons were counseled and that "residents will confirm with the attending the site of surgery an additional time after the second time out is performed and before incision is made."

In addressing Patient E's wrong-site surgery, the chief of surgery counseled the surgeons involved and reviewed steps previously implemented for ensuring correct surgical level identification. Additionally, the chief of neurosurgery reported during an interview that the installation of data ports was implemented to foster direct communication between the surgeon and the radiologist, and helped to simplify the relaying of imaging results to the surgery team.

Although facility leaders ensured RCAs were generated for each patient, the OIG identified deficiencies related to timeliness and subsequent action plans. In the absence of these deficiencies, two wrong-site surgeries may have been prevented. Surgery Service leaders implemented additional actions to improve processes for wrong-site surgeries in 2018 through 2021.

Retained Surgical Items

The OIG determined that Surgery Service leaders took actions to improve processes or address the care provided by surgeons in the instances of retained surgical items. Additionally, the OIG found that facility leaders ensured the completion of RCAs with action plans to address each occurrence of a retained surgical item. However, the OIG identified a deficiency with one patient's RCA related to timeliness. The OIG found that action plans for each event were sustained and no additional instances of retained surgical items occurred from late 2020 through the time of this inspection.

Deficiency With a Root Cause Analysis

For each of the three patients, the RCA team identified action plans to prevent similar instances of retained surgical items. The action plans included the implementation of additional steps to improve involved surgical processes. The OIG reviewed audits and facility documents related to the associated action plans and found that action plans were implemented, monitored, and sustained for the three instances of retained surgical items.

The OIG found the RCA for one patient's retained surgical item was not completed within VHA's time requirement.[36] The Deputy Director told the OIG the reason for the RCA's delayed completion was not known and explained that the former patient safety manager should have followed VHA guidance. The OIG determined that had the RCA been completed within the required time frame, a subsequent instance of retained surgical item may have been prevented.

Process Changes and Other Actions

An impactor handle broke in Patient F during the procedure as the artificial knee was being impacted at the femur. The chief of orthopedic surgery told the OIG that surgery staff did not know the instrument broke during surgery and that, after this instance of a retained surgical item, technicians were more "vigilant" about checking equipment.

For Patient G, staff identified a "broken drill bit during a routine postoperative portable radiograph of the pelvis." The chief of orthopedic surgery told the OIG that after Patient G's retained surgical item, Surgery Service leaders mandated surgical technicians inspect each drill bit and confirm the drill bits were intact. The chief of orthopedic surgery also reported implementing a requirement for post-procedure x-rays in the operating room instead of the previous practice of obtaining x-rays in the post anesthesia care unit (PACU).

For Patient H, surgery staff needed to utilize several sponges to stop bleeding during the procedure. The following day, prior to Patient H's discharge, an x-ray revealed a retained surgical sponge. The chief of orthopedic surgery explained that nurses are required to scan a patient's body with a radiofrequency wand to detect surgical sponges (embedded with alert tags) for orthopedic surgeries.[37] The chief of orthopedic surgery reported that after Patient H's instance of a retained surgical item, Surgery Service leaders immediately met with all nursing staff to review the requirement for scanning patients with wands. The OIG reviewed email correspondence and found that the chief of orthopedic surgery also addressed concerns regarding the involved surgeon through a supervisory discussion. The chief of orthopedic surgery attributed the surgeon's lapse in obtaining x-rays in the operating room to being a major "culture change" from the prior practice of obtaining post-procedure x-rays in the PACU. However, the

[36] VHA Handbook 1050.01; VHA Directive 1050.01. The RCA exceeded VHA's time requirement by 98 days.

[37] Daniel Cook, "Counts Aren't Always Correct," *Outpatient Surgery,* March 19, 2020, https://www.aorn.org/outpatient-surgery/articles/outpatient-surgery-magazine/2020/march/counts-arent-always-correct.

chief of orthopedic surgery could not provide a reason why the surgeon did not obtain postoperative x-rays in the PACU, which had been the standing practice for many years.

The OIG concluded that Surgery Service leaders implemented additional actions to improve processes or address involved surgeons in the instances of retained surgical items from 2019 through 2020. Facility leaders ensured RCAs were generated for all three instances of retained surgical items. The OIG found that action plans were sustained and no additional instances of retained surgical items occurred from late 2020 through the time of this inspection. However, one of the three instances of a retained surgical item may have been prevented if the RCA for a prior retained surgical item was completed within VHA's time requirements.

2. VISN Oversight

The OIG determined that VISN leaders provided consultation and oversight for the facility's critical surgical events. The OIG found that the VISN Chief Surgical Consultant (VCSC) provided consultation and recommendations regarding management of the provider, and that the former VISN Patient Safety Officer (PSO) reviewed the facility's RCA deficiencies with VISN and facility leaders while providing recommendations for improvement.

VHA assigns facility directors the responsibility to ensure that critical surgical events are reported to the VISN.[38] VHA policy assigns the VCSC responsibility for "overseeing and addressing any deficiencies in VISN clinical outcomes, and standards of care."[39] The VISN PSO supports the RCA process by addressing system issues that cause delays in completion of RCAs, evaluating RCAs for thoroughness, providing feedback, and confirming implementation of RCA actions.

The OIG found that VISN leaders were alerted to the eight critical surgical events when facility leaders submitted an issue brief or critical incident tracking notification for each patient. During an interview with the OIG, the chief of surgery reported that it is standard practice to immediately notify the VCSC following awareness of critical surgical events. The VCSC confirmed consistently providing advice to the chief of surgery regarding action plans for critical surgical events.

Consultation for Addressing the Provider

The OIG reviewed VHA's National Surgery Office yearly reports from fiscal years 2018 through 2021 and found the facility had the highest prevalence of wrong-site surgeries within VHA but was not an outlier for retained surgical items. In fiscal years 2018 and 2019, the facility

[38] VHA Handbook 1102.01; VHA Directive 1102.01(2).
[39] VHA Handbook 1102.01; VHA Directive 1102.01(2).

accounted for four of the six wrong-site surgeries in VISN 16. The VCSC was aware that the provider was responsible for three of those surgeries.

The VCSC reported that facility leaders took progressive actions to address the provider's wrong-site surgeries. The VCSC went on to say facility leaders took the expected course of action that included placing the provider on a performance improvement plan, changing policies and procedures, and ensuring the provider adhered to them. Further, the VCSC told the OIG of believing that the provider was putting patient safety in jeopardy after receiving notification of the third wrong-site surgery, recommending termination, and facility leaders agreeing with that course of action.

Oversight of Root Cause Analyses

The OIG reviewed the former VISN PSO's annual evaluations of the facility's patient safety program from fiscal years 2018 through 2021 and found that evaluations for fiscal years 2019 and 2020 included documentation of deficiencies with the facility's RCAs related to incomplete or past due dates, actions, and outcome measures. The evaluations also included documentation of an intent to schedule updates "to leadership" and to include progress toward addressing deficiencies.

The OIG interviewed the former VISN PSO who reported auditing RCAs for critical surgical events and confirmed the compliance and timeliness deficiencies contained in the annual evaluations were related to the RCAs referenced in this report.[40] The former VISN PSO also reported sharing analysis of the quality of the RCAs with the VISN Quality Management Officer who presented the information to the Facility Director. The analysis included instructions for facility leaders and staff to address the deficiencies and provide updates. During an interview with the OIG, the Facility Director acknowledged a history of delays in completing RCAs and confirmed receiving guidance and support from VISN leaders toward improving deficiencies. When asked about the history of delays, the Facility Director stated that "there was not an effective tracking system in place to ensure that RCAs were completed on time." The Facility Director informed the OIG that a new tracking system was implemented in August 2021, which captures a summary of the event, awareness and closure dates, and the number of days to complete the RCA.

The OIG concluded that VISN leaders provided oversight and consultation to facility leaders regarding critical surgical events. The VCSC provided consultation and recommendations to facility leaders for managing the provider to prevent further wrong-site surgeries. Additionally, the former VISN PSO conducted annual reviews of the facility's RCA process and identified deficiencies, while the VISN Quality Management Officer alerted facility leaders to areas in need of improvement.

[40] VHA Handbook 1050.01; VHA Directive 1050.01.

Conclusion

While facility and surgery leaders took progressive actions and ultimately terminated the provider's employment, staff did not maintain documentation in the provider's profile. Additionally, facility leaders failed to report the provider to the Texas SLB and NPDB, and delayed reporting the provider to the Pennsylvania SLB. Delays or failure to report clinicians to SLBs and the NPDB may result in organizations hiring providers who do not meet generally accepted standards of clinical practice, creating a concern for patient safety. Although facility leaders ensured RCAs were generated for each wrong-site surgery, the OIG identified deficiencies related to timeliness and subsequent action plans. In the absence of these deficiencies, two wrong-site surgeries may have been prevented. Surgery Service leaders implemented additional actions to improve processes for wrong-site surgeries in 2018 through 2021.

Surgery Service leaders implemented additional actions to improve processes or address involved surgeons in the instances of retained surgical items from 2019 through 2020. Facility leaders ensured RCAs were generated for all three instances of retained surgical items. The OIG found that action plans were sustained, and no additional instances of retained surgical items occurred from late 2020 through the time of this inspection. However, one of the three instances of a retained surgical item may have been prevented if the RCA for a prior retained surgical item was completed within VHA's time requirements.

VISN leaders provided oversight and consultation to facility leaders regarding critical surgical events. The VCSC provided consultation and recommendations to facility leaders for managing the provider to prevent further wrong-site surgeries. Additionally, the former VISN PSO conducted annual reviews of the facility's RCA process, identified deficiencies, and alerted VISN and facility leaders to areas in need of improvement.

Recommendations 1–3

1. The Houston VA Medical Center Director ensures that staff conduct and document focused professional practice evaluations for cause as required by the Veterans Health Administration.

2. The Houston VA Medical Center Director reviews processes for reporting providers to state licensing boards and the national practitioner data bank when a concern for patient safety is identified, and takes action to ensure compliance.

3. The Houston VA Medical Center Director reviews the processes for conducting root cause analyses to ensure that reports are completed timely and that action plans are measurable, sustainable, and monitored to completion.

Appendix A: Patient Case Summaries

Patient A

Patient A, in their 60s, had a past medical history of diabetes mellitus, high blood pressure, and obesity.[41] Patient A had constant neck pain with increased reflexes in both arms. Preoperative imaging included a magnetic resonance imaging (MRI), computed tomography scan, and x-rays of the cervical spine. Patient A's diagnosis was severe spinal column narrowing with compression of the spinal cord (spinal stenosis) at the C5-C6 level of the vertebrae and multilevel severe compression of the nerve roots that exit the spinal column (neural foraminal narrowing) with upper extremity loss of sensation, loss of function, and pain or discomfort (myelopathy). The provider saw Patient A in the clinic and discussed the option of surgery due to the severity of clinical findings and images.

In early 2018, the provider performed a laminoplasty intended for the C5 level of the vertebrae. The provider placed a spinal needle along the back of the neck to mark the planned level of the procedure prior to making an incision. The provider obtained three intraoperative x-rays to identify the correct level, however, performed an incomplete C6 laminoplasty that resulted in an unexpected fracture of the lamina upon hardware placement. The provider did not perform intraoperative fluoroscopy or obtain immediate postoperative films in the operating room or PACU.

Patient A had x-rays of the cervical spine taken on postoperative day two. On postoperative day three, an MRI confirmed the x-ray findings showing the procedure was performed on the incorrect cervical level, and an incomplete spinal decompression.

In early 2020, Patient A returned to the operating room where another surgeon removed the plate, performed a laminectomy at the intended site and stabilized the spine from C3 to C7 with a fusion using a different plate.

Patient B

Patient B, in their 70s, had a history of high blood pressure, carpal tunnel syndrome of both wrists, with weakness and numbness of the hands and legs. Preoperative imaging included x-rays of the cervical spine. The indications for surgery were weakness and numbness in both arms and hands with loss of dexterity, and an abnormal walking pattern with imbalance for three to four years.

The procedure was performed in late spring 2018 for a C4 laminoplasty with decompression at C3-C4 and C4-C5 and a plate fixation. Spinal needles marked the planned level of surgery before the incision. The surgeon used two intraoperative x-rays to identify the spinal level. The provider

[41] The OIG uses the singular form of they, "their" in this instance, for privacy purposes.

selected the incorrect level and performed the procedure at the C4-C5 and C5-C6 laminoplasty and plate fixation. Staff did not complete x-rays at the completion of the case in the operating room or the PACU. X-rays performed on the day after surgery and an MRI completed on postoperative day two confirmed the provider operated one level below the planned procedure site.

On postoperative day two, the provider informed Patient B of the incorrect level. The two surgeons and Patient B agreed upon a revision surgery at the intended level with plate fixation that occurred four days later without intraoperative complications.

Patient C

Patient C, in their 50s, had a medical history of alcoholic cirrhosis of the liver, anemia, pain (hip and low back), knee osteoarthritis, substance abuse (cocaine, alcohol), and depression. Patient C had a past surgical history of a lumbar fusion on the lower back in 2014. In mid-summer 2017, Patient C first had cervical spine surgery when the provider performed a right C6-C7 foraminotomy for neck pain and arthritis in the right hand. Although there was initial improvement, Patient C's neck pain returned and arm weakness and fingertip numbness remained. Staff completed an evaluation of Patient C using imaging and an electromyography (EMG) in the clinic to evaluate the unresolved symptoms that showed no evidence of nerve compression at the level of the cervical spine. A repeat EMG was recommended, but Patient C could not complete the exam due to an inability to tolerate nerve stimulation even at minimal levels. The MRI showed right C6-C7 foraminal stenosis, and both the MRI and x-rays demonstrated significant loss of disc space height.

The planned procedure to be completed by the provider and a neurosurgeon was to remove the C6-C7 disc, place a metallic spacer (cage) between the two vertebrae with bone graft, and a plate with screws. This procedure involved an incision along the side of the neck. The neurosurgeon began the procedure, exposing the soft tissue and the spine. The provider took over the case while the neurosurgeon left the operating room and did not return. Fluoroscopy was the intraoperative imaging modality to identify the correct level for the procedure. The provider identified the correct level for the instrumentation (plate, screws, and metallic spacer) at the C6-C7 level. However, the provider identified the incorrect level for decompression and performed the procedure on the C5-C6 level instead of the planned C6-C7 level. In late 2018 (postoperative day one), the provider, the chief neurosurgery resident, and the neurosurgeon explained the error to Patient C. The surgeons recommended that Patient C return to the operating room to decompress the C6-C7 level, and the procedure was scheduled for two days later, based on patient preference. After this discussion, Patient C was discharged to home with the plan to return for the additional procedure. Patient C called to cancel the procedure on the day before the planned revision surgery, and expressed frustration with care received.

Patient D

Patient D, in their 40s, had a history of high blood pressure and chronic nail fungal infections of the left hand. Patient D was seen by the orthopedic service for a mass (bump) on the left middle finger that was diagnosed as a mucous cyst at the joint just below the nail bed. Patient D's mass had previously been treated with antibiotics and did not resolve. The surgical plan was to excise the mucous cyst of the left middle finger just below the nailbed.

On the day of surgery, staff admitted Patient D to the orthopedic service. An orthopedic surgeon marked the operative site. In the operating room, staff placed a tourniquet on Patient D's left, operative arm. Staff noted the preoperative mass on the left middle finger to be very similar to other masses along every finger in the left hand, including the ring finger. Staff prepped and draped the arm in standard fashion. Staff incorrectly marked the left ring finger after the preparation. An orthopedic surgery resident began the case with the orthopedic surgeon scrubbed in the surgical area. Surgeons operated on the left ring finger and not the intended planned left middle finger. After identifying the error, the orthopedic surgeon conducted the correct operation. The orthopedic surgeon informed Patient D of the wrong-site surgery.

Patient E

Patient E, in their 70s, had a past medical history significant for coronary artery disease, hypertension, morbid obesity, sleep apnea, low back and knee pain, posttraumatic stress disorder (PTSD), and depression. Past surgical history included lumbar spine surgery in 2018 and 2020. Patient E described new problems including an unbalanced gait, feet numbness, and need for a cane to prevent falling while walking. X-rays showed "moderate to severe disc space narrowing" with bone spurs at C5-C6. An MRI in late summer 2020 demonstrated multilevel arthritis and disc disease, worst at C5-C6 level, and foraminal stenosis with moderate to severe spinal canal stenosis. The indications for surgery were cervical spondylosis with myelopathy with gait imbalance. The planned procedure was C5-C6 anterior cervical discectomy and fusion with instrumentation.

In late spring 2021, staff took Patient E to the operating room. A preoperative note was completed by one surgeon. A second neurosurgeon was the operating surgeon but did not write a day of surgery note. Staff did not notate any difficulties in the record with Patient E's positioning. The second neurosurgeon reviewed intraoperative x-rays after staff placed the metallic spacer (cage) and noted that the fusion was at the incorrect level. The second neurosurgeon called the other neurosurgeon explaining that a wrong-site surgery occurred and requested assistance. The surgeons decided the best action was to remove the plate and screws at the unintended level and perform the originally planned C5-C6 anterior cervical discectomy and fusion with a plate. There were no further complications, and intraoperative x-rays confirmed placement of the implants, decompression, and fusion.

Both neurosurgeons informed Patient E's spouse of the intraoperative error on the day of surgery, and the following day explained the error to the patient, including that a contributing cause of the error was Patient E's body size and "initial error in localization" of the correct level. Because an extra level of discectomy occurred, the initial (incorrect) level required fusion as well as the planned level. Patient E's postoperative course was unremarkable, and Patient E was discharged to home the following day.

Staff followed up with Patient E in the Neurosurgical clinic. At the most recent appointment for Patient E's neck in late summer 2021, a neurosurgery resident noted improvement in coordination, balance, strength, and walking. X-rays showed no change in the position of the implants. The neurosurgery resident recommended another appointment in three months for a six-month postoperative visit.

Patient F

Patient F, in their 60s, had a past medical history including knee arthritis with pain, a slow heart rate, palpitations, high blood pressure, sleep apnea, gastritis, and depression. Patient F's right knee arthritis with pain did not resolve with nonoperative management and therefore, a total knee replacement was performed in 2016. Approximately two years later, the patient developed a chronic joint infection and underwent surgery the following month to remove the right knee implant. Patient F had additional treatment with antibiotics using an antibiotic joint spacer placed in the joint and six weeks of intravenous antibiotics.

In early summer 2019, Patient F returned to the operating room for removal of the spacer and implantation of a revision total knee arthroplasty. Staff did not note any intraoperative complications. During recovery, Patient F completed postoperative x-rays of the right knee. The radiologist initially read the images that same day and documented "Evidence of total knee replacement arthroplasty." On postoperative day eight, the radiologist reviewed surgical notes entered on postoperative day four and reevaluated the postoperative x-rays. The radiologist then identified a retained surgical item in the right tibia (shin bone) just below the prosthetic implant. On postoperative day four, the inpatient orthopedic note included documentation of the first identification of a retained surgical item present in the tibia.

The retained surgical item was a metallic ring from a piece of equipment designed to impact the shin bone implant into the canal. The surgeons determined the best approach was to leave the ring in the shin bone and not re-operate. In early summer 2021, Patient F had a follow-up appointment. The patient denied any known infection and continued to experience knee pain that was described as "sometimes not too noticeable" and limited range of motion. The patient declined further surgical intervention.

Patient G

Patient G, in their 50s, had a past medical history significant for bronchitis, neck and hip pain, recurrent depression, addiction to drugs and alcohol, and high risk for suicide. Patient G's past surgical history included a previous left total hip replacement in early summer 2019. Patient G complained of increasing pain in the right hip that did not improve with nonoperative management at an orthopedic surgery appointment in mid-summer 2020.

In late summer 2020, Patient G underwent a right total hip arthroplasty, and imaging completed during the procedure showed the implant in the planned position. The surgeon re-attached the muscles overlying the back of the hip to the bone through drill holes made with a two-millimeter drill with no complications. Later that same day, a post operative x-ray obtained in the PACU revealed a piece of a broken drill bit not documented in the formal radiology report. The orthopedic surgeon identified the broken drill bit, unintentionally left in the soft tissues of the hip, on that radiograph. The orthopedic surgeon discussed the plan with Patient G to return to the operating room the same day to remove the broken drill bit. Patient G returned to the operating room where staff used imaging to locate the drill piece for removal and to confirm none remained in the wound. Patient G had an uneventful recovery after the second procedure.

Approximately two weeks later, at an orthopedic follow-up appointment, Patient G walked without any assistive devices, had no evidence of infection, showed expected hip range of motion, and a healed incision. Patient G had a scheduled orthopedic appointment four weeks later but did not return. Patient G did not complain of hip problems during the most recent care encounter.

Patient H

Patient H, in their 30s, had a past medical history of irritable bowel syndrome, epilepsy due to a noncancerous brain lesion, psychosis, illicit drug use, painful shoulders after dislocations, and high risk for suicide. After a right shoulder dislocation during a seizure, Patient H experienced multiple dislocations. In late 2020, staff admitted Patient H to the orthopedics department to realign the shoulder without the use of surgery but under sedation in the PACU. A computerized tomography scan showed a large impaction lesion (dent) in the humeral head (ball of the shoulder's ball and socket joint) that was a documented risk factor for continued, recurrent shoulder dislocations. Patient H required surgery to treat the shoulder and maintain joint stability. Patient H remained in the hospital for consultations with neurology and mental health.

Four days later, Patient H underwent a right shoulder hemiarthroplasty (placement of a metal "peg" in the indentation of the humeral head) and capsulorrhaphy (tightening of the shoulder joint soft tissues). Surgery staff reported the counts of the surgical sponges used during the procedure were correct at closure. The electronic health record included no documentation of intraoperative complications. A postoperative x-ray obtained the next day showed the implant in the planned position but also showed a fine metallic wire consistent with a retained surgical

sponge in the right armpit. The radiologist documented identification of the wire, but orthopedic notes do not include interpretation of the x-ray or discussion of the radiologists' impression. Patient H did well and was discharged to home.

Four days later, Patient H returned to the facility's Emergency Department complaining of right shoulder pain after running out of pain medication. After exhibiting no signs of infection, Patient H received non-narcotic pain medication and was advised to keep the upcoming postoperative appointment. Staff did not obtain x-rays during the Emergency Department visit. On the first postoperative visit in the clinic two days later, x-ray results again showed findings consistent with a retained sponge. The surgeon informed Patient H in the clinic of the retained sponge shown on the x-ray. The surgeon discussed management options and Patient H agreed to return to the operating room for removal of the sponge.

Staff admitted Patient H later that day and the sponge removal occurred without incident. Staff removed the sponge intact, and intraoperative and postoperative imaging showed no evidence of the sponge. At the most recent follow-up appointment in late 2022, Patient H reported less pain than before the surgery and no dislocations since the surgery, even with seizures. There was no sign of infection, motion was in the functional range, and no notation of instability. X-rays showed mild arthritis with maintained reduction and placement of the "fixation hardware." Staff advised Patient H to return to the orthopedic clinic as needed.

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: July 28, 2023

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

Subj: Healthcare Inspection—Deficiencies in Facility Leaders' Response to Critical Surgical Events at the Michael E. DeBakey VA Medical Center in Houston, Texas

To: Director, Office of Healthcare Inspections (54HL10)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. The South Central VA Health Care Network has reviewed and concurs with the actions submitted by the Michael E. DeBakey VA Medical Center, Houston, Texas, in response to open recommendations included in the Deficiencies in Facility Leaders' Response to Critical Surgical Events draft report.

2. If you have additional questions or need further information, please contact the VISN 16 Quality Management Officer.

(*Original signed by:*)

Skye McDougall, PhD
VISN 16 Network Director

Appendix C: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: July 20, 2023

From: Director, Michael E. DeBakey VA Medical Center (580)

Subj: Healthcare Inspection—Deficiencies in Facility Leaders' Response to Critical Surgical Events at the Michael E. DeBakey VA Medical Center in Houston, Texas

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

1. Thank you for the opportunity to review and respond to the draft report, *Deficiencies in Facility Leaders' Response to Critical Surgical Events at the Michael E. DeBakey VA Medical Center in Houston, Texas*. I concur with the recommendations contained in the report and corrective actions have been developed and implemented as outlined in the Director's Comments section.
2. The MEDVAMC is committed to mitigating risks, ensuring patient safety and that each and every Veteran presenting to our facility receives the highest quality care.

(*Original signed by*:)

Francisco Vazquez
Medical Center Director, Michael E. DeBakey VA Medical Center

Facility Director Response

Recommendation 1

The Houston VA Medical Center Director ensures that staff conduct, and document focused professional practice evaluations for cause as required by the Veterans Health Administration.

✓ Concur

____Nonconcur

Target date for completion: October 27, 2023

Director Comments

The Michael E. DeBakey VA Medical Center (MEDVAMC) Director recognizes the importance of ensuring that staff conduct, and document focused professional practice evaluations (FPPEs) for cause as required by VHA Handbook 1100.21 and our MEDVAMC bylaws. MEDVAMC has instituted a process to ensure FPPE for cause are conducted, documented, and tracked to completion. All FPPE for cause are monitored by the Credentialing and Privileging office, and when concluded are presented to the Credentialing and Clinical Privileging committee which meets weekly. This committee is chaired by the Deputy Chief of Staff who then reports monthly to the Clinical Executive Board.

Recommendation 2

The Houston VA Medical Center Director reviews processes for reporting providers to state licensing boards and the national practitioner data bank when a concern for patient safety is identified and takes action to ensure compliance.

✓ Concur

____Nonconcur

Target date for completion: October 27, 2023

Director Comments

The Houston VA Medical Center Director recognizes the importance of reviewing processes for reporting providers to state licensing boards (SLBs) and national practitioner data bank (NPDB) when a concern for patient safety is identified. Ensuring a culture of safety for our Veterans is a priority and MEDVAMC has a salient process in place to ensure compliance and adherence to VHA Handbook 1100.17, National Practitioner Data Bank and VHA Directive 1100.18, Reporting and Responding to State Licensing Boards. The Chief of Staff (COS) and Associate Director of Patient Care Services (ADPCS) collaborate with the Credentialing and Privileging manager when a provider is identified that meets criteria for reporting to the SLB or NPDB. The Credentialing and Privileging manager is then responsible for initiating and completing the process as outlined in VHA Handbook 1100.18. In addition, the Credentialing and Privileging manager is responsible for obtaining and reviewing all exit review forms which indicate if a provider needs to be reported. The COS and ADPCS works in tandem with the Office of Quality, and Patient Safety (QPS) to communicate, and alert them of safety concerns related to providers with clinical privileges and other credentialed personnel. Additionally, the COS, QPS and ADPCS have a standing weekly meeting to discuss issues and concerns related to quality and patient safety.

Recommendation 3

The Houston VA Medical Center Director reviews the processes for conducting root cause analyses to ensure that reports are completed timely and that action plans are measurable, sustainable, and monitored to completion.

✓ Concur

____Nonconcur

Target date for completion: October 27, 2023

Director Comments

The Houston VA Medical Center Director reviews the processes for conducting root cause analyses to ensure that reports are completed timely and that action plans are measurable, sustainable, and monitored to completion. Root Cause Analyses (RCA) at MEDVAMC are encouraged to help us improve our processes and to mitigate potential harm to our Veterans. Our process is robust; action items are tracked and achieved in a timely manner; and lessons learned are disseminated throughout various venues within the organization. Reports depicting trends, analysis, and progress on RCA's; RCA actions; and RCA outcome measures are shared through formal committees such as the QPS Committee, and MEDVAMC Governance Board. Further, MEDVAMC adheres to the VHA National Center for Patient Safety (NCPS) Guide to

Performing a Root Cause Analysis and recently published VHA Quality and Patient Safety Programs VHA Directive 1050.01.

Glossary

adverse events. "Untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers."[1]

anemia. "A condition in which you lack enough healthy red blood cells to carry adequate oxygen to your body's tissues."[2]

anterior cervical discectomy and fusion. "A discectomy is the removal of the piece of disc or the entire disc that is putting pressure on the nerves or spinal cord and causing your arm numbness, tingling, pain or weakness An anterior fusion stabilizes the vertebrae of the spine creating less chance for slippage of discs. Bone from the bone bank or iliac crest (hip) will be used as a bone graft. The graft is inserted between the vertebrae, where the disc has been removed. A plate and screws are inserted to stabilize the neck."[3]

arthritis. The swelling and tenderness of at least one joint causing joint pain and stiffness. One of the more common types of arthritis is osteoarthritis, in which the tissue that covers the ends of the bones, within the joints, breaks down.[4]

arthroplasty. "Surgical procedure to restore the function of a joint. A joint can be restored by resurfacing the bones. An artificial joint (called a prosthesis) may also be used."[5]

bone graft. "Bone grafting is a surgical procedure that uses transplanted bone to repair and rebuild diseased or damaged bones" by inserting a new piece of bone at the location in the body where a bone needs to heal or join.[6]

bone spurs. "Bone spurs, or osteophytes, are smooth, bony growths, usually near joints. They develop over time in patients with arthritis or joint damage. The feet, hands, knees and spine often develop bone spurs."[7]

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[1] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients,* October 31, 2018.

[2] "Anemia" (web page), Mayo Clinic, accessed January 24, 2023, https://www.mayoclinic.org/diseases-conditions/anemia/symptoms-causes/syc-20351360.

[3]"The Road To Recovery After Cervical Spine Surgery" (web page), Johns Hopkins Medicine, accessed June 1, 2023, https://www.hopkinsmedicine.org/orthopaedic-surgery/_documents/patient-information/patient-forms-guides/JHUCervSpineSurgeryGuide.pdf.

[4] "Arthritis" (web page), Mayo Clinic, accessed January 24, 2023, https://www.mayoclinic.org/diseases-conditions/arthritis/symptoms-causes/syc-20350772.

[5] "Arthroplasty" (web page), Johns Hopkins Medicine, accessed January 11, 2023, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/arthroplasty.

[6] "Bone Grafting" (web page), Johns Hopkins Medicine, accessed January 25, 2023, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/bone-grafting.

[7] "Bone spurs" (web page), Cleveland Clinic, accessed January 25, 2023, https://my.clevelandclinic.org/health/diseases/10395-bone-spurs-osteophytes.

capsulorrhaphy. "Suture of a cut or wounded capsule (as of the knee joint)."[8]

carpal tunnel syndrome. "A common condition that causes pain, numbness, tingling, and weakness in the hand and wrist. It happens when there is increased pressure within the wrist on a nerve called the median nerve. This nerve provides sensation to the thumb, index, and middle fingers, and to half of the ring finger. The small finger (the "pinky") is typically not affected."[9]

cervical spondylosis. "Natural wearing down of cartilage, disks, ligaments and bones in your neck. More severe cases, such as herniated disk, bone spurs or pinched nerves, are treated with injections or surgery."[10]

cirrhosis. "Late stage of scarring (fibrosis) of the liver caused by many forms of liver diseases and conditions, such as hepatitis and chronic alcoholism."[11]

community care. "VA provides care to Veterans through community providers when VA cannot provide the care needed. Community care is based on specific eligibility requirements, availability of VA care, and the needs and circumstances of individual Veterans."[12]

computed tomography scan. "Medical professionals use computed tomography, also known as CT scan, to examine structures inside your body. A CT scan uses X-rays and computers to produce images of a cross-section of your body. It takes pictures that show very thin "slices" of your bones, muscles, organs and blood vessels so that healthcare providers can see your body in great detail."[13]

coronary artery disease. "Coronary artery disease (CAD) is a condition that affects your coronary arteries, which supply blood to your heart. With CAD, plaque buildup narrows or blocks one or more of your coronary arteries. Chest discomfort (angina) is the most common symptom. CAD can lead to a heart attack or to other complications like arrhythmia or heart failure"[14]

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[8] *Merriam-Webster.com Dictionary*, "capsulorrhaphy," accessed January 25, 2023, https://www.merriam-webster.com/medical/capsulorrhaphies.

[9] "Carpal Tunnel Syndrome" (web page), Cleveland Clinic, accessed January 25, 2023, https://my.clevelandclinic.org/health/diseases/4005-carpal-tunnel-syndrome.

[10] "Cervical spondylosis" (web page), Cleveland Clinic, accessed January 25, 2023, https://my.clevelandclinic.org/health/diseases/17685-cervical-spondylosis.

[11] "Cirrhosis" (web page), Mayo Clinic, accessed January 24, 2023, https://www.mayoclinic.org/diseases-conditions/cirrhosis/symptoms-causes/syc-20351487.

[12] "Community Care" (web page), VA, accessed April 25, 2023, https://www.va.gov/COMMUNITYCARE/index.asp.

[13] "CT Scan" (web page), Cleveland Clinic, accessed January 24, 2023, https://my.clevelandclinic.org/health/diagnostics/4808-ct-computed-tomography-scan.

[14] "Coronary artery disease" (web page), Cleveland Clinic, accessed January 25, 2023, https://my.clevelandclinic.org/health/diseases/16898-coronary-artery-disease.

credentialing. "Systematic process of screening and evaluating qualifications, and other credentials, including licensure, required education, relevant training and experience and current competence and health status."[15]

critical incident tracking notification. A tool that allows facility staff to report wrong-site surgeries and surgeries with retained surgical items.[16]

critical surgical events. Includes "incorrect (wrong patient, wrong procedure, wrong site/side, wrong implant) surgery, retained surgical items, death in the operating room, death from hemorrhage within 24 hours of an operating room procedure, operating room fires, and operating room burns."[17]

dexterity. "Readiness and grace in physical activity, especially: skill and ease in using the hands."[18]

diabetes mellitus. "Diabetes happens when your body isn't able to take up sugar (glucose) into its cells and use it for energy. This results in a build up of extra sugar in your bloodstream."[19]

disc space height. Discs are soft spacers between the spinal bones that act as shock absorbers. The outside of the disc is tough and firm while the inside is a jelly-like substance, making the disc compressible. This reduces the stress on the spinal bones.[20]

electromyography. "Electromyography (EMG) is a diagnostic test to that measures how the muscles and nerves work. Providers use EMG to diagnose injuries, muscle disease and neuromuscular disorders."[21]

epilepsy. "A central nervous system (neurological) disorder in which brain activity becomes abnormal, causing seizures or periods of unusual behavior, sensations and sometimes loss of awareness."[22]

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[15] VHA Handbook 1100.19.

[16] VHA Deputy Under Secretary for Health for Operations and Management memorandum, "Critical Incident Tracking Notification (CITN)," August 4, 2010.

[17] VHA Handbook 1102.01; VHA Directive 1102.01(2).

[18] *Merriam-Webster.com Dictionary,* "dexterity", accessed January 25, 2023, https://www.merriam-webster.com/dictionary/dexterity.

[19] "Diabetes Mellitus" (web page), Cleveland Clinic, accessed January 24, 2023, https://my.clevelandclinic.org/health/diseases/7104-diabetes-mellitus-an-overview.

[20] "Degenerative Disc Disease" (web page), Johns Hopkins Medicine, accessed January 24, 2023, https://www.hopkinsmedicine.org/health/conditions-and-diseases/degenerative-disc-disease.

[21] "Electromyography" (web page), Mayo Clinic, accessed January 25, 2023, https://www.mayoclinic.org/tests-procedures/emg/about/pac-20393913.

[22] "Epilepsy" (web page), Mayo Clinic, accessed January 24, 2023, https://www.mayoclinic.org/diseases-conditions/epilepsy/symptoms-causes/syc-20350093.

fixation. "Using hardware like screws and rods to immobilize a section of spine."[23]

fluoroscopy. "A type of imaging procedure that uses several pulses of an X-ray beam to take real-time footage of tissues inside your body. Healthcare providers use fluoroscopy to help monitor and diagnose certain conditions and as imaging guidance for certain procedures."[24]

focused clinical care review. Comprehensive, retrospective review of a provider's practice to determine what additional steps may be warranted including an FPPE "for cause or adverse privileging action" when there is an identified concern or issue.[25]

focused professional practice evaluation. Focused professional practice evaluation "is a time-limited period during which the medical staff leadership evaluates and determines" the provider's professional performance. An FPPE "is required for all providers requesting initial privileges" or the granting of new additional privileges. An FPPE "may be used when a question arises regarding a privileged provider's ability to provide safe, high-quality patient care."[26]

foraminotomy. "A surgical procedure. It enlarges the area around one of the bones in the spinal column. The surgery relieves pressure on compressed nerves."[27]

gait. "A manner of walking or moving on foot."[28]

gastritis. "A condition that inflames the stomach lining (the mucosa), causing belly pain, indigestion (dyspepsia), bloating and nausea. It can lead to other problems. Gastritis can come on suddenly (acute) or gradually (chronic)."[29]

hemiarthroplasty. "For total shoulder replacement, the round end of your arm bone will be replaced with an artificial stem that has a rounded metal head (ball). The socket part (glenoid) of your shoulder blade will be replaced with a smooth plastic lining (socket) that will be held in place with special cement. If only 1 of these 2 bones needs to be replaced, the surgery is called a partial shoulder replacement, or a hemiarthroplasty."[30]

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[23] "Spinopelvic Fixation," (web page), Columbia University, accessed March 27, 2023, https://www.neurosurgery.columbia.edu/patient-care/treatments/spinopelvic-fixation.

[24] "Fluoroscopy" (web page), Cleveland Clinic, accessed January 25, 2023, https://my.clevelandclinic.org/health/diagnostics/21992-fluoroscopy.

[25] VHA Directive 1190.

[26] VHA Handbook 1100.19.

[27] "Foraminotomy" (web page), Johns Hopkins Medicine, accessed January 24, 2023, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/foraminotomy.

[28] *Merriam-Webster.com Dictionary*, "gait," accessed on January 25, 2023, https://www.merriam-webster.com/dictionary/gait.

[29] "Gastritis" (web page), Cleveland Clinic, accessed January 25, 2023, https://my.clevelandclinic.org/health/diseases/10349-gastritis.

[30] "Hemiarthroplasty" (web page), MedlinePlus, accessed January 25, 2023, https://medlineplus.gov/ency/article/007387.htm.

impactor. Used during orthopedic surgical procedures to tap implants into bone for fracture fixation or to correct an orthopedic condition such as an artificial joint component. The impactor is specially made to prevent damage to the implant and the surrounding tissues.

increased reflexes. A reflex is when a muscle immediately moves when the tendon is tapped a certain way such as the knee jerk when a provider taps the knee with a small hammer during a medical exam. Increased or hyperactive reflexes can mean there is a lesion interrupting the communication between neurons found in the brain, brainstem, or spinal cord responsible for movement.[31]

intravenous. "IV (intravenous) means giving medicines or fluids through a needle or tube (catheter) that goes into a vein."[32]

issue brief. Notification documents that provide specific information to leaders within VHA and should be submitted when sentinel events or other significant events occur.[33]

joint spacer. "An antibiotic spacer is a device placed into the joint to maintain normal joint space and alignment. It also provides patient comfort and mobility while the infection is being treated."[34]

laminoplasty. Procedure completed only on the spinal bones in the neck. This procedure "increases the space within the spinal canal by creating a hinge on the lamina, the back part of the spinal bone. Metal hardware bridges the gap in the opened section of the spine."[35]

lumbar spine. "Consists of the five vertebrae in your lower back. It provides support for the weight of your body, surrounds and protects your spinal cord, and allows for a wide range of body motions."[36]

magnetic resonance imaging. "Medical imaging technique that uses a magnetic field and computer-generated radio waves to create detailed images of the organs and tissues in your body."[37]

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[31] H. Kenneth Walker, "Deep Tendon Reflexes," chap. 72 in Clinical Methods: The History, Physical, and Laboratory Examinations, 3rd ed., eds. Kenneth Walker, W. Dallas Hall, and J. Willis Hurst (Boston: Butterworths, 1990), 365-8.

[32] "IV treatment at home" (web page), MedlinePlus, accessed January 26, 2023, https://medlineplus.gov/ency/patientinstructions/000496.htm.

[33] VHA 10N Guide: VHA Issue Briefs, June 2017.

[34] "Joint replacement infection" (web page), American Academy of Orthopaedic Surgeons (AAOS), accessed January 26, 2023, https://orthoinfo.aaos.org/en/diseases--conditions/joint-replacement-infection/.

[35] "Laminoplasty" (web page), Mayo Clinic, accessed January 24, 2023, https://www.mayoclinic.org/diseases-conditions/spinal-stenosis/multimedia/laminoplasty/img-20149228.

[36] "Lumbar spine" (web page), Cleveland Clinic, accessed January 25, 2023, https://my.clevelandclinic.org/health/articles/22396-lumbar-spine.

[37] "MRI" (web page), Mayo Clinic, accessed January 24, 2023, https://www.mayoclinic.org/tests-procedures/mri/about/pac-20384768.

morbid obesity. "A serious health condition that results from an abnormally high body mass that is diagnosed by having a body mass index (BMI) greater than 40 kg/m², a BMI of greater than 35 kg/m² with at least one serious obesity-related condition, or being more than 100 pounds over ideal body weight (IBW)."[38]

mucous cyst. "A myxoid cyst, or digital mucous cyst, is a small, noncancerous bump most often found near a joint at the end of your finger." When treatment is necessary, "surgical removal of the cyst is the most effective method."[39]

myelopathy. "Severe compression of the spinal cord can result from traumatic injury, spinal infection or other conditions. When the spinal cord compresses, it can lead to a variety of symptoms, called myelopathy. There are different types of myelopathy — cervical, thoracic, and lumbar. The location of the spinal compression determines the type."[40]

national practitioner data bank. "Secondary flagging system intended to facilitate a comprehensive review" of health care providers' professional credentials and provide ongoing monitoring of health care providers' practice. This includes providers' "licensure, professional society memberships, medical malpractice payment history, Federal health care program exclusion status, and record of clinical privileges."[41]

nerve compression. "A pinched nerve is a compressed nerve. Surrounding tissues that press on nerve roots can cause pain, numbness and tingling in different areas of your body."[42]

osteoporosis. "A disease that weakens bones" and causes "greater risk for sudden and unexpected bone fractures."[43]

palpitations. "Heart palpitations are feelings of having a fast-beating, fluttering or pounding heart. Stress, exercise, medication or, rarely, a medical condition can trigger them."[44]

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[38] "What is Morbid Obesity? Not What You Might Think" (web page), Obesity Medicine Association, accessed January 25, 2023, https://obesitymedicine.org/what-is-morbid-obesity/.

[39] "Myxoid Cyst" (web page), Cleveland Clinic, accessed June 1, 2023, https://my.clevelandclinic.org/health/diseases/23456-myxoid-cyst.

[40] "Myelopathy" (web page), Cleveland Clinic, accessed January 24, 2023, https://my.clevelandclinic.org/health/diseases/21966-myelopathy.

[41] VHA Handbook 1100.19.

[42] "Pinched Nerves" (web page), Cleveland Clinic, accessed January 24, 2023, https://my.clevelandclinic.org/health/diseases/6481-pinched-nerves.

[43] "Osteoporosis" (web page), Cleveland Clinic, accessed January 26, 2023, https://my.clevelandclinic.org/health/diseases/4443-osteoporosis.

[44] "Heart palpitations" (web page), Mayo Clinic, accessed January 25, 2023, https://www.mayoclinic.org/diseases-conditions/heart-palpitations/symptoms-causes/syc-20373196.

post anesthesia care unit. "A hospital room which is equipped with apparatus for meeting postoperative emergencies and in which surgical patients are kept during the immediate postoperative period for care and recovery from anesthesia."[45]

posttraumatic stress disorder. "A mental health issue that may develop after a traumatic event. It causes negative, anxious emotions. Some people with PTSD relive the event over and over. Others avoid any reminders of it. PTSD interferes with life, work and relationships."[46]

privileging. "The process by which a practitioner, licensed for independent practice (i.e., without supervision, direction, required sponsor, preceptor, mandatory collaboration, etc.), is permitted by law and the facility to practice independently, to provide specified medical or other patient care services within the scope of the individual's license, based on the individual's clinical competence as determined by peer references, professional experience, health status, education, training, and licensure."[47]

provider profile. A provider profile includes (when not generated as part of a 38 U.S.C. 5705-protected activity) focused professional practice evaluations. The profile may also include: "information from surgical case or invasive procedure review; infection control reviews; drug usage evaluation; medical record review; blood usage review; pharmacy and therapeutic review; and monitoring and evaluation of quality, utilization, risk, and appropriateness of care."[48]

provider profile management system. A tool "that provides VA staff and Veterans with a directory of VA providers, Department of Defense (DOD) providers, and community providers who are part of VA's network." Community providers may be excluded and considered unsuitable to provide care to patients when they have failed to meet the standard of care or had employment terminated. Termination prohibits providers from rendering care at any VHA facility.[49]

root cause analysis. "Process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls."[50]

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[45] *Merriam-Webster.com Dictionary*, "PACU/recovery room", accessed January 25, 2023, https://www.merriam-webster.com/dictionary/recovery%20room#medicalDictionary.

[46] "Post-Traumatic Stress Disorder" (web page), Cleveland Clinic, accessed January 25, 2023, https://my.clevelandclinic.org/health/diseases/9545-post-traumatic-stress-disorder-ptsd.

[47] VHA Handbook 1100.19.

[48] VHA Handbook 1100.19.

[49] *Mission Critical: Assessing the Technology to Support Community Care*, *Before the House Committee on Veterans' Affairs,* 116th Cong., (April 2, 2019) (statement of Richard A. Stone, M.D., Executive in Charge, Veterans Health Administration, Department of Veterans Affairs).

[50] VHA Handbook 1050.01; VHA Directive 1050.01.

scoliosis. "Abnormal curvature of the spine (backbone). There is a natural, forward-and-backward curve to the spine. With scoliosis, the spine rotates and develops a side-to-side curve. Curves may be as mild as 10 degrees, or as severe as 100 degrees or more."[51]

sentinel event. "Patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient" causing "death, permanent harm, or severe temporary harm."[52]

sleep apnea. "A disorder that causes you to stop breathing while asleep. Your brain tries to protect you by waking you up enough to breathe, but this prevents restful, healthy sleep. Over time, this condition can cause serious complications."[53]

soft tissue. "The soft tissues of the body include the muscles, tendons (the bands of fiber that connect muscles to bones), fat, blood vessels, lymph vessels, nerves and the tissues around joints."[54]

spinal decompression. "Different types of treatment that can offer back pain relief by taking pressure off" the of the spine for conditions such as bulging disks, degenerative disks, herniated disks, pinched nerves, and sciatica.[55]

spinal stenosis. "Narrowing of the spinal column that causes pressure on the spinal cord, or narrowing of the openings (called neural foramina) where spinal nerves leave the spinal column." Types of spinal stenosis include foraminal spinal stenosis.[56]

spine. Comprised of 33 vertebrae that are stacked together and permit movement as well as protect the spinal cord.[57]

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[51] "Adult Scoliosis" (web page), Cleveland Clinic, accessed January 26, 2023, https://my.clevelandclinic.org/health/diseases/15837-adult-scoliosis.

[52] The Joint Commission, "Sentinel Events," accessed January 3, 2023, https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/camh_24_se_all_current.pdf.

[53] "Sleep apnea" (web page), Cleveland Clinic, accessed January 25, 2023, https://my.clevelandclinic.org/health/diseases/8718-sleep-apnea.

[54] "Lumps and Bumps on Your Body: When You Should Worry"" (web page), Cleveland Clinic, accessed January 25, 2023, https://health.clevelandclinic.org/lumps-bumps-body-worry/.

[55] "Spinal Decompression Therapy" (web page), Cleveland Clinic, accessed January 25, 2023, https://my.clevelandclinic.org/health/articles/10874-spinal-decompression-therapy.

[56] "Spinal Stenosis" (web page), National Institute of Health/National Library of Medicine MedlinePlus, accessed January 24, 2023, https://medlineplus.gov/ency/article/000441.htm.

[57] "Spine structure and function" (web page), Cleveland Clinic, accessed January 27, 2023, https://my.clevelandclinic.org/health/articles/10040-spine-structure-and-function.

surgical sponge. Used "during an invasive procedure to absorb fluids or isolate tissue, with the intention of removing the absorbent material prior to completion of the procedure."[58]

tibia. "The lower leg is made up of two bones: the tibia and fibula. The tibia is the larger of the two bones. It supports most of your weight and is an important part of both the knee joint and ankle joint."[59]

universal protocol. "The Universal Protocol provides guidance for health care professionals. It consists of three key steps: conducting a pre-procedure verification process, marking the procedure site, and performing a time-out."[60]

vertebrae. Small bones of the spine, cushioning disks, nerves, joints, ligament, and muscles.[61]

[58] Victoria Steelman, Clarissa Shaw, Laurel Shine, and Abby Hardy-Fairbanks, "Retained surgical sponges: a descriptive study of 319 occurrences and contributing factors from 2012 to 2017," *Patient Safety in Surgery* 12, no. 20 (June 29, 2018), https://doi.org/10.1186/s13037-018-0166-0.

[59] "Tibia (shinbone) Shaft Fractures" (web page), American Academy of Orthopaedic Surgeons (AAOS), accessed January 26, 2023, https://orthoinfo.aaos.org/en/diseases--conditions/tibia-shinbone-shaft-fractures.

[60] "The Universal Protocol" (web page), The Joint Commission, accessed February 27, 2023, https://www.jointcommission.org/standards/universal-protocol/.

[61] "Spine Structure and Function," (web page), Cleveland Clinic, accessed January 27, 2023, https://my.clevelandclinic.org/health/articles/10040-spine-structure-and-function.

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