



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Thoracic Surgery Quality of
Care Issues and Facility
Leaders' Response at the
C. W. Bill Young VA Medical
Center in Bay Pines, Florida



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the C.W. Bill Young VA Medical Center (facility), located in Bay Pines, Florida, to evaluate allegations against a thoracic surgeon (surgeon) regarding patient deaths and surgical complications, omissions or misrepresentations of operative note documentation making surgical errors seem normal, and the facility's inappropriate reporting of the surgeon's complication rate.

The OIG reviewed similar allegations related to the surgeon's care of 19 patients in 2016, consulted a VA thoracic surgeon regarding the surgeon's practices, and issued a report in August 2017 that substantiated one of six allegations.¹ In that report, the OIG identified a deficiency in the facility's process for evaluating the competency of surgeons and made two recommendations related to focused and ongoing professional practice evaluations.

The surgeon, who was board certified in thoracic and cardiac surgery, had been in clinical practice since 2009 at an academic institution and began working at the facility in 2013 as a staff thoracic surgeon. Although the surgeon had limited experience running a program or service, the surgeon was selected in July 2014 by the then Chief of Staff to become the facility's Chief of Surgery, responsible for a spectrum of clinically and administratively complex surgical departments.

On November 9, 2017, the OIG received another complaint (that culminated in this report) about the surgeon's competency and quality of care that also included the names of five specific patients:

- Four 2017 thoracic surgery cases resulted in patient deaths and one case resulted in complications.
- The surgeon omitted or misrepresented errors in operative note documentation to make errors seem normal.
- The surgeon's complication rate was not being reported appropriately.

The Joint Commission received a similar complaint around the same time. On November 15, 2017, facility leaders paused the thoracic surgery program in response to the complaints made to the OIG and The Joint Commission and arranged a review of the thoracic surgery program by Veterans Integrated Service Network (VISN) 8. The VISN review, completed on December 5, 2017, did not identify concerns regarding the surgeon's surgical competence or quality of care. However, the VISN identified process and infrastructure weaknesses in the surgery program and recommended lowering the complexity of the thoracic cases performed at the facility until the

¹ VA OIG, *Healthcare Inspection—Quality of Care Concerns in Thoracic Surgery, Bay Pines VA Healthcare System, Bay Pines, Florida*, Report No. 17-00602-342, August 16, 2017.

hiring of a second full-time thoracic surgeon and two surgical intensivists.² Facility leaders agreed and resumed the thoracic surgery program on December 22, 2017, within the recommended limitations.

Due to the ongoing nature of concerns about the surgeon's competence and quality of care, the OIG consulted with a thoracic surgeon not associated with VA (non-VA consultant) who would not have had previous access to medical records or familiarity with the patients who allegedly received poor care. The non-VA consultant reviewed the care of the five patients identified in the 2017 allegations, as well as the 19 cases identified during the OIG's evaluation of the 2016 allegations.

The non-VA consultant identified quality of care concerns with 16 of the 24 patient cases, including preoperative planning errors, technical errors, and subsequent management of the technical errors. The OIG shared the preliminary results of the non-VA consultant's findings with VISN and facility leaders in early November 2018. In response, the facility arranged for an external contractor to complete management reviews of a selection of the surgeon's cases. In January 2019, the facility received the contractor's management review results, with five reflecting that care did not meet quality expectations. In February 2019, the surgeon was reassigned to a nonclinical care setting.

Veterans Health Administration (VHA) and VISN leaders established a panel of VHA cardiothoracic surgeons to review 22 of the 24 previously reviewed patients.³ The panel also reviewed additional selected cases, which according to the VA panel chairperson, provided a "diverse sampling of various types of [the surgeon's] thoracic surgery cases."⁴ Ultimately, in December 2019, the panel determined that the surgeon delivered thoracic surgical care within quality expectations and recommended that the surgeon's privileges "remain in place without modification." The VA panel also made recommendations regarding "programmatic issues" and recommended "an enhanced multidisciplinary approach to patient selection and preparation for surgical procedures." In December 2019, the surgeon resumed patient care.

Of the 24 cases reviewed by the non-VA consultant, the OIG substantiated a case where the surgeon omitted a surgical error from the report and also found instances in which surgical complications were unclearly or inaccurately described. The specific case involving the surgical error occurred in November 2017. Although the surgeon attributed the error to another member of the surgical team during an interview with the OIG, the OIG did not find documentation of this event in the operative report or in any portion of the postoperative documentation. Overall,

² Surgical intensivists are physicians who provide care for critically ill patients, have advanced training and experience in treating patients with complex surgical conditions, and are generally fellowship-trained.

³ Because there were no identified clinical issues, the remaining two cases were not reviewed.

⁴ A list of all the surgeon's cases was computer-generated from the VA surgery package for the entire period of practice. The first 20 cases from the list were selected for review.

the non-VA consultant found the surgeon's documentation to be unclear, incomplete, and confusing. The surgeon's poor documentation practices could affect a patient's immediate and long-term care should other clinicians make treatment decisions based on unclear or incomplete operative notes and reports. However, without directly observing the events that resulted in complications, the OIG was unable to discern whether the complications resulted during the normal course of surgery or from errors attributable to the surgeon.

The OIG did not substantiate that the facility failed to appropriately report surgical errors and complications. The National Surgery Office does not require a mandatory assessment of all thoracic surgeries. Rather, in eight-day cycles, the surgical quality nurse is required to complete and transmit Veterans Affairs Surgical Quality Improvement Program (VASQIP) assessments for the first consecutive 36 eligible surgical cases and all mandatory assessment surgical cases, which include deaths within 30 days of surgery. VASQIP is not designed to capture intraoperative morbidity, and data would not be collected on serious intraoperative complications. This review methodology meant that the surgeon's actual morbidity and mortality data were not consistently captured through the VASQIP assessment process. The VA panel members told the OIG that they reviewed the surgeon's VASQIP mortality data, did not find outliers beyond what would be expected, and considered this information when recommending the surgeon be restored to duty with no change in clinical privileges. As of August 2018, the facility elected to assess 100 percent of eligible thoracic surgery cases even though this level of review was not required by policy.

Although not specifically alleged in the 2017 complaint, the OIG found through interviews that the surgeon, in the role of Chief of Surgery, did not consistently promote a culture of safety within the Surgical Service. Some staff described the surgeon as a poor communicator who would deflect blame when something went wrong with one of [the surgeon's] cases, and would caution staff not to go "to the front office" as [the surgeon] "will know who they talk to." The OIG concluded that the surgeon's words and behavior contributed to a fearful and retaliatory environment that could lead to underreporting of quality of care concerns and promote a perception that surgical data were being manipulated in the surgeon's favor.

Further, as the Chief of Surgery, the surgeon chaired the facility's Surgical Work Group that was established to identify gaps with surgical care and recommend actions, as well as perform other quality and performance improvement activities. The OIG reviewed the Surgical Work Group meeting minutes for fiscal years 2017 and 2018 and found no evidence that the Surgical Work Group reviewed surgical deaths monthly or discussed critical surgical events, including the surgeon's cases as required. Additionally, the OIG did not find evidence of oversight of the Morbidity and Mortality Conference and found only limited evidence of other efforts to improve surgical care that aligned with the VISN Surgical Work Group and the National Surgery Office.

As a result of the allegations, VHA and VISN reviewers, facility leaders, the OIG, and the non-VA consultant evaluated the surgical competency of this specialty surgeon as well as the

environment in which surgical teams were managing patients. There were varying views of the competency of the specialty surgeon, particularly when also considering the adequacy of clinical support resources, the effectiveness of quality monitoring processes, and the caliber of collaborative clinical practice among staff, specialists, and coordinating treatment teams.

In determining whether to have the specialized surgeon resume patient care, VHA appeared to place great importance on the views of many highly qualified VA cardiothoracic surgeons who reviewed medical record documentation based on their own clinical experience. The OIG recognizes the challenges facility leaders face when assessing the competency of a highly technical surgical specialty that often treats the most complex and gravely ill patients. The OIG also recognizes that as a surgeon becomes more experienced, operative outcomes tend to improve. Ultimately, the decision on granting clinical privileges must be based on the need to promote the safety of patients and an assessment of the quality of care they are provided.

As a result, the OIG believes that it would be prudent to appoint a VHA-centralized thoracic specialty leader, whose responsibilities would be to ensure that VHA provides quality thoracic surgery and to assist facility clinical leaders to establish appropriate in-depth clinical reviews. This VHA-centralized thoracic specialty leader would ideally provide unbiased, authoritative, and prompt guidance on the most clinically sound course of action when a thoracic surgeon's practice or outcomes are under review. For example, with the events described in this report, such a specialty leader with authoritative decision-making power could have intervened and initiated a structured quality-based review that would have avoided the repeated solicitation of multiple specialists and multiple conflicting opinions of a clinician's practice. The lack of a streamlined process in this case delayed growth and improvement in the facility's cardiothoracic surgery program.

VHA will likely face similar scenarios that demand subject-matter expertise and complex decision-making, further supporting the appointment of a VHA-centralized thoracic specialty leader.

The OIG made five recommendations to the Under Secretary for Health related to a thoracic specialty leader, operative documentation requirements, the National Surgery Office's designation of surgeries requiring mandatory assessment, and peer review processes.

Five recommendations were made to the Facility Director related to operative documentation practices, professional communications, oversight of the facility's Surgical Work Group, the granting of privileges that are specific to the facility, service, and provider's competence, and institutional disclosures.

Comments

The Executive in Charge, Office of the Under Secretary for Health, responded to all recommendations, including those addressed to the Facility Director.⁵ The Executive in Charge concurred in principle with recommendations 1 and 2, concurred with recommendation 3–10, and provided acceptable action plans (see appendix C). The OIG will follow up on the planned actions until they are completed.



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⁵ The Executive in Charge, Office of the Under Secretary for Health, has the authority to perform the functions and duties of the Under Secretary for Health. Recommendations addressed to the Facility Director were provided to the VISN and Facility Directors as well as the Office of the Under Secretary for Health.

Contents

Executive Summary	i
Abbreviations	vii
Introduction.....	1
Background	1
Scope and Methodology	4
Inspection Results	6
Issue 1. Quality of Care and Evaluation.....	6
Issue 2. Documentation and Reporting of Surgical Errors and Complications.....	17
Issue 3. Culture of Safety, Retaliation, and Quality Review Processes	21
Issue 4. Facility Leaders' Actions	24
Conclusion	26
Recommendations 1–10.....	29
Appendix A: Patient Case Summary Findings	30
Appendix B: Sample Clinical Care Review Template	63
Appendix C: Under Secretary for Health Memorandum.....	65
Glossary	75
OIG Contact and Staff Acknowledgments	83
Report Distribution	84

Abbreviations

COPD	chronic obstructive pulmonary disease
COS	Chief of Staff
CT	computed tomography
DLCO	carbon monoxide diffusing capacity
EBUS	endobronchial ultrasound
EHR	electronic health record
EKG	electrocardiogram
OHI	Office of Healthcare Inspections
OIG	Office of Inspector General
PET	positron emission tomography
PFT	pulmonary function testing
SVC	superior vena cava
VASQIP	Veterans Affairs Surgical Quality Improvement Program
VATS	video assisted thoracic surgery
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the C.W. Bill Young VA Medical Center (facility) in Bay Pines, Florida, to evaluate allegations regarding [thoracic surgery](#) patient deaths and complications, omissions or misrepresentations in operative note documentation making surgical errors seem normal, and the facility's failure to appropriately report a thoracic surgeon's (surgeon) complications. According to allegations received, staff were afraid to report as they feared retaliation, and the then Chief of Staff was aware of the concerns but took no action.

Background

The facility and eight community-based outpatient clinics comprise the Bay Pines VA Healthcare System, which is part of Veterans Integrated Service Network (VISN) 8. Between October 1, 2017, and September 30, 2018, the facility served 109,473 patients and had a total bed capacity of 397 beds, including 186 inpatient beds. The facility is deemed as complexity model level 1a, and capable of providing patients with the most complex procedures and surgeries.¹ The facility's surgery service is composed of 11 specialties including vascular and thoracic surgery. According to [National Surgery Office](#) data, facility surgeons completed approximately 5,200 cases in fiscal year 2018; 121 of those cases were thoracic surgeries.

Thoracic Surgery

Thoracic surgery is a high-risk specialty involving the medical and surgical care of patients who often have underlying cardiac and respiratory disease. Surgical risks to these patients include respiratory failure, heart failure, long-term respiratory disability, and death. However, for patients with early-stage cancer, surgery provides the best option for cure.

A thorough preoperative assessment is essential for the appropriate selection of patients for surgery. Adequate staging is necessary to ensure that the patient's cancer is not too advanced to preclude successful treatment with surgery. Preoperative physiologic testing allows for the identification of patients at increased risk for poor surgical outcomes. Published, evidence-based guidelines provide direction for these assessments.

Thoracic surgeons should possess knowledge of thoracic surgical disease, sound clinical judgment, technical competency, and the ability to manage intraoperative complications and calmly navigate in critical and intense situations.

¹ VHA Directive, 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010. This directive was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1200, *Facility Procedure Complexity Designation Requirements to Perform Invasive Procedures in Any Clinical Setting*, May 13, 2019.

The surgeon under review was hired and requested privileges to practice thoracic surgery at the facility in 2013. The surgeon was [board certified](#) in thoracic and cardiac surgery and had been in clinical practice since 2009 at an academic institution. The facility's credentialing committee reviewed the surgeon's past clinical history and did not identify prior practice or professional concerns. The Facility Director approved the surgeon's initial clinical privileges in June 2013. Although the surgeon had limited experience running a program or service, on July 27, 2014, the surgeon was selected by the then Chief of Staff (a non-surgeon) to become the facility's Chief of Surgery responsible for a spectrum of clinically and administratively complex surgical departments.

Allegation History

On October 25, 2016, the OIG received anonymous allegations about the surgeon's competency, high rate of complications and patient deaths, and forbidding the [surgical critical care team](#) to care for the surgeon's patients, among other concerns. The OIG initiated an inspection in November 2016, completed site visits in November and December 2016, and published a report, in August 2017 that substantiated one of six allegations.² The OIG made two recommendations related to focused professional practice evaluation criteria and ongoing professional practice evaluation reviews.

Based on OIG on-site recommendations, the facility arranged for the thoracic surgery service to be reviewed by a thoracic surgeon from another VA facility (proctor). The review took place in December 2016 and included the proctoring of the surgeon, as well as data and chart reviews. The proctor did not identify concerns with the surgeon's technique and made general recommendations related to infrastructure, perioperative teams, and quality improvement activities. The OIG also consulted with a VA thoracic surgeon who reviewed the nine cases identified by the complainant as having poor outcomes.

On November 9, 2017, the OIG received another anonymous complaint with additional allegations regarding the surgeon's competency and quality of care:

- Four 2017 thoracic surgery cases resulted in patient deaths and one case resulted in complications.
- The surgeon omitted or misrepresented errors in operative note documentation to make errors seem normal.
- The surgeon's complications were not being reported appropriately.
- Staff were afraid to report their concerns as they feared retaliation.

² VA OIG, *Healthcare Inspection—Quality of Care Concerns in Thoracic Surgery, Bay Pines VA Healthcare System, Bay Pines, Florida*, Report No. 17-00602-342, August 16, 2017.

- The then Chief of Staff was aware of the concerns about the thoracic surgeon but took no action.

The Joint Commission also received an anonymous complaint similar to the one received by the OIG regarding the surgeon's competency and quality of care.

Facility leaders paused the thoracic surgery program on November 15, 2017, in response to the complaints made to the OIG and The Joint Commission. Facility leaders arranged a review of the thoracic surgery program by VISN 8, which was completed on December 5, 2017. The VISN 8 review did not identify concerns regarding the surgeon's surgical competence or quality of care issues. However, the VISN made several recommendations including lowering the complexity of thoracic surgical cases until a thoracic surgeon and two [surgical intensivists](#) were hired.

On December 19, 2017, the facility's [Medical Executive Council](#) unanimously concurred to resume the thoracic surgery program at the lower complexity level. On December 22, 2017, the Facility Director approved resuming the thoracic surgery program and the surgeon resumed performing operative procedures in early January 2018.

Because complaints about the surgeon's technical skills had not been resolved and because VISN reviewers recommended that the surgeon should not be performing more complex thoracic surgery procedures until additional resources were available, the OIG retained a thoracic surgery consultant not associated with VA (non-VA consultant) to assist in the inspection and ensure an independent and unbiased review of the clinical issues. The OIG initiated the inspection on February 2, 2018.

Other Key Events

Additional review activities and key events after the OIG initiated this inspection are shown below:

- *October 2018*—The non-VA consultant provided the final report of the five cases referenced in the 2017 anonymous complaint along with the 19 additional cases (October 31).
- *November 2018*—The OIG contacted the then Chief of Staff (COS) with the concerning results of the non-VA consultant's review of the 24 cases (November 2). The facility arranged for an external contractor to complete [management reviews](#) of a selection of the surgeon's cases.
- *January 2019*—The facility received the contractor's management review results, with five reflecting that care did not meet quality expectations.³

³ The five cases that did not meet quality expectations involved episodes of care in 2014 and 2015. Three of these five cases were also included in the OIG review and found to be problematic.

- *February 2019*—The surgeon stopped performing surgery and was detailed to the VISN pending the outcome of additional clinical reviews. The VISN Chief Surgical Consultant Network and the National Director of Surgery convened a panel of three VA cardiothoracic surgeons to review care provided by the surgeon (VA panel).⁴
- *Spring through fall 2019*—Focused clinical care reviews were completed by VA panel members.⁵
- *November 2019*—The VA panel submitted its final report stating that the surgeon's care met quality expectations and that the surgeon's privileges should remain in place without modification. The VA panel made recommendations regarding "programmatic issues."
- *December 2019*—The surgeon resumed patient care and continued to practice as of the time of this report.

Scope and Methodology

The OIG conducted a site visit July 31–August 1, 2018. The OIG interviewed VISN and facility leaders, and other staff with knowledge about thoracic surgery, patient safety, and other issues under review. Follow-up telephone interviews were conducted with the VISN surgical consultant and other surgeons from VISN 8.

The OIG conferred with the non-VA consultant to evaluate aspects of the facility's thoracic surgery program and to review the five cases mentioned in the 2017 complaint. After identifying quality of care concerns with the five cases, the OIG expanded the scope of the non-VA consultant's review to include 19 cases identified during the first OIG inspection on this matter.⁶

The OIG reviewed relevant VHA and facility policies and procedures, electronic health records (EHRs), credentialing and privileging documents, fiscal years 2017 and 2018 deaths within 30 days of a thoracic surgical procedure, peer review documents, Veterans Affairs Surgical Quality Improvement Program (VASQIP) data, National Surgery Office reports, pertinent

⁴ Two of the three VA panel members were chiefs of their respective surgical departments and professors of cardiothoracic surgery at academic institutions associated with their facilities. Two of the cardiothoracic surgeons each reviewed 22 of the 24 patient cases discussed in this report (see appendix A—patients 4 and 18 had no identified issues and were not reviewed). The third cardiothoracic surgeon served as "committee chair" and reviewed cases in which quality expectations were not met as determined by at least one of the VA reviewers.

⁵ VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A focused clinical care review is a clinician-specific review of "a specific area of practice, a specific time period of practice, or both, when there is an identified concern or issue."

⁶ VA OIG, *Healthcare Inspection—Quality of Care Concerns in Thoracic Surgery, Bay Pines VA Healthcare System, Bay Pines, Florida*, Report No. 17-00602-342, August 16, 2017. While 19 cases were identified during the review, not all were included in the case reviews. For the 2017 report, the OIG considered and incorporated a VA thoracic consultant's professional opinion about the quality of care in select cases.

meeting minutes, patient safety documents, and facility organizational charts. Other items reviewed included electronic mail messages and attachments to gain additional insight into facility leaders and other staff knowledge and communication of thoracic surgery concerns.

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

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

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

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

Inspection Results

Issue 1. Quality of Care and Evaluation

The OIG substantiated that four patients listed in the November 2017 complaint died in the postoperative period ([see appendix A, patients 1, 2, 3, and 4](#)) and a fifth patient experienced a complication related to the surgical procedure ([patient 5](#)). Often, however, the non-VA consultant and VA panel members reviewing these cases did not agree on whether the surgeon's practices met quality expectations or whether those practices contributed to the patients' outcomes.

The non-VA consultant reviewed the care of patients 1–5, as well as 19 additional patients (patients 6–24), to ensure an unbiased clinical review. The OIG submitted the findings of the non-VA consultant review to VISN and facility leaders. In response, a panel of VA thoracic surgeons reviewed care provided by the surgeon.

The OIG noted the non-VA consultant and the VA panel members agreed that quality expectations were met in the care of eight patients (patients 17–24). Those cases will not be discussed further. The non-VA consultant and the VA panel members agreed that quality expectations were not met in the care of one patient (patient 11). In the remaining cases, the OIG found variation of opinion among the non-VA consultant and the VA panel members as to whether quality expectations were met. The OIG recognizes that varying opinions for such reviews are not uncommon.

The non-VA consultant's overarching opinion, which was formulated after a comprehensive review of all aspects of surgical care, was of lapses in surgical judgment that were notable for preoperative planning and technical errors, as well as poor management of technical errors once incurred. Given the complexity of the cases, differing professional opinions, and the limitations of retrospective clinical reviews, this section of the report presents the non-VA consultant and VA panel members' findings in two components of care—preoperative planning and technical skills—as a way to understand the clinical issues involved with the patient cases described in this report.⁷ Patient case summaries are included in appendix A.

Preoperative Planning Errors

According to the non-VA consultant, preoperative planning errors included the selection of patients who were not reasonable candidates for surgery (see appendix A, patients 3, 6, 7, 11, 14, and 15) and failure to perform preoperative lymph node staging when indicated (patients 2, 5,

⁷ Retrospective reviews can have limitations because they are often based exclusively on information contained within the EHR that could be incomplete; providers are not typically interviewed, which could elicit additional details or extenuating circumstances.

and 13), which may have resulted in the performance of unnecessary procedures with detrimental results. Six of these patients died in the short-term postoperative period (patients 2, 3, 6, 11, 14, and 15). Patient 1 is included in table 1 because VA panel member 1 had concerns related to preoperative planning, although the non-VA consultant and VA panel member 2 did not. Table 1 reflects the findings of the non-VA consultant and the VA panel members as to whether preoperative planning errors were cited as an issue (red Yes); cited as an issue, though determined to be within quality expectations (yellow Yes with asterisk*); or not cited as an issue (green No).

Table 1. Findings of Preoperative Planning Errors

Patient	Non-VA Consultant	VA Panel Member 1	VA Panel Member 2
1	No	Yes	No
2	Yes	No	No
3	Yes	Yes*	No
5	Yes	Yes*	No
6	Yes	Yes*	Yes
7	Yes	No	No
11	Yes	Yes	Yes
13	Yes	No	No
14	Yes	Yes*	Yes*
15	Yes	Yes*	No

Source: OIG analysis

Examples A and B illustrate the non-VA consultant-identified deficiencies and the viewpoints of VA panel members 1 and 2.

Example A

The patient (patient 14) was in their 60s with [chronic obstructive pulmonary disease](#) (COPD) and non-small cell lung cancer in the right upper lung lobe, with possible involvement of the right middle and lower lobes.⁸ The patient was referred to the surgeon by a pulmonologist for consideration of surgical treatment of the lung cancer. The surgeon decided to proceed with surgery “given that patient’s TTE [[trans thoracic echocardiogram](#)] is normal and [sic] cardiology

⁸ The OIG uses the singular form of they (their) in the patient examples for the purpose of patient privacy. The patient was diagnosed with COPD. Pulmonary function testing performed approximately one and a half months prior to surgery showed that the forced expiratory volume in 1 second (FEV₁) was 59 percent of predicted and carbon monoxide diffusing capacity (DLCO) was 43 percent of predicted.

found no high-risk clinical features, and patient's inability to walk is due to [ambulation ability] more than [the patient's] breathing, as well as the fact that the tumor has defunctionalized a large portion of R (right) lung." The type of operation (removal of one lobe, two lobes, or pneumonectomy) would be determined in the operating room and the patient was advised that a pneumonectomy may be required. During surgery, the surgeon determined that a pneumonectomy was necessary to remove all of the tumor. The patient died from right heart failure the day after surgery.

Analysis

The non-VA consultant concluded that the surgeon did not perform sufficient preoperative testing to determine if the patient was a suitable candidate for pneumonectomy. Preoperative [pulmonary function testing](#) (PFT) revealed moderately reduced lung function, suggesting potential for increased surgical risk. A [quantitative radionuclide perfusion scan](#) should have been obtained in order to calculate predicted postoperative lung function, and optimally assess the patient's candidacy for pneumonectomy.⁹

VA panel member 1 cited concerns about preoperative planning but felt the care met quality expectations. VA panel member 1 noted that the pulmonary function tests were marginal and that additional testing, including a differential perfusion scan, echocardiogram, and cardiopulmonary exercise test would have been helpful in determining risk prior to pneumonectomy. However, VA panel member 1 indicated that quality expectations were met because the patient was informed of the high-risk nature of the procedure preoperatively and because the decision to proceed with surgery was multidisciplinary.

VA panel member 2 cited concerns but felt the care met quality expectations, writing "Right heart failure. Inadequate work up." VA panel member 2 noted that a preoperative quantitative perfusion scan should have been obtained if a pneumonectomy was considered to assess the additional strain that would be placed on the right heart. However, VA panel member 2 indicated that the surgeon did "due diligence" because the patient was sent to a cardiologist who opined that the patient would tolerate the pneumonectomy from a cardiac standpoint.

Example B

The patient (patient 2) was in their 70s with non-small cell cancer of the left upper lobe of the lung. Preoperative [positron emission tomography \(PET\)](#) scan findings included a suspicious lymph node in the [mediastinum](#) (L5). The patient

⁹ Brunelli A, Kim AW, Berger KI, Addrizzo-Harris DJ; *Physiologic Evaluation of the Patient With Lung Cancer Being Considered for Resectional Surgery*, 3rd ed: American College of Chest Physicians Evidenced-Based Clinical Practice Guidelines. Chest 2013; 143(5) (Suppl): e166S-e190S.

was taken to the operating room for [VATS](#) left upper lobe [wedge resection](#). The surgery was converted to [thoracotomy](#) because of lung adhesions and the patient underwent mediastinal L5 lymph node excision, followed by wedge resection.¹⁰ The patient was admitted to the surgical intensive care unit after surgery for postoperative hypotension assessment and management. The day following surgery, a cardiologist diagnosed the patient with acute coronary syndrome and the patient underwent cardiac catheterization. Immediately following the catheterization, the patient suffered a [cardiac arrest](#) and died.¹¹

Analysis

The preoperative PET scan demonstrated a suspicious lymph node (L5) in the mediastinum. The non-VA consultant noted that the L5 lymph node is not accessible via [mediastinoscopy](#) or [endobronchial ultrasound \(EBUS\)](#) though pre-resection mediastinal lymph node staging with mediastinoscopy or EBUS is indicated to sample accessible nodes for cancer. This was not performed. The non-VA consultant concluded that this staging would have allowed a more informed decision regarding operative viability. Such staging may have revealed that the patient was not an operative candidate.

VA panel member 1 did not cite concerns, writing “Death from acute post-operative MI [myocardial infarction]. The patient was evaluated by cardiology preoperatively. Cardiovascular events cannot be completely prevented, and the stress test did not show perfusion defect. The patient's underlying disease was the cause of death. The thoracic surgical care delivered was within [quality expectations].” In addition, VA panel member 1 agreed with the strategy of proceeding to VATS without preoperative lymph node staging, given inaccessibility of the L5 node to standard preoperative sampling modalities and because the patient would benefit from surgery as long as the L5 node was fully resectable.

VA panel member 2 did not cite concerns, writing that the patient had a preoperative workup, “but despite that had MI, coded after catheterization.” VA panel member 2 also agreed with the decision to proceed with surgery without preoperative node sampling, given the difficulty of accessing the L5 node and the option for postoperative adjuvant treatment if the node was positive for cancer.

Technical Errors

The non-VA consultant cited technical errors and poor management of technical errors that resulted in, or contributed to, excessive bleeding (see appendix A, patients 6, 7, 8, 10, and 13), the performance of operations more extensive than planned or indicated (patients 1, 7, 8, 12,

¹⁰ The excised mediastinal L5 node was positive for cancer.

¹¹ The patient had a negative stress test and cardiology evaluation prior to surgery.

and 13), one death on the operating room table (patient 7), and one death in the short-term postoperative period (patient 1). Table 2 reflects the non-VA consultant and VA panel members' findings as to whether technical errors were cited as an issue (red Yes); cited as an issue, though determined to be within quality expectations (yellow Yes with asterisk*); or not cited as an issue (green No). The non-VA consultant found that technical errors in the care of patients 1 and 12 were "[never events](#)."¹²

Table 2. Findings of Technical Errors

Patient	Non-VA Consultant	VA Panel Member 1	VA Panel Member 2
1	Yes	Yes	Yes*
6	Yes	No	No
7	Yes	Yes*	Yes
8	Yes	Yes*	Yes*
10	Yes	Yes*	No
12	Yes	Yes	Yes*
13	Yes	No	No

Source: *OIG analysis*

Examples C, D, and E illustrate the non-VA consultant-identified deficiencies and the viewpoints of VA panel members 1 and 2.

Example C

The patient (patient 7) was in their 70s and found to have a 1.5 centimeter (cm) squamous cell cancer in the [lingular](#) portion of the left upper lobe of the lung. The patient was taken to the operating room for VATS wedge resection and possible left upper [lobectomy](#). The operative report states that “[t]here were multiple posterior recurrent branches in a common trunk with the anterior trunk. These were encircled and an attempt to get around them with a 35 powered echelon vascular stapler was made; however, bleeding ensued from behind the anterior trunk.” The procedure was converted to thoracotomy. Subsequently, “the 35 vascular powered echelon was then used to transect the anterior trunk along with a posterior recurrent arterial branch which had the common trunk with the anterior trunk. After firing this stapler, bleeding issued from a defect in the proximal left [main pulmonary artery](#).”

¹² “Never events” are defined by the National Quality Forum (NQF) as adverse events that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and usually preventable. In this context, “never event” refers to the wrong surgical or other invasive procedure performed on a patient.

A vascular surgeon was called in to assist and the pericardium was opened to gain intrapericardial access to the left main pulmonary artery. The operative report next states that “The left main pulmonary artery was encircled. However, despite sponge stick pressure on the injury on the proximal pulmonary artery at the area where the anterior trunk branches had been [transected](#), this area continued to bleed. Further attempts to encircle the left main pulmonary artery were made and the pulmonary artery was clamped; however, bleeding from the distal pulmonary artery continued despite direct sponge stick pressure in this area.” The operative report stated that at this point in the procedure, the patient became [hypotensive](#) and received blood products, and treatment with [vasopressors](#) and calcium.¹³ The patient subsequently suffered a cardiac arrest with pulseless electrical activity.¹⁴ [Cardiac massage](#) was performed.

The operative note next reported that “the proximal pulmonary artery was stapled with a thick tissue TA [transverse anastomosis [stapler](#)] 60 staple firing. However, at this point, additional areas of bleeding followed.” The patient was subsequently also noted to be “bleeding from multiple areas of the left [atrium](#).”¹⁵ Efforts at atrial repair ensued as “the left [atrial appendage](#) was partially stapled for [hemostasis](#) with a white powered echelon staple firing” and “another area of the left atrium was staple [sic] with a green powered echelon staple firing.”¹⁶ “However, there were continued large areas of bleeding.”¹⁷ The patient received additional blood products and [vasopressor agents](#) though subsequently was noted to be “asystolic.”¹⁸ The left upper and lower lobes were then “[retracted](#) and transected” for “further exposure.” Despite attempts to “obtain hemostasis,” the patient lost an estimated 11,500 milliliters of blood and died on the operating table.¹⁹

¹³ The patient received a total of 14 units of blood in addition to other blood products and intravenous fluids.

¹⁴ Pulseless electrical activity is a type of cardiac arrest in which there is electrical activity but no pulse. This may be caused by significant blood loss.

¹⁵ During an interview, the surgeon informed the OIG that the atrial rupture was caused by the cardiac massage.

¹⁶ Surgical staplers are available in various sizes and heights that are used to accommodate different tissue thicknesses for appropriate tissue management. The color of the staple cartridge represents the dimension of the staple. Edward Chekan and Richard L Whelan. *Surgical Stapling Device-tissue interactions: what surgeons need to know to improve patient outcomes*. Med Devices (Auckl). 2014; 7: 305–318. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4168870/>. (The website was accessed on September 27, 2019.)

¹⁷ The operative report notes that “the patient did have a history of severe left atrial dilation, and the left [atrium](#) was extremely friable.”

¹⁸ Asystole is cardiac arrest with cessation of electrical activity of the heart.

¹⁹ The average adult has a blood volume of approximately five liters.

Analysis

The non-VA consultant determined that surgical removal of a 1.5 cm nodule in the lingular segment of the left upper lobe should not result in pneumonectomy and opined that multiple sequential technical errors during the procedure led to an unrecoverable situation. Further, after the first injury, consideration should have been given to gaining proximal control of the [left pulmonary artery](#) prior to progressing with the procedure, which resulted in further injury. Attempts to control pulmonary artery bleeding failed and the non-VA consultant stated that this “can only be explained by technical error, either incomplete control of the PA [pulmonary artery], or not remembering to clamp the pulmonary veins, or both.”

VA panel member 1 cited concerns about technical errors but felt the care met quality expectations, writing “[a]lthough there was a severe technical complication, events such as this could happen to any surgeon, and therefore I deem it within [quality expectations].”

VA panel member 2 cited concerns and commented that the treatment technique was not performed correctly and did not meet quality expectations. VA panel member 2 further wrote “Vascular injury can occur however it is rare that injury cannot be centrally [managed].”

Example D

The patient (patient 12), who was in their 60s with a left upper lobe mass, was taken to the operating room for lobectomy. The operative report notes that the “anterior trunk” [of the pulmonary artery] was “transected with a [Covidien gold load](#)” and subsequently states that “what had appeared to be the anterior trunk was actually a small left main pulmonary artery.” The lobectomy was converted to pneumonectomy due to the transection of the left main pulmonary artery.

Analysis

The non-VA consultant determined that the surgeon mistook the main pulmonary artery for a branch (anterior trunk) of the pulmonary artery, and as a result, inadvertently transected the main pulmonary artery. At that point, the surgeon had to remove the entire lung (pneumonectomy) instead of one lobe of the lung (lobectomy) because the main pulmonary artery supplies blood to the entire lung. The non-VA consultant considered the inadvertent transection of the main pulmonary artery as a never event, because there were no circumstances of the procedure that could explain this error. Further, the conversion from the lobectomy to pneumonectomy resulted in the unnecessary loss of a considerable amount of additional lung tissue and increased postoperative [mortality](#) risk.²⁰

²⁰ The predicted postoperative mortality associated with lobectomy is 1–2 percent; the predicted postoperative mortality associated with pneumonectomy is 5–10 percent.

VA panel member 1 documented that quality expectations were not met, stating “no vessel should be divided for a lobectomy without confirming that the main PA [pulmonary artery] is intact” and “technical surgical error led to more extensive surgery.”

VA panel member 2 believed that quality expectations were met, stating that the treatment technique was not performed correctly, but “surgery can have complications and decisions how to handle those complications [need to be made].” VA panel member 2 asserted that repair would be the optimal approach, though the surgeon was unable to repair the artery after the injury occurred.

Example E

The patient (patient 1) was in their 50s with a remote history of breast cancer and a newly identified metastasis in the upper lobe of the right lung.

The patient was taken to the operating room by the surgeon for VATS right upper lobe pulmonary wedge [metastasectomy](#) and possible lobectomy. The operative report notes that the right upper lobe metastasis was located “at the confluence of the middle upper and lower lobes,” that the tumor was “stuck” to the middle and lower lobes, and it was “unclear” whether this was due to tumor invasion or inflammatory adhesions. The surgeon decided to “resect the areas of potential crossover into the middle and lower lobes en bloc in order to ensure a negative margin.”²¹ The specimen was sent for frozen section and the “closest margin for this resection was positive for malignancy.” The surgeon opted to proceed with a “completion [sic] right upper lobectomy, likely with additional en bloc portion of the right lower lobe included.”

The operative report next states that “some bleeding issued posterior to the [superior pulmonary vein](#)” after superior pulmonary vein dissection. The procedure was converted to a posterolateral thoracotomy...²²

The note also states that “during the course of VATS dissection, peritracheal lymph nodes were excised.” Although the OIG could not confirm from the operative report or autopsy, the surgeon told the OIG that the right atrium was punctured during lung resection.²³

After the procedure was completed, the patient was admitted to the surgical intensive care unit for respiratory and hemodynamic monitoring. The day

²¹ “En bloc” refers to the removal of tissue in one piece.

²² See appendix A for a more detailed account of the operative report.

²³ The surgeon informed the OIG that a vascular surgeon who assisted with the procedure punctured the atrium. The vascular surgeon did not recall that the atrium was injured during surgery.

following surgery, the patient experienced hypotension and worsening kidney function, though the patient was communicative and tolerated extubation. On postoperative day 2, the patient remained hypotensive and cardiac enzymes were elevated. The patient was seen by a cardiologist who noted “demand ischemia [NSTEMI](#) [Non-ST-elevation myocardial infarction is a type of heart attack],” atrial fibrillation and “preserved” left and right ventricular function.²⁴ The patient developed respiratory failure and acidosis necessitating reintubation and initiation of chronic renal replacement therapy later on the second postoperative day. On postoperative day 3, the patient experienced cardiac arrest; a family member requested that resuscitative efforts be discontinued, and the patient died.

The autopsy report states that “The right atrium contains a well-defined ovoid thrombus, approximately the shape and size of a chicken egg, that fell out of the atrium during the removal of organs.” The report also noted evidence of acute right heart failure (without ventricular dilation) which was attributed to the right atrial thrombus. The cause of death was determined to be [cardiac shock](#). The surgical pathology report of tissue obtained from the operation was completed 10 days after the patient’s death and revealed cancer in two hilar lymph nodes.

Analysis

Although not clearly described in the operative note, the surgeon converted this planned VATS right upper lobe pulmonary wedge metastasectomy with possible lobectomy to a pneumonectomy. The non-VA consultant determined that the conversion to pneumonectomy in this instance was a never-event. The surgeon did not identify that the hilar lymph nodes were positive for cancer intraoperatively. The non-VA consultant stated that “proceeding beyond wedge resection in the presence of metastatic lymph nodes despite a positive [*sic*] margin was not indicated.” In addition, “performing pneumonectomy for injury to superior pulmonary vein was not necessary.”²⁵

VA panel member 1 believed that quality expectations were not met, writing “usually we do not recommend resection of breast cancer metastatic to the lungs because [there is] no definite survival benefit.” VA panel member 1 also wrote “pneumonectomy is too extensive of a procedure for metastasectomy.”

VA panel member 2 cited concerns, writing “technique not performed correctly and extent of surgery not appropriate” and “uncertain with venous injury, why pneumonectomy was ultimately needed.” However, VA panel member 2 felt that care ultimately met quality expectations

²⁴ The patient underwent echocardiograms on postoperative days two and three.

²⁵ The patient’s breast cancer had metastasized to the lymph node as well as lung tissue. The surgeon’s strategy of extending the lung resection increased the risk of surgery and was not likely to increase the patient’s survivability.

because, although surgery generally does not confer survival benefit in breast cancer patients, there are instances where surgery may be appropriate and the decision to proceed with surgery was made in a multidisciplinary fashion.

Summary of Issues When Experts Disagree

The OIG found that the non-VA consultant, who interviewed the surgeon and asked about specific cases, repeatedly cited preoperative planning, technical, and judgment errors in the care of some patients.²⁶ The VA panel members, who did not interview the surgeon, offered different perspectives.

Quality reviewers evaluate quality of care through different prisms informed by their own professional approaches and experiences. In this case, the surgeon was cleared for return to clinical duties by a panel of VA thoracic surgeons who often either disagreed about whether quality expectations were met in the identified cases or had differing opinions about the degree to which other circumstances tempered quality of care concerns. The non-VA consultant had multiple concerns and was less certain about the surgeon's ability to consistently provide safe quality care in this technically complex surgical specialty.

Ultimately, the VA panel's final determination was that the surgeon delivered thoracic surgical care within quality expectations and recommended that the surgeon's privileges "remain in place without modification." The VA panel identified "programmatic issues" and recommended "an enhanced multidisciplinary approach to patient selection and preparation for surgical procedures."²⁷ The surgeon resumed patient care on December 22, 2019.

The OIG acknowledges that recognized complications can happen to any surgeon and that multidisciplinary input is important in patient care, but in the OIG's opinion, each provider's actions and decisions should be examined independently, irrespective of whether a widely-recognized and common complication occurs during surgery.

The quality and management reviews performed by the external contractor, the non-VA consultant, and the VA panel, spanned more than one year. During this time, the surgeon was

²⁶ The surgeon blamed others involved in procedures for poor outcomes, claimed others were biased against [the surgeon] for actions taken as Chief of Thoracic Surgery, maintained that the error rate for the surgeries under review by the OIG was consistent with national averages, and asserted that the complications encountered were not "never events" because they had been encountered in the peer-reviewed medical literature.

²⁷ The VA panel review methodology consisted of panel members 1 and 2 both reviewing the 22 cases and providing an independent assessment of their findings. The panel chairperson, also a thoracic surgeon, reviewed the five cases that panel members 1 and 2 determined the standard of care was not met. The panel discussed each of the five cases in depth and made an overall decision about the standard of care. The panel chairperson also reviewed cases 1–20 from a surgical case listing for the entire period of the surgeon's practice. An additional five randomly selected cases were reviewed by the panel chairperson to assess overall surgical management and gain supporting information and validation related to the surgeon's outcomes and provision of care. The results of those five reviews were not shared with the OIG and are not discussed in this report.

alternately permitted to perform surgeries or removed from clinical duties pending the outcome of certain reviews.

The OIG recognizes that depending on the circumstances, both responses may be appropriate. If a surgeon lacks the full range of skills needed to ensure safe, quality care, then the decision to leave a surgeon in clinical practice could result in poor patient outcomes. Alternatively, removing a surgeon with adequate skills from practice for an extended period may affect the availability of some surgeries, which could also negatively affect patient care. The OIG also recognizes that as a surgeon becomes more experienced, operative outcomes tend to improve.

Ultimately, VHA and VISN reviewers, facility leaders, the OIG, and the non-VA consultant were in the position of evaluating the surgical competency of this specialty surgeon as well as the environment in which surgical teams were managing patients. While the competency of this surgeon was the subject of multiple allegations, it was also necessary to consider the adequacy of clinical support resources, the effectiveness of quality monitoring processes, and the caliber of collaborative clinical practice among staff, specialists, and coordinating treatment teams.

Decision-making, at multiple layers of leadership in the VHA system, relied heavily upon many highly qualified cardiothoracic surgeons reviewing dated surgeries, applying context to medical record documentation based on their own clinical experience, and balancing a wide spectrum of staff feedback on the leadership and surgical skills of the subject surgeon. As it relates to the 2017 allegations, VHA considered input from four different reviewers or review panels over the span of 12 months. The OIG recognizes the challenges facility leaders face when making decisions that demand an understanding of a highly technical surgical specialty that often treats the most complex and gravely ill patients.

All of the quality reviews relied upon experienced and reputable consultants but securing those subject-matter experts and coordinating those reviews was time-consuming and potentially delayed improvements to the facility's thoracic surgery program. In this context, the appointment of a VHA-centralized thoracic specialty leader, whose responsibilities would be to ensure that VA provides quality thoracic surgery and to assist facility clinical leaders to establish appropriate in-depth clinical reviews, would be prudent. This VHA-centralized thoracic specialty leader would provide unbiased, authoritative, and prompt guidance on the most clinically sound course of action when a thoracic surgeon's practice or outcomes are under review. For example, with the events described in this report, such a specialty leader with authoritative decision-making power could have intervened and initiated a structured quality-based review that would have avoided the repeated solicitation of multiple specialists and thus multiple conflicting opinions of a clinician's practice. The lack of a streamlined process in this case delayed growth and improvement in the facility's cardiothoracic surgery program.

Issue 2. Documentation and Reporting of Surgical Errors and Complications

Operative Note Documentation

The OIG substantiated that in one instance, the surgeon omitted an error from an operative note as the surgeon informed the OIG of this error during an interview. The surgeon did not explain the reason for the omission. When reviewed, the patient's operative documentation did not include discussion of the error the surgeon described.

The OIG was unable to determine whether surgical errors were made to look like normal or expected events. The OIG noted complications in several surgical cases. However, without directly observing the events that resulted in complications, the OIG was unable to discern whether the complications resulted during the normal course of surgery or from errors attributable to the surgeon. Nevertheless, in its review of operative reports, the OIG noted instances when surgical events were unclearly or inaccurately characterized as well as operative reports with descriptions of complications that were not designated appropriately.

An operative *report* must be written or dictated by the operating surgeon before the patient is transferred to the next level of care. Due to the time needed to transcribe, a dictated operative report is typically not immediately available to the operating surgeon for review and signature. In those circumstances, the *report* is not available in the patient's EHR prior to the patient's transfer to the next level of care. When the operative *report* is not immediately available, a postoperative *note* must be entered into the EHR prior to the transfer of the patient from the operating room to the next level of care so that pertinent information is available to the next caregiver.²⁸ VHA policy states that the immediate postoperative note must include complications, but does not include the same provision for operative reports.²⁹ The Joint Commission, however, provides guidance that postoperative documentation include unanticipated events or complications.

The OIG reviewed the EHRs of the 16 patients with quality of care concerns and found that all 16 patients had both immediate postoperative notes and operative reports in the EHR. The OIG identified intraoperative complications in 10 of the 16 patients. The immediate postoperative notes listed complications for 5 of the 10 patients.³⁰ Examples of omissions and complications not designated or clearly characterized as complications follow:

²⁸ VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015. The OIG uses italics in this paragraph to emphasize the differences between an operative report and an operative note.

²⁹ VHA Handbook 1907.01.

³⁰ For one of these patients (patient 13), the OIG noted that the resident entered a postoperative note that included the complication of pulmonary artery injury. The surgeon signed this note, but entered a second postoperative note one hour later, which did not include a complication line or mention pulmonary artery injury.

- Patient 16 underwent VATS lobectomy for a right upper lobe tumor. The procedure was complicated by vascular and phrenic nerve injuries. The OIG noted that the “complication” line in the immediate postoperative note was left blank. In addition, neither the vascular nor nerve injury was characterized as a complication in the operative report.
- Patient 1 underwent VATS wedge metastasectomy and attempted lobectomy, complicated by injury to the superior pulmonary vein, resulting in conversion to thoracotomy and pneumonectomy. The immediate postoperative note did not contain a “complications” line. However, the immediate postoperative note did include a “surgical findings” line which states, “VATS converted to thoracotomy for bleeding.”³¹
- Patient 12’s operative report, dictated the day after surgery, characterized “converting to thoracotomy for bleeding,” as a complication. The operative report did not designate the vascular injury, which resulted in pneumonectomy as a complication and transitioned directly from a description of a lobectomy to a description of a pneumonectomy, without explaining the rationale (vascular injury) for pneumonectomy. When interviewed, the surgeon informed the OIG that the right atrium was punctured during surgery. This event was not found in the immediate postoperative note or operative report.³²

The patient underwent a lobectomy which was converted to pneumonectomy because the main pulmonary artery (believed to be the anterior trunk of the pulmonary artery) was inadvertently transected with a stapler. The OIG noted that there was no line entitled “complications” in the immediate postoperative note and the technical error (transection of the pulmonary artery), which resulted in pneumonectomy, was not included.

The operative report explained that the “anterior trunk” was “transected with a Covidien gold load” and subsequently stated that “what had appeared to be the anterior trunk was actually a small left pulmonary artery.” However, no event was specifically designated as a complication.

- Patient 5 underwent thoracotomy with right upper lobectomy for lung cancer. The OIG noted that the operative report stated that the “membranous portion of the [bronchus intermedius](#) that had been extremely adherent to the bronchial tissues had an approximately 4mm [millimeter] defect,” implying that the defect occurred

³¹ The immediate postoperative note is required to include both findings and complications.

³² The surgeon informed the OIG that a vascular surgeon who assisted with the procedure punctured the atrium. The vascular surgeon did not recall that the atrium was injured during surgery.

spontaneously. However, this defect was a surgical complication and the immediate postoperative note and operative report both listed “none” in the complications line.³³

The OIG found that the surgeon omitted key information from operative notes and that surgical complications were not recorded or designated appropriately as complications. In addition, complications were sometimes difficult to discern because surgical events were unclearly or inaccurately characterized in operative reports. The failure to clearly describe and identify intraoperative events may affect a patient’s immediate and long-term care should other clinicians draw faulty conclusions about the patient’s health, anatomy, and recuperative ability based on incomplete operative documentation.

Reporting Compliance

The OIG did not substantiate that the facility did not report surgical errors and complications appropriately. The National Surgery Office did not require a mandatory assessment of all thoracic surgeries; therefore, the surgeon’s actual [morbidity](#) and mortality data were not consistently captured through the VASQIP assessment process.³⁴

The National Surgery Office establishes policy and provides clinical oversight for VHA surgical programs, including the guidelines for completing VASQIP assessments.³⁵ In eight-day cycles, the surgical quality nurse is required to complete and transmit VASQIP assessments for the first consecutive 36 eligible surgical cases and all mandatory assessment surgical cases. Eligible surgical cases are those that present more than a minimal risk to patients.³⁶ Mandatory assessment surgeries are a subset of the eligible surgical cases. The policy requires submission of all mandatory assessment surgeries, even if this inclusion results in the facility exceeding the 36 eligible surgical case requirement in the eight-day cycle.³⁷ The surgical quality nurse continues

³³ The operative note was not clear enough to determine whether the bronchial injury was preventable.

³⁴ VASQIP is not designed to capture intraoperative morbidity, and data would not be collected on issues such as an inadvertently severed main pulmonary artery. However, if a severed artery resulted in other issues, such as prolonged intubation or blood loss, data would be captured.

³⁵ VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013. This handbook was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1102.01(1) *National Surgery Office*, May 22, 2019.

³⁶ Based upon Current Procedural Terminology (CPT) codes, a surgical case is either eligible or ineligible for VASQIP assessment.

³⁷ The mandatory assessment surgeries currently include bariatric surgery, cardiac surgery, craniotomy, esophagectomy, pancreatectomy, hepatectomy/bile duct tumor resection, and solid organ transplant.

to follow the eligible surgical cases, and any mandatory assessment surgeries, for 30 days post-procedure, then transmits the VASQIP assessments to the National Surgery Office.³⁸

In December 2017, the Facility Director approved a reduction in the complexity level of thoracic surgical cases performed at the facility following The Joint Commission and VISN reviews of thoracic surgery cases, and based on a facility Medical Executive Council recommendation. The facility defined lower complexity cases as those that

- Did not involve tumors invading or encasing the great vessels,
- Did not have preoperative imaging results showing that a pneumonectomy may be required for complete tumor resection, and,
- Did not involve return to the operating room for revision.

The OIG reviewed the National Surgery Office quarterly reports from October 1, 2016, through September 30, 2018, as well as facility data to determine the accuracy of reported surgical errors and complications. Surgical morbidity includes surgical errors and complications within 30 days of surgery, and surgical mortality includes deaths within 30 days of surgery. The facility's 30-day morbidity rate was an [outlier](#) from January 1, 2017, to March 31, 2017, exceeding the expected morbidity for that quarter. The morbidity rate for January 1, 2018, to March 31, 2018, which included thoracic surgical cases performed after the facility changed to a lower complexity level, also exceeded the expected morbidity for that quarter. The facility's 30-day mortality was not an outlier in the quarterly reports for October 1, 2016, through September 30, 2018.

Six patients died within 30 days of thoracic surgery from October 1, 2016, through September 30, 2018; however, only one death was assessed by the surgical quality nurse.³⁹ The OIG noted that an assessment was not completed for the other five cases and the quarterly reports did not include all thoracic surgery cases because they were not mandatory assessment surgeries and did not occur within the first consecutive 36 eligible surgical case assessment requirement. Thoracic surgery is not considered a mandatory assessment surgery, which would have required a 100 percent assessment. The VA panel members told OIG that they reviewed the surgeon's VASQIP mortality data, did not find outliers (beyond what would be expected), and considered this information when recommending the surgeon be restored to duty with no change in clinical privileges. However, had all of the mortalities been included in VASQIP assessment, the OIG

³⁸ VHA Handbook 1102.01. Quarterly National Surgery Office reports of surgical outcomes are forwarded to VISN and facility Surgical Work Groups to enable evaluation of facility surgical programs for long-term trending and national comparisons of outcomes.

³⁹ These included four deaths reviewed by the non-VA consultant (patients 1, 2, 3, and 4) and two additional deaths identified through documents received from the facility.

found that it is likely that that the surgeon's observed (actual) mortalities would have been higher than what was expected if all the case mortalities had been included in the VASQIP review.

The then COS reported that as of August 2018, the facility elected to assess 100 percent of eligible thoracic surgery cases even though this level of review was not required by policy.

Issue 3. Culture of Safety, Retaliation, and Quality Review Processes

The OIG substantiated that some staff feared retaliation for discussing or reporting concerns about the surgeon's cases, which may have suppressed some reporting of [adverse events](#) or close calls. The OIG also found that two quality review and oversight processes did not sufficiently ensure that the surgeon's cases were consistently being evaluated according to VHA policy.⁴⁰

Leaders are central to creating a culture of safety and quality. Leaders in VHA are responsible for ensuring veterans receive high quality health care that is safe and timely. Further, leaders establish the organization's culture through their words and behavior.⁴¹

VHA medical facilities have systemic quality management processes in place that are designed to identify and respond to key quality, safety, and value concerns. The structure of these processes must conform to VHA policy so that leaders and managers have confidence in the integrity of quality review and oversight findings.⁴²

The OIG reviewed the culture of safety within Surgical Service, the peer review structure and its processes, and the [Surgical Work Group](#) structure and its oversight.⁴³

Surgical Service Culture and Leadership

The surgeon, who was also the Chief of Surgery at the time of the OIG's review of the 2017 allegations, did not consistently promote a culture of safety within the Surgical Service and some staff feared retaliation. Facility policy states that service chiefs are responsible for "supporting a blame-free, protected environment that encourages the systematic identification and reporting of Adverse Events, Sentinel Events, and Close Calls."⁴⁴ The facility's medical staff bylaws state

⁴⁰ VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value*, August 2, 2013. This directive was in effect during the time frame of the events discussed in the report; it was rescinded in October 2019 to avoid "conflict with modernization efforts as they are being rolled out as part of the new VHA governance process."

⁴¹ Leadership in Healthcare Organizations. *A Guide to Joint Commission Leadership Standards. A Governance Institute White Paper*, Winter 2009. https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/wp_leadership_standardspdf.pdf?db=web&hash=86F0223A5C016F833DA3DDB1C62F5D20. (The website was accessed on February 16, 2020.) VHA Directive 1026.

⁴² VHA Directive 1026.

⁴³ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011; VHA Directive 1026; VHA Handbook 1102.01.

⁴⁴ VHA Handbook 1050.01.

that providers are expected to “fulfill their obligations to maximize the safety of patient care by behaving in a manner that promotes both professional practice and a work environment that ensures high standards of care.”⁴⁵

During interviews, several facility staff told the OIG about intimidating or otherwise unsatisfactory encounters with the surgeon. Specifically, staff described the surgeon as a poor communicator who made “unilateral decisions,” was “defensive” and “unwilling to listen,” and who would deflect blame when something went wrong with one of [the surgeon’s] cases. One staff member told the OIG of not reporting concerns about the surgeon, stating the surgeon said not to go “to the front office” as [the surgeon] “will know who they talk to.” Another staff member reported “a definite power differential” and that people were “afraid to argue with [the surgeon].” Several staff members reported a general concern about retaliation.

Email documentation appeared to support employees’ perceptions of intimidation and improper use of power. On July 31, 2018, the OIG interviewed the surgeon and discussed the 24 cases under review in detail. On August 2, the surgeon sent an email to the facility’s privacy officer, writing “as we discussed, there is evidence of unauthorized access to a Veterans chart within the last 12 months.” One patient’s name was provided in the email. The surgeon then wrote, “please provide a list of everyone who accessed [the] chart within that timeframe.” The privacy officer responded that, for technical reasons, the information could not be retroactively retrieved on that patient. The surgeon later wrote, “would you please provide full access reports for the same concern for [seven patient names].” On August 3, 2018, the surgeon acknowledged in an email that the access reports provided did not show a “breach” (unauthorized access) for the previous year and then asked the privacy officer to provide the reports back to November 2016. Ultimately, the surgeon requested access reports for 21 patients, all of whom were included in either the first OIG review in 2016 or the second review initiated after the 2017 allegations. When the information was retrievable, those access reports were provided to the surgeon.

The OIG could not identify a clinically or administratively relevant purpose for the surgeon’s expanded requests for access reports for these 21 specific patients going back nearly two years. The OIG noted that the scope of the information requested could have potentially provided the surgeon with the identity of the original (2016) and subsequent (2017) complainant(s).

The OIG concluded that the surgeon’s words and behavior contributed to a fearful and retaliatory environment that could lead to underreporting of quality of care concerns and promote a perception that surgical data were being manipulated in the surgeon’s favor. The surgeon was no longer the Chief of Surgery upon resuming clinical care in late 2019; nonetheless, the surgeon retained a position of power in the operating room during surgical cases. In that context, the surgeon’s conduct still had the potential to negatively affect patient care and safety.

⁴⁵ Facility Bylaws.

Surgical Work Group

The OIG determined that the surgeon, who was also the Chief of Surgery and the Surgical Work Group chairperson at the time of the OIG's review of the 2017 allegations, did not ensure the facility's Surgical Work Group adhered to VHA policy in the review of surgical deaths or critical surgical events and did not provide oversight of the [Morbidity and Mortality Conference](#) as required by VHA policy.

VHA policy requires a facility Surgical Work Group to identify gaps with surgical care and recommend actions and perform various other quality and performance improvement activities.⁴⁶ This includes providing oversight of the Morbidity and Mortality Conference, reviewing surgical deaths monthly, and evaluating critical surgical events.

The OIG reviewed facility Surgical Work Group meeting minutes for October 1, 2016, through September 30, 2018. Although the Surgical Work Group reviewed the National Surgery Office quarterly reports, there was no evidence that the Surgical Work Group reviewed surgical deaths monthly or discussed critical surgical events, including the surgeon's cases. Additionally, the OIG did not find evidence of oversight of the Morbidity and Mortality Conference. The OIG concluded that because the Surgical Work Group did not comply with VHA guidelines for review and oversight of specified surgery-related activities, the facility missed opportunities to improve surgical care that aligned with the VISN Surgical Work Group and the National Surgery Office.

Peer Review

The OIG determined that the peer review process did not ensure that the surgeon, who was a member of the Peer Review Committee and under review, was excluded and did not have direct involvement with committee decisions for the final peer review levels that involved the surgeon's cases.

VHA policy establishes a peer review process to improve care provided to veterans.⁴⁷ Peer review is a quality assurance process carried out initially by a similarly qualified practitioner and then finalized by a peer review committee. Initial peer reviews are given a Level 1, 2, or 3 based on what a similarly qualified practitioner would have done with the same set of clinical

⁴⁶ VHA Handbook 1102.01.

⁴⁷ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. This directive was in effect during the time of events discussed in this report; it was rescinded and replaced by VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

circumstances as the provider under review.⁴⁸ All Level 2 and 3 initial peer reviews are evaluated by the peer review committee to determine a final peer review level.

VHA policy states that peer review committee members must abstain from a review of any case in which there is a conflict of interest, a lack of the specialized knowledge required, or for any other reason, the member is unable to conduct an objective, impartial, accurate, and informed review.⁴⁹ Facility policy further states that the facility's Peer Review Committee members may not have direct involvement with the episode of care under review.⁵⁰

The OIG reviewed the facility's Peer Review Committee minutes and noted that a majority of the cases discussed in this report underwent initial peer review. The minutes indicated that the surgeon was present as a member at two meetings when two of the peer reviews were presented for discussion; the surgeon was excused for a third meeting when two additional peer reviews were presented.

During the three meetings, the surgeon provided written and verbal rebuttals related to the four cases, which is an appropriate and expected part of the peer review process.¹ However, the minutes did not reflect that, after making the verbal rebuttals to the Peer Review Committee, the surgeon left the room or abstained from discussion of the cases at issue.

The OIG concluded that the apparent presence of the surgeon during the Peer Review Committee deliberations and final peer review level decisions for the surgeon's cases, without documentation that the surgeon abstained, did not meet the intent of VHA policy. The policy is designed to limit the potential for providers whose cases are being reviewed to exert influence over the Peer Review Committee's final peer review level determinations.

Issue 4. Facility Leaders' Actions

Response After Notification of the November 2017 Allegations

The OIG did not substantiate that the then COS failed to address concerns about the thoracic surgeon's practices and outcomes. Facility leaders were not thoracic surgeons and therefore had to rely on the opinions of subject matter experts outside the facility.

⁴⁸ According to VHA Directive 2010-025, Level 1 peer review score indicates that most experienced, competent providers would have managed the case in a similar manner. Level 2 peer review score indicates that the most experienced, competent providers might have managed the case differently. Level 3 peer review score indicates that the most experienced, competent providers would have managed the case differently. According to VHA Directive 1190, November 21, 2018, the definition of Level 2 was revised to be the level at which most experienced and competent clinicians might have managed the case differently, but it remains within the standard of care.

⁴⁹ VHA Directive 2010-025.

⁵⁰ Facility Memorandum 516-15-11-076, *Peer Review for Quality Management*, December 2015.

After the 2017 allegations to the OIG and The Joint Commission, facility leaders paused the thoracic surgery program on November 15, 2017, and arranged a VISN review of the thoracic surgery program. The VISN 8 review, completed on December 5, 2017, did not identify concerns regarding the surgeon's surgical competence or quality of care issues, but did make recommendations including lowering the complexity of thoracic surgical cases until additional specialists were hired. On December 19, 2017, the facility's Medical Executive Council recommended the thoracic surgery program recommence at the lower complexity level. On December 22, 2017, the Facility Director approved resuming the thoracic surgery program and the surgeon told the OIG of resuming surgical procedures in early January 2018.

In November 2018, the OIG contacted VISN and facility leaders to discuss the findings of the non-VA consultant's review. In response, the facility referred 14 cases for outside management review by an external contractor agency.⁵¹ The contractor agency reviews, which the facility received around January 10, 2019, indicated that quality expectations were not met in 5 of the 14 referred cases.⁵² The surgeon was removed from providing patient care on February 1, 2019, to allow the completion of facility, VISN, and OIG pending reviews.⁵³ The surgeon resumed patient care on December 22, 2019, after completion of facility and VISN reviews and leaders determined care could be continued. The OIG found facility leaders' actions as described above to comport with VHA policies.

While not allegations, the OIG identified two leadership-related issues—one involving the surgeon's clinical privileges and the other involving [institutional disclosures](#)—that were not managed in accordance with VHA policy.

Clinical Privileges and Complexity

The OIG determined that facility leaders failed to adjust the surgeon's clinical privileges to reflect the change to a lower complexity level of surgeries for more than one year.

Clinical privileging is the process by which a provider is permitted by law to provide medical care services within the scope of the individual's license. Clinical privileges are specific to the facility resources, services, and provider's clinical competence; only privileges for procedures provided by the VHA facility may be granted to a provider.

As noted previously, a "thoracic surgery pause" was implemented on November 15, 2017, in response to the multiple complaints regarding the surgeon's quality of care. The Facility Director

⁵¹ The other 10 cases had previously been reviewed by the external contractor agency as part of the facility's peer review process.

⁵² According to the Executive in Charge, "The surgeon was not on duty due to government travel and annual leave from January 10, 2019, through January 31, 2019."

⁵³ This report includes the results of the OIG's review. The VISN and facility informed the OIG of the results of their completed reviews in late 2019.

approved a change for thoracic surgery to only include lower complexity cases and reinitiated the thoracic surgery program on December 22, 2017. While the former COS informed the OIG in January 2019 that the surgeon's clinical privileges reflected the VISN recommendation that the facility do only lower complexity cases, the OIG found that the change in privileges did not occur until February 1, 2019, over a year after the programmatic change in complexity.

The OIG found no evidence that the surgeon performed procedures beyond the approved lower complexity surgeries during this time.

Institutional Disclosure

The OIG determined that facility leaders did not ensure institutional disclosures were performed on appropriate cases that had not met quality expectations as reported by the non-VA consultant or VA panel members.

VHA policy requires institutional disclosures to inform patients or, when appropriate, their personal representatives, that an adverse event occurred associated with VA medical care that resulted in, or is reasonably expected to result in, serious injury or death.⁵⁴ Although some of the 16 cases discussed in this report met criteria for institutional disclosure, the OIG did not find documented evidence that consideration was given to the need for institutional disclosures, or that institutional disclosures occurred. For example, patient 11, in their 50s with a history of pulmonary hypertension, COPD, obesity, diabetes, and cirrhosis of the liver, died postoperatively after planned pneumonectomy. The non-VA consultant and both VA panel members agreed that quality expectations were not met, and the non-VA consultant and panel member 1 both wrote that the patient was not a pneumonectomy candidate due to a history of pulmonary hypertension, lung disease, and multiple medical comorbidities.

The intent of institutional disclosure is to fully inform patients and their families about all clinically significant facts related to the harm caused by VA medical care and options to pursue potential compensation. When institutional disclosures are not completed as required, patients and their families may inadvertently be denied their rights.

Conclusion

The OIG substantiated that four patients died in the postoperative period and a fifth patient experienced a complication related to the thoracic surgical procedure. The OIG conferred with a non-VA thoracic consultant who identified quality of care concerns with the five cases. The OIG then expanded the scope of the non-VA consultant's review to include the 19 cases identified during a previous inspection on this matter. The non-VA consultant noted quality of care concerns regarding 16 of the 24 cases. The non-VA consultant's concerns focused on surgical

⁵⁴ VHA Handbook 1004.08. *Disclosure of Adverse Events to Patients*, October 2, 2012.

judgment and included errors in preoperative planning, technical errors, and poor management of technical errors, once incurred.

In November 2018, the OIG contacted VISN and facility leaders to discuss the findings of the non-VA consultant's review. In response, the facility referred 14 of the 24 non-VA consultant-reviewed cases for outside management review by a non-VA contracted agency. The contracted agency reviews, which were received by the VISN and facility in January 2019, indicated that quality expectations were not met in 5 of the 14 referred cases. The surgeon was removed from clinical duties on February 1, 2019. The VISN convened a panel of VA thoracic surgeons to review care provided by the surgeon, including the cases reviewed by the OIG's non-VA consultant.

When comparing the quality review findings, the OIG noted that the non-VA consultant and the VA panel members agreed that quality expectations were met in the care of eight patients and not met in the care of one patient. In the remaining cases, the OIG found wide variation of opinion among the non-VA consultant and the VA panel members as to whether quality expectations were met. Because quality reviewers evaluate quality of care through different prisms informed by their own professional approaches and experiences, differences of opinion are not uncommon.

The non-VA consultant had multiple concerns about the surgeon's ability to consistently provide safe quality care in this technically complex surgical specialty. However, the VA panel's final determination was that the surgeon delivered thoracic surgical care within quality expectations and recommended that the surgeon's privileges "remain in place without modification." The VA panel identified "programmatic issues" and recommended "an enhanced multidisciplinary approach to patient selection and preparation for surgical procedures." The surgeon resumed patient care on December 22, 2019.

The quality and management reviews performed by the external contractor, the non-VA consultant, and the VA panel, spanned more than one year. During this time, the surgeon was alternately permitted to perform surgeries or removed from clinical duties pending the outcome of certain reviews. To assure prompt action in this type of scenario, a VHA-centralized thoracic specialty leader to provide unbiased and authoritative guidance about the safety and advisability of a surgeon continuing clinical duties versus removing the surgeon from practice pending more in-depth reviews would be prudent.

The OIG substantiated that the surgeon omitted an error from an operative note, but the OIG was unable to determine whether surgical errors were made to look like normal or expected events. The OIG noted instances when reviewing operative reports that surgical events were unclearly or inaccurately characterized, as well as operative reports with descriptions of complications that were not designated appropriately. For example, intraoperative complications were identified in 10 patients' EHRs, but the immediate post-operative notes only listed complications for 5 of the 10 patients.

The OIG did not substantiate that the facility failed to report surgical errors and complications. The National Surgery Office did not require a mandatory assessment of all thoracic surgeries, and, therefore, the surgeon's actual morbidity and mortality data were not consistently captured through the VASQIP assessment process. As of August 2018, the facility elected to assess 100 percent of eligible thoracic surgery cases.

The OIG substantiated that some staff feared retaliation for discussing or reporting concerns about the surgeon's cases, which may have suppressed some reporting of adverse events or close calls. During interviews, several facility staff told the OIG about intimidating or otherwise unsatisfactory encounters with the surgeon and reported general concerns about retaliation. Email documentation appeared to support employees' perceptions of intimidation and improper use of power. Specifically, the surgeon requested reports showing the employees who accessed the EHRs for 21 of the 24 cases included in the OIG's reviews. The OIG noted that the scope of the information requested could have potentially provided the surgeon with the identity of the complainant(s). While the surgeon was no longer the Chief of Surgery after resuming clinical duties in 2019, the surgeon retained a position of power in the operating room during surgical cases and the surgeon's conduct still had the potential to negatively affect patient care and safety.

The OIG also found that two quality review and oversight processes did not sufficiently ensure that the surgeon's cases were consistently being evaluated according to VHA policy. The surgeon, who was also the Chief of Surgery during the time of the events discussed in the report, did not ensure the facility Surgical Work Group reviewed surgical deaths or critical surgical events and did not provide oversight of the Morbidity and Mortality Conference. Further, the peer review process did not ensure that the surgeon, who was a member of the Peer Review Committee and under review, did not have direct involvement with committee member decisions for the final peer review levels that involved the surgeon.

The OIG did not substantiate that the then COS did not take action related to concerns about the thoracic surgeon's practices and outcomes. Facility leaders, including the then COS, instituted a thoracic surgery "pause" in November 2017, secured both internal and external quality reviews on several occasions, reduced the complexity of thoracic surgeries that could be performed at the facility, and removed the surgeon from practice for more than 10 months at one point.

The OIG determined, however, that facility leaders failed to adjust the surgeon's clinical privileges to reflect the change to the lower complexity level for more than one year, and that leaders did not ensure institutional disclosures were performed on appropriate cases.

Recommendations 1–10⁵⁵

1. The Under Secretary for Health designates a thoracic specialty leader who has the authority to review all aspects of the personnel and management actions and can provide unbiased, authoritative, and timely guidance to facilities on the most clinically sound course of action when a thoracic surgeon's practice or outcomes are under review, in order to ensure that VA provides high quality care.
2. The Under Secretary for Health outlines general parameters and triggers for when facilities without local thoracic surgery expertise engage the thoracic specialty leader and how the thoracic specialty leader's decisions and guidance will be documented.
3. The Under Secretary for Health clarifies Veterans Health Administration policy regarding providers' responsibilities to document complications in operative reports.
4. The Under Secretary for Health reevaluates the eligible and mandatory assessment surgery cases reported to the National Surgery Office to determine if thoracic cases should be included in the list of mandatory assessment cases, and modifies the list as appropriate.
5. The Under Secretary for Health defines expectations for peer review committee members whose cases are being reviewed to leave the room during those deliberations, provides guidance on how that recusal is to be annotated in the Peer Review Committee minutes, and updates Veterans Health Administration policy, as needed.
6. The C.W. Bill Young VA Medical Center Director enhances processes to identify the existence of omissions or misrepresentations in operative note documentation and takes action based on identified deficiencies, if any.
7. The C.W. Bill Young VA Medical Center Director takes action to ensure that the surgeon is aware of, and complies with, expectations for professional communications and supporting staff to report adverse events and close calls.
8. The C.W. Bill Young VA Medical Center Director ensures the C.W. Bill Young VA Medical Center Surgical Work Group provides oversight as required by Veterans Health Administration policy and monitors for compliance.
9. The C.W. Bill Young VA Medical Center Director confirms processes are in place to ensure providers' clinical privileges are specific to the facility and service, and are based on each provider's clinical competence, and monitors for compliance.
10. The C.W. Bill Young VA Medical Center Director reviews whether the cases reflected in tables 1 and 2 in this report meet criteria for institutional disclosure and takes action as appropriate.

⁵⁵ Recommendations directed to the Under Secretary for Health were submitted to the Executive in Charge who has the authority to perform the functions and duties of the Under Secretary for Health.

Appendix A: Patient Case Summary Findings⁵⁶

Case Summaries	
Patient 1	
Outcome	Postoperative death⁵⁷
History	<p>The patient was in their 50s with a remote history of breast cancer confined to the breast and treated with chemotherapy and hormone therapy. The patient underwent computed tomography (CT) scan of the chest which demonstrated a new lesion in the right upper lobe of the lung. Biopsy of the lesion showed metastatic breast cancer. The patient was evaluated by the surgeon for consideration of resection of metastatic disease in the lung.</p> <p>The patient was taken to the operating room after the consultation for right upper lobe pulmonary wedge metastasectomy and possible lobectomy. The operative report notes that the right upper lobe metastasis was located “at the confluence of the middle and upper lobes,” that the tumor was “stuck” to the middle and lower lobes, and it was “unclear” whether this was due to tumor invasion or inflammatory adhesions. The surgeon decided to “resect the areas of potential crossover into the middle and lower lobes en bloc in order to ensure a negative margin.” The specimen was sent for frozen section and the “closest margin for this resection was positive for malignancy.” The surgeon opted to proceed with a “completion right upper lobectomy, likely with additional en bloc portion of the right lower lobe included.”</p> <p>The operative report next states that “some bleeding issued posterior to the superior pulmonary vein” after superior pulmonary vein dissection. The report also states that “during the course of VATS dissection, peritracheal lymph nodes were excised.” The procedure was converted to a posterolateral thoracotomy. Subsequently, “the pericardium was opened and the pulmonary artery between the superior vena cava and the ascending aorta in the transverse pericardial sinus was identified because of the bleeding posterior to the superior pulmonary vein and it was decided to obtain control of the right proximal pulmonary artery in the transverse pericardial sinus.⁵⁸ The inferior pulmonary vein was dissected. It was transected with a Covidien staple firing with the toe. The right mainstem bronchus was then freed from the main pulmonary artery proximally. The right mainstem bronchus was stapled with a TA stapler. The pulmonary artery was then dissected. It was transected with a white powered echelon staple firing. The right lower lobe was passed off as specimen. Portion of the middle lobe was transected after thoracotomy. It was transected with a green powered echelon staple firings and passed off table as specimen. At this point, it was found that the bleeding was coming from the posterior component of the very proximal right superior pulmonary vein. A green powered echelon staple firing was placed on the superior pulmonary vein at the level of the atrium in order to obtain control of the area. An additional white load was used to transect the</p>

⁵⁶ The OIG summarized the non-VA consultant opinions except in those instances where indicated with quotation marks. The non-VA consultant has reviewed and concurred with the OIG summarizations.

⁵⁷ A postoperative death is one that occurs within 30 days of surgery.

⁵⁸ A description of pneumonectomy begins here. The surgeon does not state what efforts were made to control bleeding or the rationale for proceeding to pneumonectomy in the operative report.

Case Summaries	
	<p>remainder of the superior pulmonary vein. The completion right upper lobe was then passed off as a specimen.”</p> <p>The note also states that “during the course of VATS dissection, peritracheal lymph nodes were excised.” Although the OIG could not confirm from the operative report or autopsy, the OIG was told by the surgeon that the right atrium was punctured during the procedure.⁵⁹</p> <p>After the procedure was completed, the patient was admitted to the surgical intensive care unit for respiratory and hemodynamic monitoring. The day following surgery, the patient experienced hypotension and worsening kidney function, though the patient was communicative and tolerated extubation. On postoperative day 2, the patient remained hypotensive and cardiac enzymes were elevated. The patient was seen by a cardiologist who noted “demand ischemia NSTEMI,” atrial fibrillation and “preserved” left and right ventricular function.⁶⁰ The patient developed respiratory failure and acidosis necessitating reintubation and initiation of chronic renal replacement therapy later on the second postoperative day. On postoperative day three, the patient experienced cardiac arrest and a family member requested that resuscitative efforts be discontinued and the patient died.</p> <p>An autopsy was performed. The autopsy report states that “the right atrium contains a well-defined ovoid thrombus, approximately the shape and size of a chicken egg, that fell out of the atrium during the removal of organs.” The report also noted evidence of acute right heart failure (without ventricular dilation), which was attributed to the right atrial thrombus. The cause of death was determined to be cardiac shock. Additionally, the surgical pathology report of tissue obtained from the operation was completed 10 days after the patient’s death and revealed cancer in two hilar lymph nodes.</p>
Non-VA Consultant Findings	<p>The operative report describes a wedge resection, not segmentectomy, and transitions directly from a performance of lobectomy to performance of pneumonectomy without explaining why or whether any attempt to control bleeding was made.</p> <p>Pneumonectomy during a planned wedge metastasectomy is a “never-event.”</p> <p>Positive lymph nodes were not identified before the surgeon decided to proceed with lobectomy. “Proceeding beyond wedge resection in the presence of metastatic lymph nodes, despite a positive [sic] margin, was not indicated.”</p> <p>“Performing pneumonectomy for injury to the superior pulmonary vein is not necessary.”</p>
VA Panel Findings	<p>Standard of care met: Inter-rater Disagreement</p> <p>Reviewer 1</p> <p>Standard of care met: No</p>

⁵⁹ The surgeon informed the OIG that a vascular surgeon who assisted with the procedure punctured the atrium. The vascular surgeon did not recall that the atrium was injured during surgery.

⁶⁰ The patient underwent echocardiograms on postoperative days two and three.

Case Summaries

	<p>Components of care findings:</p> <p>Was the indication for surgery appropriate and the planned procedure appropriate? No</p> <p>“Usually we do not recommend resection of breast cancer metastatic to the lungs because no definite survival benefit.”</p> <p>Was the extent of surgery appropriate: No</p> <p>“Pneumonectomy is too extensive of a procedure for metastasectomy.”</p> <p>Was the treatment technique performed correctly? No</p> <p>Operative technical complications -- see above</p> <p>Was the patient injured as a result of any of the above components of care? Yes</p> <p>“The patient did not tolerate the extensive surgery and died.”</p> <p>Was there complication(s) from this surgery and if so, was it within standard of care for this patient?</p> <p>“Death No I do not think the thoracic surgical care was within standard of care for this patient.”</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the extent of surgery appropriate? No</p> <p>Was the treatment technique performed correctly? No</p> <p>Was Postoperative Management appropriate? Surgical Team and ICU [intensive care unit]? No</p> <p>Was the patient injured as a result of any of the above components of care? Yes</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“Uncertain with venous injury, why pneumonectomy was ultimately needed FEV, 1.8 analong [sic] lead to pneumonectomy unknown differential perfusion.”</p> <p>“Surgical resection is not typically the chosen therapeutic option, especially in location that could require pneumonectomy.”</p> <p>“Survival data was not improved with resection in breast as opposed to other (colon/sarcoma) types of metastatic disease.”</p>
Peer Review	Yes
Institutional Disclosure	No
Patient 2	
Outcome	Postoperative death
History	The patient was in their 70s with non-small cell cancer of the left upper lobe of the lung. Preoperative positron emission tomography (PET) scan findings included a suspicious lymph node in the mediastinum (L5). The patient was

Case Summaries	
	<p>taken to the operating room for video assisted thoracic surgery (VATS) left upper lobe wedge resection. The surgery was converted to thoracotomy because of lung adhesions. The patient underwent mediastinal L5 lymph node excision, followed by wedge resection.⁶¹ The patient was admitted to the surgical intensive care unit following surgery for postoperative hypotension. The day following surgery, the patient experienced nausea, vomiting and chest pain with elevated cardiac enzymes and electrocardiogram (EKG) changes. The patient underwent cardiac catheterization. Immediately following the procedure, the patient suffered a cardiac arrest with pulseless electrical activity and died.⁶²</p>
Non-VA Consultant Findings	<p>"The preoperative PET scan indicated a suspicious AP [anterior posterior] window ("prevascular") lymph node." "This is an indication for pre-resection invasive mediastinal lymph node staging with EBUS or mediastinoscopy. If this staging demonstrated malignancy, the patient would not have undergone the procedure, which resulted in a postoperative death."</p>
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was Postoperative Management appropriate? Surgical Team & ICU [intensive care unit]? No</p> <p>"Somewhat slow to respond to symptoms of MI [myocardial infarction]."</p> <p>"Post-operatively [the patient] was noted to be persistently hypotensive requiring additional fluid boluses [and] had increased chest tube output. Hb [hemoglobin] stable. Had an episode of nausea/vomiting. Troponins and EKG [electrocardiogram] were completed showing elevation in troponins. A cardiology consult was placed. Patient was noted to be nauseous again in the AM on POD [postoperative day] #1 with associated chest pain. Another EKG was completed showing ST depression. Cardiology saw patient, placed [the patient] on nitro drip, and sent patient emergently to cath [cardiac catheterization] lab, at this point the next morning POD #1 ~ 9 am. While undergoing left heart catheterization, patient sustained a cardiac arrest. [The patient] was in PEA [pulseless electrical activity] throughout, required intubation along with multiple rounds of CPR [cardiopulmonary resuscitation]. Patient ultimately was pronounced deceased."</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>Death from acute postoperative MI. The patient was evaluated by cardiology preoperatively. Cardiovascular events cannot be completely prevented, and the stress test did not show perfusion defect. The patient's underlying disease was the cause of death. The thoracic surgical care delivered was within standards of care.</p>

⁶¹ The excised mediastinal L5 node was positive for cancer.

⁶² The patient had a negative stress test and cardiology evaluation prior to surgery.

Case Summaries

	<p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>“Patient had work up for pre op but despite that had MI, coded after catheterization.”</p> <p>Components of care findings: No comments included in review</p>
Peer Review	Yes
Institutional Disclosure	No

Patient 3

Outcome	<p>Postoperative death</p> <p>Innominate vein injury</p>
History	<p>The patient was in their 70s with a left lower lobe lung nodule (preoperative biopsy non-diagnostic) and a mass (sarcoma) located at the junction of the mediastinum and left lung, discovered during the evaluation of a compression fracture of the thoracic spine. A PET CT scan and bone scan showed uptake in the pulmonary lesions and thoracic spine. A biopsy of the spine at an outside facility was non-diagnostic.</p> <p>At the facility, the patient underwent bronchoscopy followed by left thoracoscopy and left lower wedge resection. Frozen section analysis demonstrated granuloma. The surgeon proceeded to anterior thoracotomy via the second interspace “to obtain better exposure for the dissection of the tumor.” The surgeon noted that the “anterior mediastinal tumor was found to be stuck to the sternum” and that there was an area of “indurated tissue with whitish looking tumor at the anterior aspect of the clavicular head, as well as a high and the sternum [<i>sic</i>].” These areas were biopsied and determined to be spindle cell tumor.</p> <p>The tumor was dissected off the sternum. The tumor was characterized as “completely affixed” and during dissection “bleeding ensued from the left innominate vein.” A vascular surgeon was called in to assist. An attempt to transect the innominate vein with a stapler was unsuccessful. Areas of the vein that were bleeding were clamped and a median sternotomy was performed. The patient underwent ligation of the innominate vein and resection of the anterior mediastinal mass. Following this, the “pedicle of tumor” adherent to the sternum and clavicular head was resected. The surgery lasted approximately eight hours and the patient experienced an estimated blood loss of two liters.</p> <p>Postoperatively, the patient developed pneumonia and a CT scan showed debris in the trachea and left mainstem bronchus, with collapse of a portion of the left lung. The patient also developed a deep venous thrombosis and was started on an anticoagulant. The patient subsequently experienced a gastrointestinal bleed, necessitating transfusion. The patient suffered a cardiac arrest and died on postoperative day 15.</p> <p>An autopsy determined the cause of death to be respiratory failure and noted gastrointestinal bleeding from metastatic sarcoma in the small bowel as a possible contributor to the patient’s demise. In addition, the autopsy found abnormal vertebral marrow, suggestive of necrotic metastatic tumor in the spine.</p>

Case Summaries	
Non-VA Consultant Findings	<p>“Numerous errors in staging and intraoperative conduct,” including chosen operative approach.</p> <p>The non-diagnostic spine biopsy should have been referenced in the operative report, as well as the rationale and decision to proceed with surgery.</p> <p>The approach to the anterior mediastinal mass through the left 2nd intercostal space was careless. The tumor may have involved this area and the innominate vein may have required resection, but it should have been done by an approach that allowed access to both the proximal and distal ends of the vessel.</p> <p>Postoperatively, bronchoscopy should have been performed after tracheal debris was noted in the CT scan.</p>
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the indication for surgery appropriate and the planned procedure appropriate? No</p> <p>“There was no pre-op note by the attending surgeon, and no documented discussion with the patient.”</p> <p>Was the decision for surgery appropriately discussed and in the correct order with other oncologic disciplines? No</p> <p>“There was no other oncology specialty involved in surgical planning.”</p> <p>Was the extent of surgery appropriate? No</p> <p>“Left VATS was converted to thoracotomy, for left lower lobe wedge resection, then median sternotomy, resection of anterior mediastinal mass, ligation of innominate vein</p> <p>I think better planning should have prevented both a thoracotomy and sternotomy.”</p> <p>Was the treatment technique performed correctly? No</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care?</p> <p>“Death after postoperative DVT [deep venous thrombosis], aspiration pneumonia, GI bleed.</p> <p>Yes, I believe the care delivered was within acceptable standards.</p> <p>There was a technical surgical issue with the bleeding from the innominate vein, but this can happen in any operation by any surgeon. This was an extensive surgery with two major incisions, which can be expected to be morbid. The ultimate postoperative outcome was complicated by medical issues.”</p> <p>Additional comments:</p> <p>“This was an extensive surgery with two major incisions, which can be expected to be morbid. The ultimate postoperative outcome was complicated by medical issues: DVT, aspiration pneumonia, GI bleed, death.”</p>

Case Summaries	
	<p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the indication for surgery appropriate and the planned procedure appropriate? Yes</p> <p>“not sure if best plan, but multidisciplinary decision.”</p> <p>Was the treatment technique performed correctly? No</p> <p>“except that got help and repositioned”</p> <p>Was the patient injured as a result of any of the above components of care? Yes</p>
Peer Review	Yes
Institutional Disclosure	No
Patient 4	
Outcome	Postoperative death
History	The patient was in their 70s and underwent open lung biopsy for diagnostic purposes and died from respiratory failure resulting from interstitial pulmonary fibrosis.
Non-VA Consultant Findings	No issues identified
VA Panel Findings	VA did not perform a review of this patient's care.
Peer Review	Yes
Institutional Disclosure	No
Patient 5	
Outcome	Bronchial Defect
History	<p>The patient was in their 70s and underwent CT scan of the chest that showed an opacity in the proximal airways of the posterior segment of the right upper lobe of the lung. A subsequent bronchoscopy revealed a polypoid appearing lesion with near complete obstruction, involving the posterior segment of the right upper lobe. Biopsy was positive for squamous cell carcinoma. A PET scan did not reveal other concerning lesions.⁶³ Preoperative PFTs were consistent with a known diagnosis of COPD.</p> <p>The patient was taken to the operating room and underwent a flexible bronchoscopy, right thoracotomy with right upper lobectomy, and thoracic lymphadenectomy. The bronchoscopy showed a “posterior right upper lobe tumor seen in the posterior segment of the right upper lobe” and the surgeon decided to proceed with thoracotomy rather than thoracoscopy. The operative note states that</p>

⁶³ The PET scan did describe lesions in the gastrointestinal tract, though these lesions had been previously evaluated with endoscopy.

Case Summaries	
	<p>the “tumor was found to be extremely proximal posteriorly to the origin of the right upper lobe.”</p> <p>After the lobectomy was completed, the surgeon noted that the “membranous portion of the bronchus intermedius that had been extremely adherent to the bronchial tissues had an approximately 4mm [millimeter] defect,” necessitating “bronchoplasty” with intercostal muscle flap. The patient’s postoperative course was complicated by aspiration pneumonia, respiratory failure requiring intubation, and atrial fibrillation. Approximately one month after surgery, the patient was discharged to the facility Community Living Center Rehabilitation unit.</p>
Non-VA Consultant Findings	<p>The tumor was located in the proximal airways (T2) and “the patient should have had pre-resection mediastinal lymph node staging with mediastinoscopy.”</p> <p>Technically, this was a repair of a bronchial injury. Bronchoplasty refers to the complex closure of a bronchus during resection.</p> <p>“The operative note is not clear enough to determine if the bronchial injury was preventable.” “The injury itself did not likely contribute to the long hospital course and discharge to a non-independent status.”</p>
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the decision for surgery appropriately discussed and in the correct order with other oncologic disciplines? No</p> <p>“...pre-op note indicates patient may require a sleeve resection or a pneumonectomy, but patient did not have complete pulmonary function tests to include DLCO, and... did not have split perfusion scan to ensure patient was an appropriate candidate for a pneumonectomy. [The patient] also did not have invasive mediastinal staging with either an EBUS or mediastinoscopy, which I believe should be performed prior to considering patient for a pneumonectomy or sleeve resection due to a central lung nodule.”</p> <p>Was the extent of surgery appropriate? Yes</p> <p>“Ultimately the patient had a lobectomy with bronchial margin negative on intra-operative frozen section, so more extensive resection was not needed.”</p> <p>Was the treatment technique performed correctly? Yes</p> <p>Technical error of intraoperative injury to bronchus intermedius was recognized and repaired. Postoperative course with prolonged air leak.</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes.</p> <p>“Acute respiratory failure requiring bronchoscopy and re-intubation on POD#1. Remained intubated until POD#8. Developed Serratia odorifera and Klebsiella pneumonia, presumed aspiration pneumonia. Prolonged air leak with SQ [subcutaneous] emphysema; chest tubes removed POD#30. Despite postoperative complications, my judgment is that the overall care met basic standards for thoracic surgery. The complications that occurred can happen with any lung</p>

Case Summaries	
	<p>surgery. Although I would have done more preop testing and invasive staging, those factors did not directly affect the outcomes of this case.”</p> <p>Additional comments:</p> <p>“The correct surgery was performed, but with significant postoperative morbidity, with prolonged intubation, aspiration pneumonia, and prolonged air leak. [The patient] was incompletely staged pre-operatively for the stage and location of the tumor. Ultimately patient did get discharged and tumor was completely resected, so no long term harm came to the patient. Aspiration pneumonia and prolonged air leaks are known complications of lung surgery.”</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“But within standard of care. Atrial fibrillation is common. Vocal cord dysfunction typically not from node dissection [<i>sic</i>] in right side cancer.”</p>
Peer Review	Yes
Institutional Disclosure	No
Patient 6	
Outcome	<p>Postoperative death</p> <p>CVA</p> <p>Bronchopleural fistula</p>
History	<p>The patient was in their 60s with stage IIIA lung cancer and completed radiation therapy but was unable to complete chemotherapy due to weakness and frailty. The patient was seen by the surgeon for consideration of surgical management of lung cancer.</p> <p>At the preoperative visit, approximately two and a half weeks prior to surgery, the patient resided in a nursing home, could walk “a couple of yards/feet” with a walker, had difficulty completing activities due to weakness. The patient was also underweight (Body Mass Index 18) and using supplemental tube feeds.</p> <p>The patient underwent flexible bronchoscopy, cervical mediastinoscopy, right thoracoscopy converted to right thoracotomy with right pneumonectomy, thoracic lymphadenectomy, dissection, and intercostal muscle flap buttressing of the bronchial stump. The surgery lasted 4 hours and 11 minutes and resulted in an estimated blood loss of 500 cc. The patient developed a bronchopleural fistula. On postoperative day 4, in the setting of atrial fibrillation, the patient suffered a large stroke. The patient died under hospice care on postoperative day 27.</p>
Non-VA Consultant Findings	<p>“Rationale for surgery- that patient would not tolerate more chemotherapy is not supportable.”</p> <p>“Right pneumonectomy after preoperative therapy is certainly more dangerous than more chemotherapy.”</p>

Case Summaries	
	<p>Blood loss (500 cc), duration of surgery (>4 hours), and bronchopleural fistula suggest that patient selection and technique were possibly issues.</p> <p>Bronchopleural fistulas are more common in this scenario - patients undergoing pneumonectomy after preoperative chemoradiotherapy.</p>
VA Panel Findings	<p>Standard of care met: Inter-Reviewer Disagreement</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“Death due to post-op [postoperative] stroke and bronchopleural fistula. The question on this case was whether this patient should have had surgery at all. [The patient] was at very high risk, and definitive chemo-radiation is a reasonable treatment choice for stage IIIA NSCLC [non-small cell lung cancer]. Pneumonectomy is known to be very risky, with high morbidity and mortality, and of uncertain benefit for stage IIA N2 disease. There was no immediate preop PET/ CT to confirm no spread of disease preop. The carotid stenosis was not mentioned as a risk factor for stroke in the preop notes. However, multidisciplinary consultants were involved in the decision-making, so all of the judgment does not fall only on the surgeon. So therefore, I think the care delivered by the surgeon is within standards of care.”</p> <p>Additional comments:</p> <p>“The question on this case was whether this patient should have had surgery at all. [The patient] was at very high risk, and definitive chemo-radiation is a reasonable treatment choice for stage IIIA NSCLC.”</p> <p>Reviewer 2</p> <p>Standard of care met: No</p> <p>Components of care findings:</p> <p>Was the indication for surgery appropriate and the planned procedure appropriate? No</p> <p>Was the patient injured as a result of any of the above components of care? Yes</p> <p>Were there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“Mortality for pneumonectomy after chemoradiation for lung cancer as high as 25% (especially on right side.)”</p>
Peer Review	Yes
Institutional Disclosure	No
Patient 7	
Outcome	Intraoperative death

Case Summaries

History

The patient was in their 80s with history of remote Whipple procedure, pulmonary embolism, inferior vena cava filter placement, diabetes, and chronic obstructive pulmonary disease (COPD).⁶⁴ The patient was found to have a 1.5 centimeter (cm) squamous cell cancer in the lingular portion of the left upper lobe of the lung and was taken to the operating room for VATS wedge resection and possible left upper lobectomy.

The operative report states that "There were multiple posterior recurrent branches in a common trunk with the anterior trunk. These were encircled and an attempt to get around them with a 35 powered echelon vascular stapler was made; however, bleeding ensued from behind the anterior trunk." The procedure was converted to thoracotomy. Subsequently, "the 35 vascular powered echelon was then used to transect the anterior trunk along with a posterior recurrent arterial branch which had the common trunk with the anterior trunk. After firing this stapler, bleeding issued from a defect in the proximal left main pulmonary artery."

A vascular surgeon was called in to assist and the pericardium was opened to gain intrapericardial access to the left main pulmonary artery. The operative report next states that "The left main pulmonary artery was encircled. However, despite sponge stick pressure on the injury on the proximal pulmonary artery at the area where the anterior trunk branches had been transected, this area continued to bleed. Further attempts to encircle the left main pulmonary artery were made and the pulmonary artery was clamped; however, bleeding from the distal pulmonary artery continued despite direct sponge stick pressure in this area." The operative report states that at this point in the procedure, the patient became hypotensive and received blood products, and treatment with vasopressors and calcium.⁶⁵ The patient subsequently suffered a cardiac arrest with pulseless electrical activity.⁶⁶ Cardiac massage was performed during resuscitation.

After describing the cardiac arrest, the operative note reports that "the proximal pulmonary artery was stapled with a thick tissue TA 60 staple firing. However, at this point, additional areas of bleeding followed." The patient was subsequently also noted to be "bleeding from multiple areas of the left atrium." Efforts at atrial repair ensued as "the left atrial appendage was partially stapled for hemostasis with a white powered echelon staple firing" and "another area of the left atrium was staple [sic] with a green powered echelon staple firing." "However, there were continued large areas of bleeding."⁶⁷ The patient received additional blood products and vasopressor agents though [the patient] became "asystolic."⁶⁸ The left upper and lower lobes were then "retracted and transected" for "further

⁶⁴ The surgeon noted that the Whipple procedure was performed for presumed lymphoma, though the pathology was benign.

⁶⁵ The patient received a total of 14 units of blood in addition to other blood products and intravenous fluids.

⁶⁶ Pulseless electrical activity is a type of cardiac arrest in which there is electrical activity but no pulse. This may be caused by significant blood loss.

⁶⁷ The operative report notes that "the patient did have a history of severe left atrial dilation, and the left [atrium](#) was extremely friable."

⁶⁸ Asystole is cardiac arrest with cessation of electrical activity of the heart.

Case Summaries	
	<p>exposure.” Despite attempts to “obtain hemostasis,” the patient lost an estimated 11,500 milliliters of blood and died on the operating table.⁶⁹</p>
Non-VA Consultant Findings	<p>“Multiple sequential technical errors with the procedure led to an unrecoverable situation. After the first injury, consideration should have been given to gaining proximal control of the left pulmonary artery (prior to further progress of the procedure, which led to further injury).”</p> <p>“Attempts to control the pulmonary artery subsequently failed to control bleeding, which can only be explained by technical error, either incomplete control of the pulmonary artery, or not remembering to clamp the pulmonary veins, or both.”</p> <p>“The fact that the tumor was a 1.5 cm nodule in the lingular segment of the left upper lobe further supports that the procedure should not have resulted in pneumonectomy.”</p> <p>Questionable decision to proceed with surgery given age, comorbidities, and patient preference for radiation therapy.</p>
VA Panel Findings⁷⁰	<p>Standard of care met: Inter-Reviewer Disagreement</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>“Although there was a severe technical complication, events such as this could happen to any surgeon, and therefore I deem it within standards of care. Conversion to thoracotomy was performed, control of the main PA [pulmonary artery] was attempted, and another surgeon was called in to assist. So it appears that all efforts were made to try to help the patient.”</p> <p>Components of care findings:</p> <p>Was the treatment technique performed correctly? No</p> <p>“Left main pulmonary artery was damaged, and despite best efforts, control of the bleeding was not obtained, and the patient died. 14 units of blood and 4 FFP [fresh frozen plasma] transfused. Operative notes indicate friable tissues and enlarged left atrium.”</p> <p>Was the patient injured as a result of any of the above components of care? Yes</p> <p>“Death in the OR”</p> <p>Was there a complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“Death in the OR caused by technical surgical complication. Although there was a severe technical complication, events such as this could happen to any surgeon, and therefore I deem it within standards of care.”</p> <p>Additional Comments:</p>

⁶⁹ The average adult has a blood volume of approximately five liters.

⁷⁰ Reviewer 2 initially submitted handwritten copies of the reviews. Upon request from the OIG, Reviewer 2 resubmitted the reviews in typed format. Responses included in this report are taken from the typed reviews.

Case Summaries	
	<p>“Patient with adequate pulmonary function and performance status seems to have been a candidate for lobectomy or at least segmentectomy. Pre-op note indicates his plan was wedge resection possible lobectomy.”</p> <p>“Damage to the left main pulmonary artery led to the intraoperative death of the patient.”</p> <p>Reviewer 2</p> <p>Standard of care met: No</p> <p>Components of care findings:</p> <p>Was the treatment technique performed correctly? No</p> <p>Was the patient injured as a result of any of the above components of care? Yes</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“Vascular injury can occur however it is rare that injury cannot be centrally [managed].”</p>
Peer Review	Yes
Institutional Disclosure	No (A clinical disclosure was performed. ⁷¹)

Patient 8	
Outcome	Unplanned pneumonectomy due to pulmonary artery injury
History	<p>The patient was in their 60s and underwent bronchoscopy followed by VATS resection of a left upper lobe pulmonary nodule, suspicious for malignancy. The left upper lobe nodule was sent for frozen section analysis. The operative report noted that “the specimen was reviewed by four pathologists whose consensus was that this was a non-small cell carcinoma most likely of pulmonary origin.” The surgeon noted that there would still be “further testing to follow.”</p> <p>The surgeon decided to proceed with lobectomy. “The superior pulmonary vein was dissected.” The surgeon noted that “in passing the stapler behind the vein bleeding ensued which was controlled with pressure.” Shortly after, the surgeon reported that attempts to delineate the plane behind the superior pulmonary vein “were met with, again, bleeding that could not easily be controlled.” The procedure was converted to thoracotomy. The superior pulmonary vein was transected, and bleeding was “found to be at the very base medially of the anterior trunk” [of the pulmonary artery]. An artery stapler was used to treat the area of bleeding. However, the surgeon noted that “a new area of bleeding distal to distal lateral, and posterior, to the anterior trunk stump was created during this process.” This injury was described as “two approximately 1 to 2-millimeter holes approximately 5-millimeter apart.” Additional surgeons were called in to assist.</p> <p>The pericardium was opened, and tourniquets were placed on the proximal and distal aspects of the pulmonary artery. The left upper lobectomy was completed.</p>

⁷¹ VHA Directive 1004.08. Clinical disclosure is a process by which the patient’s clinician informs the patient or the patient’s personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the course of care.

Case Summaries	
	<p>The patient was transfused and “pressure was taken off the area of bleeding.” The operative report notes that “perfuse [sic] bleeding was seen from this area despite the Rommel tourniquet being completely tightened.” Further attempts at exposure and hemostasis were made, though “the two small holes with the 5mm [millimeter] bridge of artery between them became one contiguous hole as the bridge opened.” The surgeon could not achieve adequate exposure of the “approximately 8 mm [millimeter] hole.” The proximal pulmonary artery was stapled, and this was followed by left pneumonectomy, “given the magnitude of the arterial injury, and the fragility of the tissues in this area with surrounding hematoma and adventitial friability.”</p> <p>The patient experienced a 2000 cc blood loss.</p> <p>Pathology revealed metastatic malignant melanoma.</p>
Non-VA Consultant Findings	<p>“Multiple, sequential technical errors leading to bleeding, with associated errors in judgment.”</p> <p>“A 1.2 cm nodule is not associated with a difficult lobectomy and should never lead to pneumonectomy.”</p> <p>“Result is even more unfortunate in learning the final pathology was melanoma, not lung cancer.”</p>
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Component of care findings:</p> <p>Was the decision for surgery appropriately discussed and in the correct order with other oncologic disciplines? Yes</p> <p>“I did not find a tumor board discussion. No prior biopsy. But this decision-making for a nodule concerning for malignancy in a patient who can likely tolerate surgical biopsy (by PFTs and functional status) is reasonable and appropriate.”</p> <p>Was the extent of surgery appropriate? No</p> <p>“LUL [left upper lobe] lung nodule, +FDG avidity on PET, suspicious for malignancy. L VATS with planned wedge and possible lobectomy, was converted to thoracotomy and pneumonectomy, with lymphadenectomy. Initial wedge resection for diagnosis was interpreted by the pathologists as NSCLC, likely pulmonary origin. The decision was then made to proceed with lobectomy. The left PA was injured during surgery, necessitating the more extensive procedure. 5 units prbcs [packed red blood cells] and 1 unit platelets transfused. Final pathology malignant melanoma. (Intraoperative diagnosis by pathology was incorrect). Wedge resection would have been the appropriate treatment for metastatic melanoma. However, severe bleeding can occur in any thoracic procedure, and the bleeding was the reason the surgical resection became more extensive.”</p> <p>Was the treatment performed correctly? No</p> <p>“See above”</p> <p>Was the patient injured as a result of any of the above components of care? Yes</p> <p>“See above”</p>

Case Summaries	
	<p>Were there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“Yes, my opinion is that the thoracic surgical care the patient received is within the standards of care.”</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Component of care findings:</p> <p>Was the extent of surgery appropriate? No</p> <p>Was the treatment technique performed correctly? No</p>
Peer Review	No
Institutional Disclosure	No
Patient 9	
Outcome	Esophageal leak, respiratory failure requiring tracheostomy, abdominal wound infection
History	<p>The patient was in their 60s with adenocarcinoma of the esophagus. The patient was seen by a surgical oncologist at a local cancer center who opined that the patient was not a candidate for surgery because of underlying medical conditions of obesity and COPD, as well as treatment with high-dose steroids. An endoscopic ultrasound performed at the cancer center characterized the lesion as being a 2 cm polypoid lesion (T1bN0MX) and identified a smaller lesion on the contralateral esophageal wall that was not biopsied.</p> <p>The surgeon noted speaking with the gastroenterologist who performed the EUS [endoscopic ultrasound]. The gastroenterologist opined that the tumor “looks to have deep sm [submucosal] invasion and that given [the] size of 2 cm and a second lesion make [the patient] not a great candidate for curative endoscopic therapy.” The surgeon opted to proceed with an esophagectomy in consideration of potential curative outcome.</p> <p>The patient subsequently underwent an eight-hour Ivor Lewis esophagogastrectomy. Subsequent to the procedure, the patient developed respiratory failure requiring tracheostomy, a leak resulting from perforation of the gastric remnant, and an abdominal wound infection. The patient was hospitalized for approximately three months. The final pathology report revealed one area of adenocarcinoma focally involving the submucosa (T1b). Lymph nodes were negative for malignancy.</p>
Non-VA Consultant Findings	<p>There is no evidence to support the claim that the patient was not a candidate for endoscopic mucosal resection (EMR) (local resection). “The standard of care would be to attempt EMR and if margins are positive, esophagogastrectomy is indicated.”</p> <p>Early-stage esophageal cancer surgery should not take eight hours to complete; “this suggests significant lack of expertise. This is supported by a 3-month</p>

Case Summaries	
	length-of-stay. The minimum number of cases should be 15-20" per year to perform this operation. ⁷²
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: yes</p> <p>Components of care findings:</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>"Postoperative course was complicated by anastomotic leak and respiratory failure, likely aspiration pneumonia per notes. Transferred to ICU [intensive care unit] and reintubated. EGD [esophagogastroduodenoscopy] showed ~1cm dehiscence of staple line. Tracheostomy was performed to help with weaning from ventilator. [The patient's] abdominal wound became infected, and washout of an abdominal abscess adjacent to the j tube was performed. Prolonged hospital stay. My opinion is that the thoracic surgical care the patient received was within standards of care."</p> <p>Additional comments:</p> <p>"All of the above appears appropriate and within standards of care. Not all complications can be prevented, especially in high-risk operations in patients with significant comorbidity."</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the indication for surgery appropriate and the planned procedure appropriate? Yes, "for the stage of the disease."</p> <p>Additional comments:</p> <p>"Known comorbid condition increasing risk conditions. Temporary tracheostomy suspicious minimally invasive that options were discussed, such as EMR."</p>
Peer Review	No
Institutional Disclosure	No
Patient 10	
Outcome	Innominate vein injury
History	The patient was in their 70s with planned wedge resection versus VATS lobectomy for right lower lobe squamous cell carcinoma. In addition to the right lower lobe

⁷² Metzger R, et al. High volume centers for esophagectomy: what is the number needed to achieve low postoperative mortality? Dis Esophagus 2004; 17:310-314. (Aims to establish number of esophagectomies needed to attain an acceptable mortality rate: Established benchmark of 20 esophagectomies per year). Including this patient, the facility performed six esophagectomies in fiscal year 2015, nine esophagectomies in fiscal year 2016 and fiscal year 2017, and four in fiscal year 2018. The surgeon participated in all but two of these procedures.

Case Summaries	
	<p>lesion, a preoperative PET scan also showed a suspicious anterior mediastinal (prevascular) lymph node.</p> <p>The patient was taken to the operating room and underwent bronchoscopy and thoracoscopy. The lymph node of concern was identified. The operative report states "[t]his [lymph node] was grasped, and it was dissected off the innominate vein to which it was attached. Taking down these attachments, what appeared to be fibrous attachments of the node to the innominate vein, were transected using the harmonic scalpel with a resultant rapid rate bleeding." The procedure was converted to thoracotomy and a second surgeon was called in to assist.</p> <p>The source of bleeding was determined to be a 1 cm injury to the innominate vein, "extending near the junction of the superior vena cava and innominate vein." Hemostasis was achieved, and the patient received 6 units of blood. The lymph node was excised, and frozen section determined that it was benign. A right lower lobectomy was then completed.</p> <p>The patient experienced an 1800 cc blood loss.</p>
Non-VA Consultant Findings	Lobectomy was complicated by bleeding, resulting from a careless error. Bleeding and conversion were totally unjustified.
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the treatment technique performed correctly? No</p> <p>"The procedure was initially attempted VATS, but the patient had an anterior mediastinal node which was biopsied at surgery, and found to be a benign calcified node. The node was in the region of the thymus and the dissection of the node resulted in injury to the innominate vein, necessitating the thoracotomy for control of bleeding. EBL [estimated blood loss] was 1800 ml, and 6 units of prbcs [packed red blood cells] were transfused. In my opinion, the anatomy and location of the innominate vein should have been definitively identified before attempting to resect the node. (And if not feasible to do so, then the node will not be able to be safely resected.) However, this type of event can happen to any thoracic surgeon, and the important fact is that the bleeding was controlled and the patient was able to have definitive lung resection and survived."</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>"See above."</p> <p>"I believe the thoracic surgical care delivered to this veteran was within standards of care."</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p>

Case Summaries	
Peer Review	No
Institutional Disclosure	No
Patient 11	
Outcome	Postoperative death
History	<p>The patient was in their 60s with a history of pulmonary hypertension, COPD, obesity, diabetes, and cirrhosis of the liver.⁷³ CT angiography of the chest was ordered because the patient was coughing up blood. The CT showed a left hilar soft tissue density, three cm in its largest dimension. The radiologist noted that the lesion caused “mass effect on the left main pulmonary artery, segmental branches of the left upper lobe pulmonary arteries and causes suspected occlusion of a segmental bronchus left upper lobe supplying the lingula.” The patient subsequently underwent bronchoscopy with biopsy which was positive for squamous cell carcinoma.</p> <p>The patient was evaluated by the surgeon who opined that based on CT angiography results, resection of the tumor would require left pneumonectomy because a sleeve procedure would not provide a cancer-free margin. Other preoperative testing included an echocardiogram performed two days prior to surgery which showed moderate pulmonary hypertension and pulmonary function testing performed the day prior to surgery which revealed diminished diffusing capacity (64 percent of predicted). No documentation was found in the EHR showing that the results were reviewed by the surgeon.⁷⁴</p> <p>The patient underwent left thoracotomy with left pneumonectomy and thoracic lymphadenectomy. The Anesthesia note states that a left sided double lumen endotracheal tube was used during surgery. Postoperatively, the patient was hypoxic and was transferred to the SICU [surgical intensive care unit] for close monitoring. The patient experienced continued hypoxia and developed acute kidney injury. On postoperative day 2, the patient was noted to be somnolent and required intubation. An echocardiogram showed findings consistent with right heart failure. Later on postoperative day 2, the patient experienced cardiac arrest with pulseless electrical activity and died.</p>
Non-VA Consultant Findings	<p>The patient was inoperable for pneumonectomy due to history of pulmonary hypertension, lung disease and multiple medical comorbidities.</p> <p>It is not clear why an attempt was not made to perform a sleeve resection.</p> <p>“A right sided dual lumen ETT [endotracheal tube] should have been used.”</p>
VA Panel Findings	<p>Standard of care met: No</p> <p>Reviewer 1</p> <p>Standard of care met: No</p>

⁷³ Three years prior to surgery, the patient underwent right heart catheterization, which demonstrated an elevated pulmonary artery pressure of 62/29 mm Hg and pulmonary vascular resistance 3.6 (no units given).

⁷⁴ Preoperative [pulmonary function testing](#) results revealed the potential for increased surgical risk. A [quantitative radionuclide perfusion scan](#) should have been obtained to calculate predicted postoperative lung function, and optimally assess the patient’s candidacy for pneumonectomy.

Case Summaries

	<p>Components of care findings:</p> <p>Was the indication for surgery appropriate and the planned procedure appropriate? No</p> <p>“Patient had moderate pulmonary hypertension diagnosed preoperatively and was high risk for pneumonectomy. Patient did not have adequate staging or pre-op work up.”</p> <p>Was the decision for surgery appropriately discussed and in the correct order with other oncologic disciplines? No</p> <p>“See above”</p> <p>Was the extent of surgery appropriate? No</p> <p>“Surgery was too extensive for what [the patient] could tolerate considering patient underlying risk factors.”</p> <p>Was the treatment technique performed correctly? No</p> <p>“No trial of PA clamping was documented. The hemodynamics showed that the patient's heart clearly did not tolerate PA clamping yet the surgeon proceeded with pneumonectomy.”</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“Yes surgery was complicated with death from right heart failure, and the standard of care was not met.”</p> <p>Reviewer 2</p> <p>Standard of care met: No</p> <p>Components of care findings:</p> <p>Was the indication for surgery appropriate and the planned procedure appropriate? No</p> <p>Was the extent of surgery appropriate? No</p> <p>Was the treatment technique performed correctly? No</p> <p>Was the patient injured as a result of the above components of care? Yes</p>
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Peer Review	Yes
Institutional Disclosure	No

Patient 12

Outcome	Unplanned pneumonectomy
History	The patient was in their 60s with an incidentally found left upper lobe mass taken to the operating room for lobectomy. The operative report notes that the “anterior trunk” [of the pulmonary artery] was “transected with a Covidien gold load ” and subsequently states that “what had appeared to be the anterior trunk was actually a small left main pulmonary artery.” The lobectomy was converted to pneumonectomy due to the transection of the left main pulmonary artery.

Case Summaries	
Non-VA Consultant Findings	<p>"Never-event" caused by "indefensible" technical error.</p>
VA Panel Findings	<p>Standard of care met: Inter-Reviewer Disagreement</p> <p>Reviewer 1</p> <p>Standard of Care Met: No</p> <p>Components of care findings:</p> <p>Was the extent of surgery appropriate? No</p> <p>"VATS LUL [left upper lobe] lobectomy was planned. During the operation, a technical error was recognized after division of the vessels. "At this point, it was noted that what had appeared to be the anterior trunk was actually a small left main pulmonary artery. Hence, a posterolateral thoracotomy was performed...." Attempt to re-anastomose the PA was unsuccessful due to short cuff of proximal PA, and the procedure was converted to pneumonectomy. Pathology T2bN0, stage IIA. RA ABG [room air arterial blood gas] showed PO2 47mmHg. Thus, the patient did not tolerate the pneumonectomy well, and would have been better served with lobectomy. Discharged, on home oxygen."</p> <p>Was the treatment technique performed correctly: No</p> <p>"During the operation, a technical error was found after division of the vessels. "At this point, it was noted that what had appeared to be the anterior trunk was actually a small left main pulmonary artery. Hence, a posterolateral thoracotomy was performed...." Attempt to re-anastomose the PA was unsuccessful due to short cuff of proximal PA, and the procedure was converted to pneumonectomy.</p> <p>My opinion is that no vessel should be divided for a lobectomy without confirming that the main PA is intact. At least the error was recognized, and an attempt was made to re-anastomose, but this was not successful in salvaging the technical error."</p> <p>Was the patient injured as a result of any of the above components of care: Yes</p> <p>Was there complication(s) from this surgery and if so, was it within the standards of care? Yes.</p> <p>"I do not believe the thoracic surgical care administered to this patient is within standards of care."</p> <p>Additional comments:</p> <p>"technical surgical error led to more extensive surgery"</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>"Surgery can have complications and decisions how to handle those complications. Optimally reconstruction would be better however the patient refused."</p> <p>Components of care findings:</p> <p>Was the extent of surgery appropriate: No</p>

Case Summaries

	Was the treatment technique performed correctly? No Was the patient injured as a result of any of the above components of care? Yes "decreased lung capacity"
Peer Review	No
Institutional Disclosure	No

Patient 13

Outcome	Unplanned pneumonectomy Bronchopleural fistula 2.6 liter blood loss
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History	<p>The patient was in their 60s and presented for VATS right upper lobectomy for a suspicious 1.5 cm central, spiculated nodule identified on a CT scan.</p> <p>The patient was taken to the operating room. The operative report notes that the "The pulmonary hilum was densely adhered with a thick layer of inflammatory fibrous tissue. The mediastinal pleura lateral to the phrenic nerve was opened, and the superior pulmonary vein was dissected. The anterior trunk was also dissected. The superior pulmonary vein and the plane between the pulmonary artery and the anterior trunk was defined and dissected; however, in attempting to dissect this plane, bleeding from the anterior trunk of the pulmonary artery ensued. Sponge stick pressure was applied to this area. An attempt was then made to dissect the superior pulmonary vein again from the pulmonary artery. However, this could not be done safely." The procedure was converted to lateral thoracotomy. Additional attempts were made to dissect the superior pulmonary vein and "in attempting to bluntly dissect around the superior pulmonary vein with finger dissection, the injury to the anterior trunk appeared to be worsened."</p> <p>Subsequent to this, the operative note states that "the pericardium medial to the phrenic nerve was then opened and attempts were made to reflect the atrium and dissect out the superior pulmonary vein, as well as the pulmonary artery. The superior pulmonary vein was dissected and was transected with a white powered echelon staple firing. The right main pulmonary artery was attempted to be dissected; however, dense adhesions in this area made it impossible to safely dissect the pulmonary artery. The superior vena cava and the ascending aorta were then retracted away from each other, and the right main pulmonary artery traveling posteriorly and perpendicularly was attempted to be dissected. It could not be safely dissected despite multiple attempts due to extremely dense adhesions posteriorly and to the apex. Concern for major vascular injury here prompted us to desist our efforts in dissecting the pulmonary artery here. The superior pulmonary vein was again attempted to be defined. A portion of the vein was transected apically using a gold Covidien staple firing. The inferior pulmonary vein was attempted to be defined and dissected; however, this also was densely fused to the pulmonary hilum."</p> <p>The surgeon determined that a pneumonectomy would be required, because the "dense fusion of the entire pulmonary hilum the worsening vascular injury as planes that did not exist due to these dense adhesions were attempted to be dissected." The operative report describes the pneumonectomy as follows: "The pulmonary hilum was then dissected and a TA 60 stapler was placed around the left pulmonary hilum. This was fired and the pulmonary artery right mainstem bronchus, superior</p>
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Case Summaries	
	<p>and inferior pulmonary veins were transected en block. The specimen was then cut and passed off the table.”</p> <p>The patient lost 2.6 liters of blood during the operation.</p> <p>Postoperative pathology revealed invasive adenocarcinoma associated with sillicotic nodules (insufficient material to evaluate for pneumoconiosis, fibrosis) with final staging T1b, pN0.</p> <p>The patient’s initial postoperative course was complicated by dysphagia and aspiration pneumonia, resulting in PEG [percutaneous endoscopic gastrostomy] tube placement. The patient was discharged to a rehabilitation center on postoperative day 18 and subsequently underwent multiple hospital admissions for treatment of pleural effusions and was eventually diagnosed with a bronchopleural fistula. The patient was transferred to a different VA and underwent closure attempts of the fistula with glue products on three occasions.⁷⁵The patient was transferred back to the facility and later diagnosed with pulmonary tuberculosis. While at the facility, the patient received one additional glue treatment of the fistula. The patient died four months after surgery.</p>
Non-VA Consultant Findings	<p>“The lesion is characterized as ‘central’ which indicates mediastinal staging” which was not performed.</p> <p>“Pneumonectomy is performed without individual hilar dissection, without diagnosis, and resulted to be a T1 tumor.”</p> <p>“Postoperative bronchopleural fistula [is] predictable due to conduct of the operation” (stapling across the hilum).</p> <p>“Errors that led to pneumonectomy, [that] would have been avoidable by most surgeons.”</p> <p>Once difficulties were encountered and it was determined that a standard technique was not likely to be successful, a prudent strategy would have been to open the pericardium to obtain proximal encirclement of the pulmonary artery. If bleeding occurred, the pulmonary artery could be clamped, potentially avoiding the need for pneumonectomy.</p>
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes.</p> <p>“Bronchopleural fistula and death. This is a known complication from pneumonectomy. I believe the thoracic surgical care was within standards of care.”</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p>

⁷⁵ The glue treatment was not available at the facility during this time period.

Case Summaries	
	<p>Was the extent of surgery appropriate? No</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p>
Peer Review	Yes
Institutional Disclosure	No
Patient 14	
Outcome	Postoperative death
History	<p>The patient was in their 60s with non-small cell cancer in the right upper lobe of the lung, with possible involvement of the right middle and lower lobes. The patient was evaluated by a pulmonologist who noted that the patient had “severe copd/emphysema on optimum inhaler therapy” and referred the patient to the surgeon for consideration of surgical treatment of lung cancer.</p> <p>The patient was seen in consultation by the surgeon and a physician assistant approximately two weeks later. The thoracic surgery consultation note contains the results of pulmonary function tests obtained approximately one month prior to the surgery appointment, though the note does not discuss whether the results impacted the patient’s risk or the decision to proceed with surgery. No additional pulmonary testing is recommended.⁷⁶ The surgeon noted agreeing to operate “given that patient’s TTE is normal aand [sic] cardiology found no high-risk clinical features, and patient’s inability to walk is due to [ambulatory capability] more than [the] breathing, as well as the fact that the tumor has defunctionalized a large portion of [the patient’s] R (right) lung.” The surgeon planned to do an initial mediastinoscopy, and if negative, proceed to “R VATS, likely thoracotomy with R upper lobectomy, possible bilobectomy, possible R pneumonectomy with possible chest wall resection.”</p> <p>The patient was taken to the operating room. Lymph nodes obtained during mediastinoscopy were negative for cancer. Bronchoscopy revealed “abnormal tumor within the anterior segment of the right upper lobe, and abnormal mucosa of the right upper lobe extending into the right mainstem bronchus.” No pleural studding or chest wall invasion were noted during thoracoscopy. A thoracotomy was performed. The operative note states that the tumor was found to be “on the right main pulmonary artery and adherent to the right mainstem bronchus inferiorly” and “it was determined that a right pneumonectomy would need to be done in order to clear all tumor.” The morning following surgery, the patient experienced low blood pressure and anuria. An echocardiogram showed findings consistent with right heart failure and the patient died later the same day. The physician death certificate note lists the cause of death as heart failure.</p>
Non-VA Consultant Findings	<p>“It is not clear that pneumonectomy was required.”</p> <p>“Numerous judgment errors regarding eligibility for pneumonectomy.” Preoperative pulmonary function testing revealed a moderately reduced FEV₁ (55% predicted) and DLCO (43% predicted). These pulmonary function results “are not compatible with postoperative lung function.” Predicted postoperative lung function was not</p>

⁷⁶ The patient’s forced expiratory volume in 1 second (FEV₁) was 59 percent of predicted and DLCO was 43 percent of predicted.

Case Summaries

determined as the patient did not undergo a quantitative radionuclide perfusion scan. The rationale for proceeding with surgery was not documented.

“The complication of early right heart failure on postoperative day 1 is predictable, preventable or both.” Death on postoperative day 1 in the absence of acute MI or PE [pulmonary embolus] is usually avoidable.

VA Panel Findings

Standard of care met: Yes

Reviewer 1

Standard of care met: Yes

Components of care findings:

Was the indication for surgery appropriate and the planned procedure appropriate?
Yes

“The patient was described as a high-risk candidate, with history of COPD, actively smoking, and marginal PFTs. Seen by cardiology and pulmonary preoperatively. Preop note by [surgeon] states that the patient understood the risk associated with right lung resection, possible pneumonectomy.”

Was the decision for surgery appropriately discussed and in the correct order with other oncologic disciplines? Yes

“Multiple specialists evaluated the patient before surgery. However, the PFTs were marginal and I did not see a differential perfusion scan prior to plan for possible pneumonectomy.”

Was the extent of surgery appropriate? Yes

“The operative note describes a situation where pneumonectomy was required for complete resection of the central lung tumor.”

Was there complication(s) from this surgery and if so, was it within the standard of care? Yes.

“Death from right heart failure after right pneumonectomy. The risks associated with right pneumonectomy in a patient such as this one are very high. The PFTs were quite marginal for a pneumonectomy. The charting documented discussion of risk with the patient. [The patient] was seen by other medical specialists preoperatively. Mortality in the literature is upwards of 15%. In my opinion, the thoracic surgical care delivered was within standards of care, albeit in a high-risk situation that was understood.”

Reviewer 2

Standard of care met: Yes

Components of care findings:

Was the indication for surgery appropriate and the planned procedure appropriate?
No

“pneumonectomy directly resulted in right heart failure”

Was the decision for surgery appropriately discussed and in the correct order with other oncologic disciplines? No

Was the patient injured as a result of any of the above components of care? Yes

Case Summaries	
	<p>Was there complication(s) from this surgery and if so, was it within standard of care? Yes</p> <p>"Right heart failure. Inadequate work up."</p> <p>Additional comments:</p> <p>"If consideration on pneumonectomy recommend quantitative perfusion scan, and echo should be performed to confirm right heart for increased resistance."</p>
Peer Review	Yes
Institutional Disclosure	No
Patient 15	
Outcome	Postoperative death
History	<p>The patient was in their 60s with cirrhosis of the liver, esophageal varices, hypertension, COPD (FEV₁ 1.36 64%, reduced DLCO 7.1 39%) and biopsy proven, 2.5 cm adenosquamous carcinoma of the lung, who underwent bronchoscopy, right thoracoscopy with right lower lobe wedge resection and thoracic lymphadenectomy. On postoperative day 4, a feeding tube was placed due to poor oral intake. The patient experienced multiple episodes of emesis during tube placement and was subsequently diagnosed with aspiration pneumonia and required intubation. Over the ensuing days, the patient developed right heart failure and kidney failure, requiring hemofiltration. The patient's family requested comfort care measures and the patient died on hospital day 12.</p>
Non-VA Consultant Findings	<p>"The patient was inoperable medically and should not have been offered surgery in this setting." It is unclear why surgery was chosen over stereotactic body radiation therapy (SBRT), given the small size of the lesion and medical comorbidities.</p>
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the indication for surgery appropriate and the planned procedure appropriate? No</p> <p>"This patient had uncompensated cirrhosis and therefore surgical risk was extremely high. There are alternatives including SBRT which would be more appropriate."</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>"Death</p> <p>Yes, I believe the thoracic surgical care was within standards of care, however, the risk of surgery was extremely high for this patient."</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Component of care findings:</p>

Case Summaries	
	<p>Was the indication for surgery appropriate and the planned procedure appropriate? No</p> <p>Was the patient injured as a result of any of the above components of care? Yes</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Blank though comment below</p> <p>“Death: Palliative case involvement early in process would have been appropriate but is hard at time for treating tumor.”</p>
Peer Review	Yes
Institutional Disclosure	No
Patient 16	
Outcome	<p>Vascular Injury</p> <p>Phrenic Nerve Injury</p>
History	<p>The patient was in their 50s with right upper lobe tumor who underwent right thoroscopic upper lobectomy complicated by a superior vena cava (SVC) injury and undocumented blood loss.</p> <p>The operative note states that “A lesion in the superior mediastinum anterior to the SVC was identified. It was approximately 4 to 5 millimeter in diameter and purplish-black. It was grasped and the mediastinal pleura overlying it was opened and further dissecting it to delineate what the structure was; however, it began bleeding and it became clear that the lesion was intimately associated with superior vena cava.”⁷⁷</p> <p>Efforts to repair the SVC were described in the operative report as follows: “The area of bleeding was grasped with a clamp and sealed underneath with a white powered Echelon staple firing and excellent resulting hemostasis. However, the medial staples were inspected and found to be intersecting the phrenic nerve along the superior vena cava. This was carefully inspected and it was found that the nerve itself was not at all transected and there were staples only on a superficial portion of the phrenic nerve.” A second thoracic surgeon was called into the operating room and it was determined that no further intervention for the nerve would be beneficial. Postoperatively, the patient was admitted to the SICU. On hospital day three the patient was transferred to a medical floor and on hospital day five discharged home. A postoperative chest x-ray showed moderate elevation of the right hemidiaphragm. A sniff test performed approximately three and a half years after discharge, showed no excursion of the right hemidiaphragm.⁷⁸</p>
Non-VA Consultant Findings	<p>“Avoidable injury due to lack of judgment and technical error.”</p> <p>The lesion was not recognized as vascular and associated with the SVC. There are no significant lymph nodes anterior to the vena cava. The phrenic nerve is anterior to the vena cava and easily seen. The surgeon was not meticulous in the approach</p>

⁷⁷ The immediate post-operative note states that the injury occurred while the surgeon was attempting to “obtain additional lymph nodes.

⁷⁸ A sniff test uses fluoroscopy to evaluate movement of the diaphragm during breathing and a forceful sniff. No diaphragmatic excursion was noted in the case patient, suggesting phrenic nerve injury.

Case Summaries	
	to repairing the vessel. Instead of suturing the vessel, the surgeon used a stapler, resulting in transection of the phrenic nerve.
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the treatment technique performed correctly? Yes</p> <p>“Technical issue during surgery of injury to the SVC, but it was recognized and repaired, without much blood loss. The repair was reported to be near the phrenic nerve, and the right hemidiaphragm was elevated after surgery. The patient was discharged home on oxygen, but otherwise appears to have tolerated the surgical resection without major postoperative morbidity.”</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes.</p> <p>“See above.</p> <p>My opinion is that this patient’s thoracic surgical care falls within standards of care.”</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care concerns:</p> <p>Was the treatment technique performed correctly? No</p> <p>“Operative injury to SVC phrenic nerve injury with diaphragm paralysis”</p> <p>Was the patient injured as a result of any of the above components of care? Yes</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“diaphragm paralysis.”</p>
Peer Review	No
Institutional Disclosure	No
Patient 17	
Outcome	Postoperative death
History	The patient was in their 60s and underwent open lung biopsy for diagnostic purposes and died from respiratory failure caused by interstitial pulmonary fibrosis.
Non-VA Consultant Findings	No issues identified
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p>

Case Summaries	
	<p>Were there complication(s) from this surgery and if so, was it within the standard of care? Yes.</p> <p>“The patient died from complications of [the patient’s] disease (interstitial lung disease), which was perhaps exacerbated by the surgical biopsy. However, the surgical management is within standards of care.”</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings: None</p>
Peer Review	Yes
Institutional Disclosure	No
Patient 18	
Outcome	<p>Postoperative death</p> <p>Sternal wound infection</p>
History	The patient was in their 60s and underwent a subxiphoid pericardial window for pericardial tamponade, in the context of likely cancer diagnosis (definitive diagnosis was not established at the time of death). Approximately two weeks after discharge, the patient was admitted for treatment of a sternal wound infection. During this hospitalization, imaging revealed tumor invasion of the SVC and right atrium. The patient was transferred to hospice care and died the day of transfer.
Non-VA Consultant Findings	No issues identified
VA Panel Findings	VA did not perform a review of this patient's care.
Peer Review	Yes
Institutional Disclosure	No
Patient 19	
Outcome	Postoperative death
History	The patient was in their 60s and underwent incision and drainage of a chest wall abscess with biopsies of the first rib and pectoralis major muscle. The patient died from acute respiratory failure and complications of sepsis.
Non-VA Consultant Findings	No issues identified
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p>

Case Summaries	
	<p>“Death. The patient was extremely critically ill. Although the operation was complicated by death, the operation was not the cause of death. Rather the patient's underlying conditions caused the poor outcome. The thoracic surgical care delivered was within the standards of care.”</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings: None</p>
Peer Review	Yes
Institutional Disclosure	No
Patient 20	
Outcome	Expected postoperative course
History	The patient was in their 60's with a history of squamous cell carcinoma of the left upper lobe of the lung with radiographic first rib involvement (Pancoast tumor). The patient underwent staging mediastinoscopy (negative) followed by left upper lobectomy with en bloc resection of ribs 1 and 2.
Non-VA Consultant Findings	No issues identified
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“The postoperative course was complicated by mucous plugging, atrial tachycardia, LUE [left upper extremity] swelling (after subclavian and IJ [internal jugular] vein resection), and long hospitalization. These are expected complications after a big operation such as this. My opinion is that the thoracic surgical care delivered here was within standards of care.”</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p>
Peer Review	No
Institutional Disclosure	No
Patient 21	
Outcome	Phrenic nerve injury

Case Summaries	
History	The patient was in their 60s with a 1.5 cm right lower lobe lung nodule who underwent bronchoscopy followed by right lower lobe wedge resection via VATS. The specimen was sent for frozen section and was positive for squamous cell carcinoma. The operative report states, "at this point, it was observed that the phrenic nerve anterior to the inferior pulmonary vein had been transected" and "it was at this level that the right phrenic nerve was inseparable from the right lower pulmonary lobe due to dense adhesions." The procedure was converted to thoracotomy, with right lower lobe wedge resection followed by right lower lobectomy, right upper lobe wedge resection and lymph node excision. A plastic surgeon was called in to assist with phrenic nerve repair.
Non-VA Consultant Findings	"A 1.5 cm nodule is almost never "inseparable" from the phrenic nerve. This injury was almost certainly preventable. A surgical pathology report would need to document that the tumor directly invaded the nerve for this to be considered unavoidable, which is unlikely and would be heralded by preop [preoperative] diaphragm paralysis (not noted in this case)."
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the treatment technique performed correctly? No</p> <p>"Intra-operative complication of right phrenic nerve injury which was repaired by plastic surgery."</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care?</p> <p>"Yes (above), within the standard of care."</p> <p>Additional Comments:</p> <p>"Nerve injury immediately recognized and repaired. Patient tolerated procedure."</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the patient injured as a result of any of the above components of care? Yes.</p> <p>"surgical injury but recognition"</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>"as above"</p>
Peer Review	No
Institutional Disclosure	No
Patient 22	
Outcome	Expected postoperative course

Thoracic Surgery Quality of Care Issues and Facility Leaders' Response
at the C. W. Bill Young VA Medical Center in Bay Pines, Florida

Case Summaries	
History	The patient was in their 60s and underwent right thoracoscopy converted to thoracotomy and right upper lobectomy and thoracic lymphadenectomy. Operative pathology demonstrated non-small cell carcinoma.
Non-VA Consultant Findings	No issues identified.
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the treatment technique performed correctly? Yes</p> <p>“Conversion to thoracotomy was good judgment when the vascular anatomy could not be defined with VATS technique.”</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“Post-op [postoperative] course complicated by mucous plugging requiring bronchoscopy, POD #5, and atrial fibrillation. This patient had significant preoperative co-morbidities and complications such as these are expected, especially with need for thoracotomy. My opinion is that the thoracic surgical care received by this veteran was within standards of care.”</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p>
Peer Review	No
Institutional Disclosure	No
Patient 23	
Outcome	Postoperative death
History	The patient was in their 60s with a history of pulmonary embolism and squamous cell carcinoma of the lung who underwent right lower lobe wedge resection and lymph node dissection via VATS. The patient was treated with anticoagulants. Six days after hospital discharge, the patient presented to an outside hospital in cardiac arrest and died on the day following admission. Prior to death, the patient was diagnosed with coagulopathy and respiratory failure attributed in part to a hemothorax.
Non-VA Consultant Findings	No issues identified.
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p>

Case Summaries	
	<p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“Death likely caused by right hemothorax at surgical site, with hypercoagulability caused by anticoagulation, prescribed for history of PE. Severe bleeding on POD #8 occurred while at home, with cardiac arrest, subsequent anoxic brain injury, and death at an outside hospital. In my opinion, the care of the thoracic surgeon was within the standards of care. Late surgical site bleeding while on anticoagulation is unusual but a known risk.”</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the decision for surgery appropriately discussed and in the correct order with other oncologic disciplines? [Blank until quote cited below]</p> <p>“unknown if radiation oncology scans/consultation.”</p> <p>Was the patient injured as a result of any of the above components of care? Yes</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p>
Peer Review	Yes
Institutional Disclosure	No
Patient 24	
Outcome	Expected postoperative course
History	The patient was in their 50s with papillary thyroid carcinoma who underwent thoracoscopy converted to mini-thoracotomy for resection of a mediastinal tumor. Intraoperative pathology identified the mediastinal tumor as (metastatic) papillary thyroid carcinoma
Non-VA Consultant Findings	No issues identified.
VA Panel Findings	<p>Standard of care met: Yes</p> <p>Reviewer 1</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the indication for surgery appropriate and the planned procedure appropriate? No.</p> <p>“Indications for surgery were questionable, Metastatic papillary thyroid – multiple neck masses w biopsy neck showing papillary --but no preop diagnosis of chest mass and primary was not yet controlled – and high risk w BMI 60.”</p>

Case Summaries	
	<p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“Yes, there was a complication of sudden death. Yes, the care given was within standards of care.”</p> <p>Reviewer 2</p> <p>Standard of care met: Yes</p> <p>Components of care findings:</p> <p>Was the indication for surgery appropriate and the planned procedure appropriate? Yes</p> <p>“Multidisciplinary planning”</p> <p>Was there complication(s) from this surgery and if so, was it within the standard of care? Yes</p> <p>“but within standard of care because of multidisciplinary plan.”</p>
Peer Review	Yes
Institutional Disclosure	No

Source: Non-VA Consultant and VA Panel Reviews

Appendix B: Sample Clinical Care Review Template

Focused Clinical Care Review by Panel - Confidential Information⁷⁹

Surgical Provider:

1. **CASE REVIEW** - Please answer all questions and provide comments on each question as needed.

A. General Information:

Case Selection _____ Interrater Review/Listing _____ Random

Patient's Name:

Social Security Number: (last four)

DOB:

Date of Surgery:

Summary:

B. Components of Care:

(1) Was the indication for surgery appropriate and the planned procedure appropriate?

_____ YES _____ NO _____ NA

Comments:

(2) Was the decision for surgery appropriately discussed and in the correct order with other oncologic disciplines?

_____ YES _____ NO _____ NA

Comments:

(3) Was the extent of surgery appropriate?

_____ YES _____ NO _____ NA

Comments:

(4) Was the treatment technique performed correctly?

_____ YES _____ NO _____ NA

Comments:

(5) Was the patient's condition properly monitored by the surgeon?

And Documented?

_____ YES _____ NO _____ NA

Comments:

(6) Was Postoperative Management appropriate? Surgical Team & ICU?

_____ YES _____ NO _____ NA

⁷⁹ The OIG requested clarification from facility leaders regarding the "confidentiality" of the focused clinical care review documents provided to the OIG and was notified that the documents were not considered protected under 38 U.S.C. § 5705 and its implementing regulations.

Comments:

(7) Was the patient injured as a result of any of the above components of care?
____ YES ____ NO ____ NA

Comments:

(8) Was there complication(s) from this surgery and if so, was it within the standard of care? **If yes, please explain**
____ YES ____ NO ____ NA

Comments:

C. Summary Judgment of Standard of Care: The summary judgment need not reflect the prior answers. Extenuating circumstances, such as lack of consensus about correct therapy or diagnosis (even among experts), complexity of the case or the degree of emergency in the case, etc, can be considered in making a determination of **standard of care**.

(1) The following is a list of aspects of care to be considered when making your summary judgement:

- (a) Choice of diagnostic test,
- (b) Timely ordering of diagnostic tests,
- (c) Addressing abnormal results of diagnostic tests,
- (d) Timeliness of diagnosis,
- (e) Appropriateness of diagnosis to evidence,
- (f) Timing of treatment initiation,
- (g) Appropriateness of treatment to condition,
- (h) Adequacy of technique during procedure,
- (i) Recognition and communication of critical clues to patient's condition during a period of clinical deterioration,
- (j) Timely initiation of appropriate actions during a period of clinical deterioration,
- (k) Issues related to [resident](#) supervision,
- (l) Appropriate/complete medical record documentation, and
- (m) Other relevant aspects of care (specify).

Additional Notes/Comments:

2. SUMMARY OF REVIEW:

A. Based on your review, determine if the care provided by the surgeon met the standard of care:

___ **Standard of Care MET**

___ **Standard of Care NOT MET**

B. Additional Comments: In the following space make any additional comments that you may find pertinent to the issues surrounding this case.

3. REVIEWERS SIGNATURE:

Appendix C: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: October 22, 2020

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

Subj: Healthcare Inspection—Thoracic Surgery Quality of Care Issues and Facility Leaders' Response at the C.W. Bill Young VA Medical Center in Bay Pines, Florida

To: Director, Office of Healthcare Inspections (54HL03)

1. Thank you for the opportunity to review and comment on the Thoracic Surgery Quality of Care Issues and Facility Leaders' Response at the C. W. Bill Young VA Medical Center in Bay Pines, Florida.
2. The Veterans Health Administration (VHA) concurs in principle with recommendations 1 and 2. VHA concurs with recommendations 3 through 10. VHA also provides technical comments for consideration.
3. If you have any questions, please contact Karen Rasmussen, M.D., Director, GAO-OIG Accountability Liaison Office at VHA10BGOALAction@va.gov.

(Original signed by:)

Richard A. Stone, M.D.

Executive in Charge Response⁸⁰

Recommendation 1

The Under Secretary for Health designates a thoracic specialty leader who has the authority to review all aspects of the personnel and management actions and can provide unbiased, authoritative, and timely guidance to facilities on the most clinically sound course of action when a thoracic surgeon's practice or outcomes are under review, in order to ensure that VA provides high quality care.

Executive in Charge Comments

VHA concurs in principle. VHA continues to evolve historical processes as described below. Each element of the recommendation is addressed below without being limited/dependent on a single individual.

Formal delegated authority and policy delineate the roles of Chiefs of Staff and medical facility Directors in the responsibility for personnel actions and quality oversight of all clinical programs, including thoracic surgery. Current processes and structure address review and oversight of scarce physician resources and solo providers for routine and for-cause quality processes. Veterans Integrated Service Network (VISN) Chief Medical Officers, the VACO [VA Central Office] Office of Medical Staff Affairs and national program offices, including National Surgery Office, have defined roles to support medical facility leadership for triggered reviews.

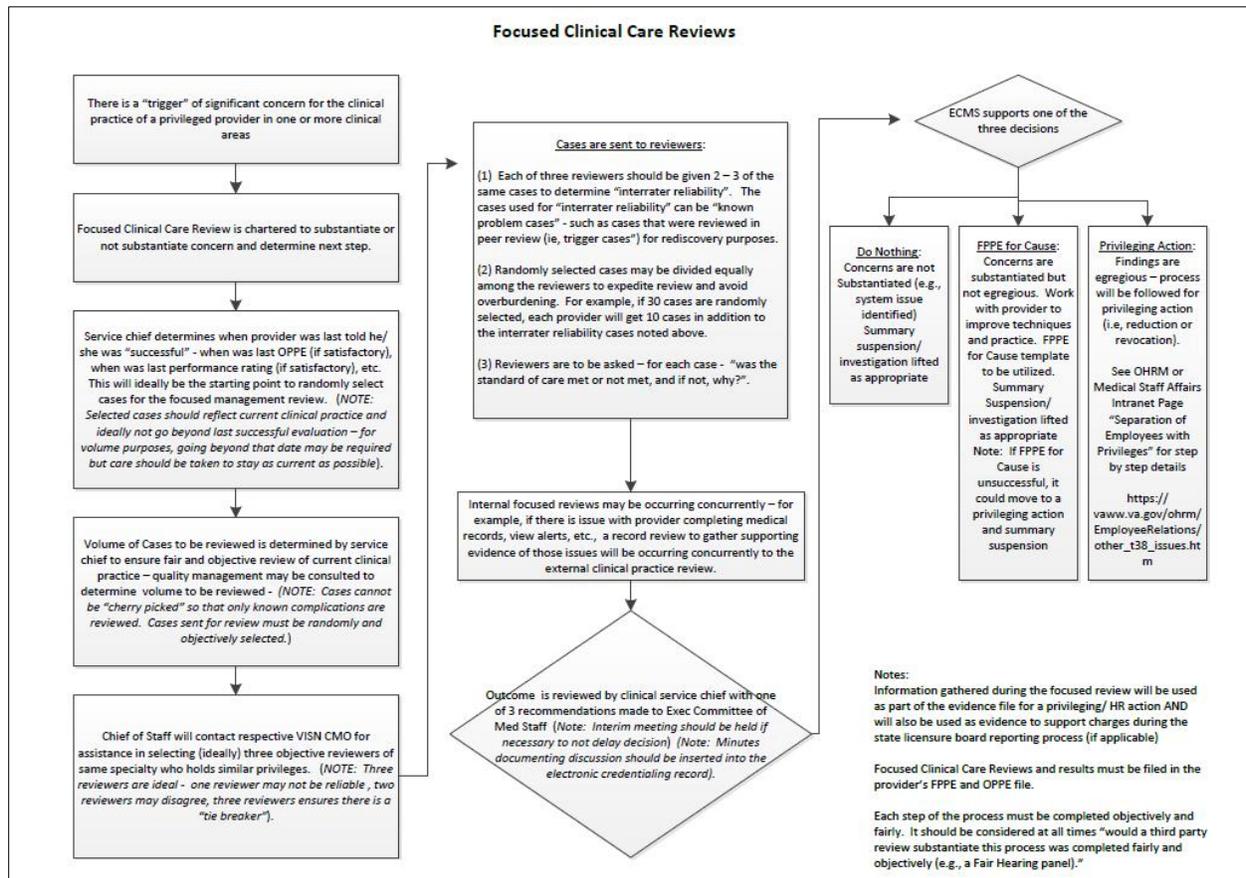
Guidance published by the VA Central Office, Office of Medical Staff Affairs defines the formal review process when triggered by clinical care concerns. In summary, when a clinical performance concern is noted, a Focused Clinical Care Review (FCCR) is triggered and must be conducted by reviewer(s) of the same specialty external to the facility to ensure objectivity. The facility Chief of Staff is required to notify the VISN Chief Medical Officer of the FCCR, and identification of appropriate clinical reviewers external to the facility are coordinated at the regional level through the VISN Chief Medical Officer.

External reviewers for FCCR are required to be of the same specialty as the clinician being reviewed and must be able to provide objective and unbiased reviews of clinical performance. In cases where regional expertise in the same specialty is not available, Chief Medical Officers identify experts outside the region through collaboration with other VISN Chief Medical Officers and/or through the Office of Medical Staff Affairs or national program offices. National program

⁸⁰ The Executive in Charge, Office of the Under Secretary for Health, has the authority to perform the functions and duties of the Under Secretary for Health. Recommendations addressed to the Facility Director were provided to the VISN and Facility Directors. The Executive in Charge provided responses to all recommendations.

specialists such as the chair of the cardiothoracic surgery advisory board may be consulted for assistance to identify reviewers with specific expertise or for scarce specialties.

The current FCCR process requires a determination regarding validity of the clinical care concern and identification of the level of risk and recommendations. Results of FCCR include recommendation to medical Facility Director to: (1) do nothing (specialty specific physician review determines clinical care concern was not substantiated); (2) a clinical concern exists and; therefore, a Focused Professional Practice Evaluation (FPPE) for Cause (an opportunity to improve under close monitoring) should be implemented; or (3) a privileging action. Generally, the reviews are retrospective chart reviews but may also involve direct observation when indicated.⁸¹



VHA Directive 1102.01, National Surgery Office, defines the organizational structure, procedures, and responsibilities of the National Surgery Office (NSO). Quality processes are

⁸¹ "Provider Competency and Clinical Care Concerns," VHA Support Service Center. (This is an internal VA website not publicly accessible.)

facilitated through an identified VISN Chief Surgical Consultant (VCSC), an interdisciplinary VISN Surgical Workgroup (which includes required membership by the VISN Chief Medical Officer), an interdisciplinary Facility Surgical Workgroup (which includes required membership by the facility Chief of Staff), and multi-specialty national Surgical Advisory Boards.

Within the current structure of the NSO, requested expertise and consultation is readily accessible to leadership at the local, VISN, and national levels regarding any surgical issue, including thoracic surgery expertise. This available consultation is not provided to supplant facility leadership responsibilities for management and resolution of personnel actions. Consultation is provided in support of existing VHA national policy and processes defined by Office of Medical Staff Affairs. National program specialists may be consulted to review findings from FCCRs at the request of facilities or VISNs. Facilities may utilize information from consultations in their deliberation processes to determine appropriate privileging or personnel actions.

VHA concurs in principle with the recommendation for specialty support, including thoracic surgery, as defined above. However, such specialty experts cannot usurp authority of medical facility Directors for personnel or privileging actions.

Status: N/A Target Completion Date: N/A

OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 2

The Under Secretary for Health outlines general parameters and triggers for when facilities without local thoracic surgery expertise engage the thoracic specialty leader and how the thoracic specialty leader's decisions and guidance will be documented.

Executive in Charge Comments

VHA concurs in principle. Processes as outlined in response to Recommendation 1 include triggers for Focused Clinical Care Review (FCCR) and define roles for involvement of national program specialists to support facility and Veterans Integrated Service Network (VISN) leaders for personnel and privileging actions. Formal decisions remain the responsibility of medical facility Directors.

Current policy directs that quality processes such as peer review and professional practice reviews be performed externally for single practitioners. VISN Chief Medical Officers are supported by other VISNs, VACO Office of Medical Staff Affairs and national program offices as needed.

Specific to surgery, the National Surgery Office supports delivery of surgical services through an established quality improvement program and monitoring of surgical quality improvement activities at the national, regional, and local levels. These processes are supported and facilitated through an identified VISN Chief Surgical Consultant (VCSC), an interdisciplinary VISN Surgical Workgroup, an interdisciplinary Facility Surgical Workgroup, and multi-specialty national Surgical Advisory Boards. VISN Surgical Workgroups have policy-based responsibility for review of mortality audits and oversight of all surgical quality data from each network surgery program.

The VA Surgical Quality Improvement Program (VASQIP) serves as the primary tool for measurement of the quality of surgical outcomes. These clinically derived data are validated, formatted, and analyzed to characterize prevailing mortality and morbidity rates, both unadjusted and risk adjusted. Accurate, comparable, and actionable data are provided to VA medical facilities and VISNs for surgical program assessment and quality improvement. Programs whose outcomes deviate significantly from national averages for mortality or morbidity are reviewed to determine corrective interventions. Triggers for VISN or National Surgery Office (NSO) action and documentation is dependent upon the degree or persistence of quality concerns at a VA medical facility as defined in Directive 1102.01, National Surgery Office. Through 18 specialty-specific Surgical Advisory Boards, including cardiothoracic surgery, the NSO ensures specialty specific expertise is available and accessible to support and facilitate quality assurance and quality improvement processes for national site visits or to support facility/VISN processes.

Specific to the recommendation, the NSO will continue to provide support as defined in the above response. Designation of a single thoracic surgery expert is not advisable as there are several thoracic surgery subspecialties including esophageal surgery, foregut diseases, lung transplantation, lung cancer, and minimally invasive surgery. The NSO will provide indicated thoracic surgery subject matter experts as recommended.

Status: Implementation of VISN Surgery Integrated Clinical Community is ongoing.

Target Completion Date: June 30, 2021

Recommendation 3

The Under Secretary for Health clarifies Veterans Health Administration policy regarding providers' responsibilities to document complications in operative reports.

Executive in Charge Comments

Concur. The Health Information Management (HIM) Program Office will be reviewing the existing documentation requirements in VHA Handbook 1907.01 and the HIM Program Guide regarding documentation of complications in operative reports and reconciling with The Joint Commission documentation requirements by submitting a clarifying question to The Joint

Commission to determine if VHA policy needs updating. The HIM Program Office will also collaborate with the Office of Quality, Safety, and Value and the National Surgery Office to define the definition of a complication before, during, and after an operation or procedure. The documentation requirements in VHA Handbook 1907.01 and the HIM Program Guide will be updated accordingly with a review from the Office of General Counsel.

Status: Ongoing Target Completion Date: January 31, 2021

Recommendation 4

The Under Secretary for Health reevaluates the eligible and mandatory assessment surgery cases reported to the National Surgery Office to determine if thoracic cases should be included in the list of mandatory assessment cases and modifies the list as appropriate.

Executive in Charge Comments

Concur. As defined in Directive 1102.01, National Surgery Office, a review of operative procedures by current procedural terminology (CPT) codes for VASQIP eligibility and for mandatory assessment by subject matter experts occurs annually. National Surgery Office will complete annual thoracic surgery CPT codes per the defined standard process.

Status: Ongoing Target Completion Date: June 30, 2021

Recommendation 5

The Under Secretary for Health defines expectations for peer review committee members whose cases are being reviewed to leave the room during those deliberations, provides guidance on how that recusal is to be annotated in the Peer Review Committee minutes, and updates Veterans Health Administration policy, as needed.

Executive in Charge Comments

Concur. VHA Directive 1190, Peer Review for Quality Management, Appendix A 1a (6)b states “The numbers of members that constitute a quorum must be at least a majority of voting members. No Peer Review Committed (PRC) member may have direct involvement with the episode of care under review.”

VHA Directive 1190, Appendix A 1e describes what PRC members must do. A responsibility listed is “Abstain from the discussion of any case when there is a conflict of interest or, for any other reason, the PRC member is unable to conduct an objective, impartial, accurate, and informed review.”

The intent of these above referenced sentences together is:

- The provider whose care is under review not be present during the case deliberation.
- The provider whose care is under review not be present during the final level assignment determination.
- The disposition of the case will be communicated in the same manner as non-member providers whose care is under review.

VHA Directive 1190 also requires discussions are recorded in formal meeting minutes Appendix A 2(l) and that clinician participation is to be documented in the PRC minutes Appendix A 2(m).

Appendix A 2(l) states “Ensuring that formal discussions regarding a peer review occurring during PRC meetings are recorded in formal meeting minutes. Documentation relevant to any Peer Review for Quality Management must be maintained in a secure manner.”

Appendix A 2(m) states (in part) “...Clinician participation is to be documented in the PRC minutes...” VHA will reinforce communication to VISN liaisons and field facilities going forward to include documentation that reflects compliance with the clarification related to abstention from peer review committee deliberations as described.

Status: Complete Completion Date: September 2020

OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 6

The C.W. Bill Young VA Medical Center Director enhances processes to identify the existence of omissions or alterations in operative note documentation and takes action based on identified deficiencies.

Executive in Charge Comments

Concur. The Bay Pines VAHCS [VA Healthcare System] Surgical Service with assistance from Quality Systems Service will develop a retrospective audit tool to validate content of the Surgical Operative Note and Operative Report against standard documentation requirements (VHA Handbook 1907.01, Health Information Management and Health Records, pages 50-52; section x. Surgeries and Procedures, subsection (2) Immediate Post-operative Note and subsection (3) Operative Report) to identify any omissions or alterations in documentation.

Ten percent of all operating room (OR) invasive surgical procedure cases will be randomly selected by the Surgical Quality Nurse monthly for review against the standardized elements within the developed audit tool over 6 continuous months. The Surgical Quality Nurse will present the results at the Facility Surgical Work Group then report the data at the Medical

Executive Council. The Medical Executive Council will identify any deficiencies and make the determination of the need for any action(s). Surgical Service leadership will conduct training for all surgeons on operative note and operative report documentation requirements before the first audit review cycle occurs.

Status: Ongoing Target Completion Date: May 1, 2021

Recommendation 7

The C.W. Bill Young VA Medical Center Director takes action to ensure that the surgeon is aware of, and complies with, expectations for professional communications and supporting staff to report adverse events and close calls.

Executive in Charge Comments

Concur. The C.W. Bill Young VA Medical Center Chief of Staff will meet with the surgeon and convey expectations for professional communications by October 2, 2020. The Bay Pines Patient Safety Officers will provide 'Stop the Line' and Joint Patient Safety Reporting (JPSR) training to Surgery Service providers and support staff. A minimum of 90 percent of these providers and staff will complete the training by December 18, 2020, as evidenced by attendance records. Additionally, High Reliability Organization (HRO) baseline training will be conducted facility-wide with all Surgery Service providers and support staff completing training by June 30, 2021, as evidenced by attendance records.

Status: Ongoing Target Completion Date: June 30, 2021

Recommendation 8

The C.W. Bill Young VA Medical Center Director ensures the C.W. Bill Young VA Medical Center Surgical Work Group provides oversight as required by Veterans Health Administration policy and monitors for compliance.

Executive in Charge Comments

Concur. The Bay Pines Chief of Staff actively participates and reviews the Surgical Work Group requirements and actions as defined in VHA Directive 1102.01(1) to ensure compliance. Monthly reports are presented and reviewed at the Medical Executive Council and documented in the council minutes.

Status: Complete and ongoing Target Completion Date: N/A

OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 9

The C.W. Bill Young VA Medical Center Director confirms processes are in place to ensure providers' clinical privileges are specific to the facility and service, and are based on each provider's clinical competence, and monitors for compliance.

Executive in Charge Comments

Concur. The Bay Pines VAHCS Director made the administrative decision to restrict specifically defined thoracic surgery procedures. This defined what procedures would be done and this action supersedes the authority of individual provider clinical privileges. The Bay Pines VAHCS did this in December 2017, and has maintained these limitations at this time.

Annually, the Medical Executive Council reviews all clinical privilege form templates to confirm that core and supplemental clinical privileges offered are specific to the facility and service. This recommendation was completed for all service lines over the last 12 months for fiscal year 2020. This recommendation will be further delineated on the actual privilege form template for the two Bay Pines VA thoracic surgeons by December 4, 2020, based on the thoracic surgery program restriction currently in effect.

Status: Ongoing Target Completion Date: November 1, 2020

OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 10

The C.W. Bill Young VA Medical Center Director reviews whether the cases reflected in tables 1 and 2 in this report meet criteria for institutional disclosure and takes action as appropriate.

Executive in Charge Comments

Concur. The facility tasked a multi-disciplinary team to complete medical record reviews of all cases identified by the OIG. A total of 22 reviews were completed. One case was identified as meeting the criteria listed in VHA Handbook 1004.08, Disclosure of Adverse Events to Patients, for institutional disclosure. It was noted that institutional disclosure had been completed on October 13, 2016, for the event occurring on September 26, 2016. No other case met the criteria for institutional disclosure. The facility has a proactive and robust process of identifying significant events that require evaluation for clinical and/or institutional disclosure.

Status: Complete Completion Date: June 1, 2020

OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Glossary

To return, press and hold alt+left arrow

adverse events. Untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical facility, outpatient clinic, or other VHA facility.¹

atrial appendage. A small muscular pouch attached to each atrium of the heart.²

atrium. The upper chamber of the heart that receives incoming blood. There are two atriums—one on the left side of the heart and one on the right side.³

bilobectomy. The surgical removal of two lobes of the right lung, either right upper and middle or right lower and middle.⁴

board-certified surgeon. A surgeon who has completed at least five years of residency training following medical school, meets all American Board of Surgery requirements, and successfully completed a board examination process. Board certification is in addition to medical licensure.⁵

bronchus. The large airway that leads from the windpipe (trachea) to the lung.⁶

bronchus intermedius. One of the branches of the right main bronchus of the lungs; the other branch is the right upper lobe bronchus.⁷

cardiac arrest. The abrupt loss of heart function, breathing and consciousness, typically due to an electrical disturbance in the heart. Cardiac arrest can lead to death if not treated immediately.⁸

¹ VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, March 4, 2011.

² Cleveland Clinic, *Left Atrial Appendage & Closure*. <https://my.clevelandclinic.org/health/treatments/17167-left-atrial-appendage--closure>. (This website was accessed on October 7, 2019.)

³ Mayo Clinic, *Chambers of the heart*. <https://www.mayoclinic.org/chambers-and-valves-of-the-heart/img-20007497>. (The website was accessed on June 17, 2019.)

⁴ American Lung Association, *Lung Cancer Surgery*. <https://www.lung.org/lung-health-and-diseases/lung-disease-lookup/lung-cancer/patients/treatment/types-of-treatment/lung-cancer-surgery.html>. (This website was accessed October 3, 2019.)

⁵ American Board of Surgery, *About ABS certification*. <http://www.absurgery.org/default.jsp?publiccertprocess>. (The website was accessed June 17, 2019.)

⁶ National Cancer Institute, *Bronchus*. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/bronchus>. (The website was accessed on June 18, 2019.)

⁷ Radiopaedia, *Bronchus intermedius*. <https://radiopaedia.org/articles/bronchus-intermedius?lang=us>. (The website was accessed on June 17, 2019.)

⁸ Mayo Clinic, *Sudden cardiac arrest*. <https://www.mayoclinic.org/diseases-conditions/sudden-cardiac-arrest/symptoms-causes/syc-20350634>. (The website was accessed on June 17, 2019.)

cardiac massage. The manual application of rhythmic pressure, either externally through compression of the chest wall, or internally by direct squeezing of the heart through an opening in the chest to resuscitate a person experiencing cardiac arrest.⁹

cardiac shock. A rare, but life-threatening condition where the heart is unable to pump enough blood to meet the body's needs. About half the patients who develop cardiogenic shock survive.¹⁰

chronic obstructive pulmonary disease (COPD). A chronic inflammatory lung disease that causes obstructed airflow from the lungs. Symptoms include breathing difficulty, cough, mucus (sputum) production and wheezing and often caused by long-term exposure to irritating gases or particulate matter, most often from cigarette smoke. People with COPD are at increased risk of developing heart disease, lung cancer and a variety of other conditions.¹¹

covidien gold load. A type of surgical stapler.

electrocardiogram (EKG). A common test used to detect heart problems and monitor the heart's status. During the test, sensors are placed on the chest and limbs to detect the electrical activity of the heart.¹²

endobronchial ultrasound or EBUS. An imaging and tissue sampling procedure used to aid in the diagnosis of "lung cancer, infections and other diseases causing enlarged lymph nodes in the chest." The instrument is inserted into the lungs through the trachea, which allows doctors to access the chest without the need of an incision. The instrument is fitted with an ultrasound processor and ultrasound images of the tissues are obtained in the chest in real time.¹³

hemostasis. The stoppage of bleeding.¹⁴

hypotension/hypotensive. The state of having low blood pressure. Hypotension is a systolic blood pressure reading lower than 90 millimeters of mercury (mm Hg) (the top number) or

⁹ Merriam-Webster, *Definition of cardiac massage*. <https://www.merriam-webster.com/medical/cardiac%20massage>. (The website was accessed on June 17, 2019.)

¹⁰ Mayo Clinic, *Cardiogenic shock*. <https://www.mayoclinic.org/diseases-conditions/cardiogenic-shock/symptoms-causes/syc-20366739>. (The website was accessed on June 18, 2019.)

¹¹ Mayo Clinic, *COPD*. <https://www.mayoclinic.org/diseases-conditions/copd/symptoms-causes/syc-20353679>. (The website was accessed on September 27, 2019.)

¹² Mayo Clinic, *Electrocardiogram (ECG or EKG)*. <https://www.mayoclinic.org/tests-procedures/ekg/about/pac-20384983>. (The website was accessed on June 17, 2019.)

¹³ UC San Diego Health, *Endobronchial ultrasound (EBUS)*. <https://health.ucsd.edu/specialties/pulmonary/procedures/Pages/endobronchial.aspx>. (The website was accessed on June 17, 2019.)

¹⁴ Merriam-Webster, *Hemostasis*. <https://www.merriam-webster.com/dictionary/hemostasis>. (The website was accessed on October 7, 2019.)

diastolic blood pressure reading lower than 60 mm Hg (the bottom number). Symptoms from hypotension include dizziness and fainting and can be life-threatening.¹⁵

institutional disclosure. A formal process used by facilities to inform the patient or the patient's representatives that an adverse event has occurred related to the care rendered at the facility that is expected to have resulted in, death, or serious injury. Specific information about the patient's rights and recourse options is also provided.¹⁶

left pulmonary artery. A branch of the main pulmonary artery, the left pulmonary artery supplies the left lobe of the lung with blood.¹⁷

lingular. A portion of the left upper lobe of the lung.¹⁸

lobectomy. A common surgical procedure performed to remove a diseased lobe of the lung. The lungs have sections called lobes. The right lung has three lobes while the left lung has two lobes. After removal of the diseased portion, the remaining healthy lung tissue can function as normal.¹⁹

main pulmonary artery. The artery that supplies blood to the entire lung. It originates from the lower chamber of the heart and divides into the right and left pulmonary arteries.²⁰

management review. A peer review conducted for administrative purposes; it is not considered confidential or privileged information. The results of these reviews can result in personnel actions such as restrictions in the care a provider can participate in at the facility.²¹

mediastinoscopy. A procedure that utilizes a special camera, light, and tool to view organs between the lungs and lymph nodes and to sample tissues. The instrument is inserted into the chest through an incision above the breast bone.²²

¹⁵ Mayo Clinic, *Low blood pressure (hypotension)*. <https://www.mayoclinic.org/diseases-conditions/low-blood-pressure/symptoms-causes/syc-20355465>. (The website was accessed on June 17, 2019.)

¹⁶ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012.

¹⁷ Radiopaedia, *Left pulmonary artery*. <https://radiopaedia.org/articles/left-pulmonary-artery?lang=us>. (The website was accessed on June 17, 2019.)

¹⁸ Merriam-Webster, *Lingula*. <https://www.merriam-webster.com/medical/lingula>. (The website was accessed on July 22, 2019.)

¹⁹ Johns Hopkins, *Lobectomy*. https://www.hopkinsmedicine.org/healthlibrary/test_procedures/pulmonary/lobectomy_92,p07749. (The website was accessed on June 17, 2019.)

²⁰ Loyola University, Stritch School of Medicine, *Main pulmonary artery*., http://www.meddean.luc.edu/lumen/meded/radio/curriculum/Vascular/pulmonary_artery_teach.htm. (The website was accessed on June 17, 2019.)

²¹ VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

²² National Cancer Institute, *Mediastinoscopy*. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mediastinoscopy>. (The website was accessed on June 17, 2019.)

mediastinum. The area between the lungs including the heart, large blood vessels, the trachea, the esophagus, the thymus, and lymph nodes but not including the lungs.²³

Medical Executive Council. A council primarily responsible for the governance of the independent medical staff of the facility. The Medical Executive Council makes decisions related to policies, procedures, and rules that affect the practice of staff including decisions related to credentialing and privileging of providers in the facility.²⁴

metastasectomy. A surgery where one or more metastases (tumors formed from cells that have spread from a primary tumor) are removed. When all metastases are removed, it is called a complete metastasectomy.²⁵

morbidity. The complications or undesirable side effects following surgery or medical treatment. Morbidity rate refers to the number of complications or undesirable side effects relative to the number of all surgeries or treatments.²⁶

Morbidity and Mortality Conference. A meeting of medical staff and their trainees where complex cases and adverse events are discussed in a safe and transparent setting with the goal of improving patient care.²⁷

mortality. Death or related to death. The mortality rate is the number of a particular group of patients who die each year.²⁸

never events. “Unambiguous,” “serious,” and “usually preventable” medical errors. The term originates from the early 2,000’s and now consists of 29 events grouped in seven categories: surgical or procedural, product or device, patient protection, care management, environmental, radiologic, and criminal. Due to the severe nature of these events and the significant consequences to patients, there have been efforts by multiple regulatory and legislative bodies to force healthcare entities to make disclosures when these types of events occur and to analyze methods to reduce their occurrence.²⁹

²³ National Cancer Institute, *Mediastinum*. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mediastinum>. (The website was accessed on June 17, 2019.)

²⁴ Henry Mayo Newhall Hospital, *Medical Executive Committee*. <https://www.henrymayo.com/about-us/our-people/medical-executive-committee/>. (The website was accessed on July 22, 2019.)

²⁵ National Cancer Institute, *Metastasectomy*. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/metastasectomy>. (The website was accessed on June 17, 2019.)

²⁶ Merriam-Webster, *Morbidity*. <https://www.merriam-webster.com/dictionary/morbidity>. (This website was accessed on June 22, 2019.)

²⁷ Emory University School of Medicine Morbidity and Mortality Conference. <http://www.gynob.emory.edu/education/conferences/mm.html>. (This website was accessed on July 22, 2019.)

²⁸ Merriam-Webster, *Mortality*. <https://www.merriam-webster.com/dictionary/mortality>. (The website was accessed on June 22, 2019.)

²⁹ Agency for Healthcare Research and Quality, *Never Events*. <https://psnet.ahrq.gov/primers/primer/3/never-events>. (The website was accessed on June 17, 2019.)

National Surgery Office. The VHA program office that is responsible for operational oversight and policy of surgical programs including surgical outcomes data production and analysis.³⁰

non-ST-elevation myocardial infarction (NSTEMI). A type of heart attack from a partial blockage of a coronary artery.³¹

outlier. A status established by the statistical confidence parameters of the observed/expected ratio. The observed/expected ratio can be elevated but insignificant if constructed on a small number of cases.³²

positron emission tomography (PET). An imaging procedure that uses a small amount of radioactive sugar injected into a vein to identify cancer cells within the body. After the injection, a scanner is used to make detailed, computerized pictures of the body.³³

phrenic nerve. A nerve running from the spinal cord to the diaphragm that causes the diaphragm to relax and contract, helping to control breathing.³⁴

physician assistant. A medical professional trained and licensed to do medical procedures, take medical histories, and conduct physical exams, under the supervision of a physician.³⁵

pneumonectomy. A surgical procedure in which an entire lung is removed. A pneumonectomy is most often performed to address cancer of the lung that cannot be treated by removal of a smaller portion of the lung.³⁶

pulmonary function testing (PFT). Noninvasive tests used by physicians to determine how well the lungs are working. Pulmonary function tests measure lung volume, capacity, rates of flow, and gas exchange.³⁷

³⁰ VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013. This handbook was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1102.01(1) *National Surgery Office*, May 22, 2019.

³¹ American Heart Association, *Treatment of a Heart Attack*. <https://www.heart.org/en/health-topics/heart-attack/treatment-of-a-heart-attack>. (The website was accessed on October 7, 2019.)

³² National Surgery Office, *Outlier*. [NSO Quarterly Report Interpretation](#).

³³ National Cancer Institute, *Positron emission tomography (PET)*. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/pet-scan>. (The website was accessed on June 17, 2019.)

³⁴ National Cancer Institute, *Phrenic nerve*. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/phrenic-nerve>. (The website was accessed on June 17, 2019.)

³⁵ National Cancer Institute, *Physician assistant*. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/physician-assistant>. (The website was accessed on June 17, 2019.)

³⁶ Johns Hopkins Medicine, *Pneumonectomy*. https://www.hopkinsmedicine.org/healthlibrary/test_procedures/pulmonary/pneumonectomy_135,391. (The website was accessed on June 17, 2019.)

³⁷ Johns Hopkins Medicine, *Pulmonary function tests*. <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/pulmonary-function-tests>. (The website was accessed on June 17, 2019.)

quantitative radionuclide perfusion scan. A test that assesses the general perfusion of the lungs and evaluates lung function, especially before surgery to remove tumors or pieces of the lung. This test may also be used preoperatively to predict what the anticipated lung function will be after resection of the lung tissue.³⁸

resident. A physician in training. Residents have graduated from medical school and awarded a medical doctor degree and are in specialty training.³⁹

retracted. A movement of a body part in the posterior direction; being drawn backwards.⁴⁰

superior pulmonary vein. A blood vessel that returns blood from the upper and lower lobes of the lungs to the left atrium of the heart.⁴¹

superior vena cava. A major blood vessel of the body that receives blood from the upper half of the body (excluding the heart) and returns it to the right atrium of the heart.⁴²

surgical intensivist. A surgeon who provides care for critically ill patients. Also known as a critical care physician, the intensivist has advanced training and experience in treating this complex type of patient and is generally fellowship trained.⁴³

surgical critical care team. A team of specialists who diagnose and treat a wide variety of clinical problems in critically ill surgical patients in intensive care units.⁴⁴

surgical margins or margins. The edge or border of tissue removed during cancer surgery. Margins may be positive or negative, depending on the presence or absence of cancer cells.⁴⁵

Surgical Work Groups. Established groups who meet at a regional and facility level to aid in the coordination and management of surgical programs within VA facilities. They meet regularly

³⁸ Cleveland Clinic, *What is a lung quant scan?* <https://my.clevelandclinic.org/health/diagnostics/17189-lung-quant-scan>. (The website was accessed on June 17, 2019.)

³⁹ Harvard Medical School, *Should I see a resident doctor?* <https://www.health.harvard.edu/healthcare/should-i-see-a-resident-doctor>. (The website was accessed on June 17, 2019.)

⁴⁰ Merriam-Webster, *Retraction*. <https://www.merriam-webster.com/dictionary/retraction#medicalDictionary>. (The website was accessed on October 7, 2019.)

⁴¹ Radiopaedia, *Pulmonary veins*. <https://radiopaedia.org/articles/pulmonary-veins?lang=us>. (The website was accessed on June 17, 2019.)

⁴² Superior vena cava, Radiopaedia.org, <https://radiopaedia.org/articles/superior-vena-cava?lang=us>. (The website was accessed on June 17, 2019.)

⁴³ UMass Memorial Medical Center, *Surgical Intensivist*. <https://www.umassmemorialhealthcare.org/umass-memorial-medical-center/services-treatments/critical-care/what-intensivist>. (The website was accessed on July 15, 2019.)

⁴⁴ American College of Physicians, *Critical care medicine*. <https://www.acponline.org/about-acp/about-internal-medicine/subspecialties/additional-training-options/critical-care>. (The website was accessed on June 17, 2019.)

⁴⁵ National Cancer Institute, *Margins*. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/margin>. (The website was accessed on June 17, 2019.)

and assess items such as: improving practice and patient safety, reviewing data, monitoring compliance with VHA regulations and reviewing surgical outcomes.⁴⁶

thoracic surgery. Surgery that involves the organs of the chest, in addition to the tube between the mouth and stomach (esophagus), the airway (trachea), and the rib cage and breast bone (chest wall).⁴⁷

thoracotomy. A surgical incision of the chest wall, providing access to the lungs, heart, esophagus, diaphragm, and the portion of the aorta that passes through the chest cavity. A thoracotomy allows for the examination, treatment, or removal of any of these chest cavity organs.⁴⁸

transected. To cut or divide crossways.⁴⁹

transthoracic echocardiogram. A test that uses sound waves to produce images of the heart to allow the provider to see the heart beating and blood pumping. This is the most common type of echocardiogram and is noninvasive.⁵⁰

transverse anastomosis (TA) stapler. A noncutting stapler that produces multiple rows of staples. The specimen generally needs to be cut with a scalpel after being stapled by a TA stapler.⁵¹

Tumor Board. A group of doctors and other health care providers with different specialties that meets regularly to discuss cancer cases and share knowledge. The board's goal is to determine the best possible cancer treatment and care plan for an individual patient.⁵²

vasopressor agents. A drug that causes a rise in blood pressure by exerting a constriction on the blood vessels.⁵³

video assisted thoracic surgery (VATS). Thoracic surgery that uses a special video camera and requires smaller incisions than traditional surgery. This minimally invasive approach generally

⁴⁶ VHA Directive 1102.01(1), *National Surgery Office*, April 24, 2019.

⁴⁷ Mayo Clinic, *Thoracic surgery*. <https://www.mayoclinic.org/departments-centers/thoracic-surgery/sections/overview/ovc-20421043>. (The website was accessed on June 17, 2019.)

⁴⁸ American Lung Association, *Lung procedures & tests*. <https://www.lung.org/lung-health-and-disease/lung-procedures-and-tests/thoracotomy.html>. (The website was accessed on June 17, 2019.)

⁴⁹ Merriam-Webster, *Transect*. <https://www.merriam-webster.com/dictionary/transect>. (The website was accessed on October 7, 2019.)

⁵⁰ Mayo Clinic, *Echocardiogram*. <https://www.mayoclinic.org/tests-procedures/echocardiogram/about/pac-20393856>. (The website was accessed on October 7, 2019.)

⁵¹ UpToDate, *Bowel resection*. <https://www.uptodate.com/contents/bowel-resection-techniques>. (The website was accessed on October 7, 2019.)

⁵² National Cancer Institute, *Tumor board review*. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/tumor-board-review>. (The website was accessed on June 17, 2019.)

⁵³ Merriam-Webster, *Vasopressor*. <https://www.merriam-webster.com/dictionary/vasopressors>. (The website was accessed on October 7, 2019.)

results in a shorter operating time, reduced postoperative morbidity, and allows an earlier return to normal activity than with thoracotomy.⁵⁴

wedge resection. A surgical procedure that involves the removal of a small, wedge-shaped portion of diseased lung along with healthy tissue that surrounds the diseased area. The surgery is typically performed to remove a small tumor or to diagnose lung cancer; it can be performed by VATS surgery or a thoracotomy.⁵⁵

⁵⁴ Mayo Clinic, *Video assisted thoracic surgery (VATS)*. <https://www.mayoclinic.org/tests-procedures/video-assisted-thoracic-surgery/about/pac-20384922>. (The website was accessed on June 17, 2019.)

⁵⁵ National Cancer Institute, *Wedge resection*. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/wedge-resection>. (The website was accessed on June 17, 2019.)

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