



DEPARTMENT OF VETERANS AFFAIRS  
**OFFICE OF INSPECTOR GENERAL**

*Office of Healthcare Inspections*

VETERANS HEALTH ADMINISTRATION

Surgical Adverse Clinical  
Outcomes and Leaders'  
Responses at the Columbia  
VA Health Care System in  
South Carolina



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## Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations of adverse clinical outcomes related to three patients' surgical or invasive procedure(s) at the Columbia VA Health Care System (facility) in South Carolina.<sup>1</sup> The OIG identified additional concerns regarding facility processes and facility leaders' responses to the adverse clinical outcomes for two of the three patients, as well as, facility staff's compliance with patient informed consent and time-out protocols.<sup>2</sup>

### Adverse Clinical Outcomes

The OIG substantiated three patients experienced adverse clinical outcomes related to surgical or invasive procedure(s):

- Patient A—incorrect placement of chest catheter and tube in early summer 2021
- Patient B—wrong site surgery for a toe amputation in early fall 2020
- Patient C—complication from a robotic-assisted [laparoscopic hemicolectomy](#) in early 2021<sup>3</sup>

The OIG found concerns with the quality of care for Patients A and B but did not find concerns related to the quality of care for Patient C.

### Patient A: Incorrect Placement of Chest Catheter and Tube

Patient A, who was in their 50s, had a complex medical history that included [nasopharyngeal carcinoma](#) treated with [chemotherapy](#) and [radiation therapy](#) resulting in a severe radiation injury to the jaw.<sup>4</sup> Consequently, the patient had limited mouth opening (approximately one centimeter). The patient presented to the facility's Emergency Department with right upper abdominal and right-sided [pleuritic chest pain](#) associated with shortness of breath. A [computerized tomography](#) scan (CT scan) of the abdomen and pelvic region showed a large right

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<sup>1</sup> In the context of this report, the OIG defines an adverse clinical outcome as any incident, complication, or adverse event related to an invasive procedures or surgical intervention, regardless of the incident, complication, or adverse event being a known risk or leading to an increased level of care.

<sup>2</sup> The Joint Commission, *National Patient Safety Goals*, January 2020. A time-out includes all relevant members of the procedure team who conduct a final assessment to identify and verify the patient, site, and procedure are correct.

<sup>3</sup> The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

<sup>4</sup> The OIG uses the singular form of they (their) in this instance for privacy purposes.

lung pleural effusion.<sup>5</sup> The patient was admitted to the intensive care unit. In an attempt to drain the patient's pleural effusion, a medical [intensivist](#) attempted to place a [pigtail catheter](#) (catheter) in the [pleural cavity](#) (space between the layers of [pleura](#)) and, later, a thoracic surgeon placed a [chest tube](#). Neither successfully drained the pleural effusion.

The OIG identified clinical care deficiencies made by the medical intensivist and the thoracic surgeon that led to a series of unplanned events and contributed to the patient's death. The medical intensivist placed the catheter in the wrong location. The medical intensivist assumed that the catheter was correctly placed and attributed the lack of fluid return to clotted blood. Prior to confirming the catheter's location, as required by Veterans Health Administration (VHA) policy, the medical intensivist administered [tissue plasminogen activator](#) (tPA) and [dornase alfa](#) to dissolve the clotted blood.<sup>6</sup> Subsequently, the medication was not delivered into the pleural cavity. The patient's medical status rapidly declined following the medical intensivist's administration of tPA.

A thoracic surgeon was consulted to evaluate the patient's rapid decline and possible hemothorax.<sup>7</sup> The thoracic surgeon focused efforts on treating the patient's pleural effusion and placed a chest tube in a second attempt to drain the fluid. After learning that neither the catheter nor the chest tube was correctly placed, the thoracic surgeon determined a surgical [laparotomy](#) was needed to identify and treat the source of the patient's bleeding. The procedure was scheduled for the next day. The surgeon explained that the patient's medical history and anticipation of a difficult airway situation in the operating room factored into the decision to operate the following day when full operating room support would be available.

The following day, the patient died in the facility's operating room. The OIG found that the facility's lack of resources, specifically, ear, nose, and throat physicians, interventional radiologists, and full evening operative room support, limited the clinical interventions needed for the patient's care. The OIG determined the patient's medical complexities exceeded the facility's capabilities to provide quality surgical care.

During the inspection, the OIG also identified deficiencies in the facility's quality management processes regarding this incident including insufficient peer reviews and peer review committee

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<sup>5</sup> Veterans Health Library, "pleural effusion," accessed July 27, 2021, <http://www.veteranshealthlibrary.va.gov/Search/3,40414>. A pleural effusion is a build-up of excess fluid between the layers of the pleura that line the outside of the lungs.

<sup>6</sup> For purposes of this report, the OIG will use tPA when referring to the combination of tPA and dornase alfa.

<sup>7</sup> *Merriam-Webster.com Dictionary*, "hemothorax," accessed November 16, 2021, <https://www.merriam-webster.com/medical/hemothorax>. A hemothorax is blood in the pleural cavity.

practices and delays in the initiation of an [institutional disclosure](#) and completion of a [root cause analysis](#).<sup>8</sup>

The facility failed to complete a peer review to evaluate the care the thoracic surgeon provided. A risk manager said this did not occur because of a lack of documentation indicating the thoracic surgeon's awareness that the chest tube had been incorrectly placed. The OIG did not find that VHA policy provides exceptions for conducting peer reviews based upon a provider's lack of awareness. Additionally, although the facility completed a peer review to evaluate the care provided by the medical intensivist, the peer review committee did not identify areas for improvement.<sup>9</sup> The OIG had concerns with the committee's review but was unable to evaluate the rationale for the decision since the discussion was not captured in the meeting minutes as required. The facility's peer review committee documented a generic statement in lieu of case-specific committee discussion when reviewing an initial peer review rating. The OIG reviewed additional peer review committee meeting minutes and found a practice of documenting a generic statement instead of case-specific discussion when reviewing peer review ratings.

Facility leaders did not conduct an institutional disclosure as soon as possible or within 72 hours per VHA policy but waited nearly four months after the patient's death to initiate contact with the patient's family.<sup>10</sup> Quality management staff followed an inherited practice, that was not based in policy, of waiting for the completion of an autopsy before determining whether an institutional disclosure would be conducted. This practice resulted in the delay of patients or their representatives being advised of their rights and resources.

The Facility Director and patient safety staff did not complete a root cause analysis within the required 45-day time frame, delaying the opportunity for facility leaders to identify and address system vulnerabilities. The facility Quality Manager attributed the root cause analysis completion delay to competing priorities and staff shortages (staff detailed to other services to assist with COVID-related needs, staff retirements, and lengthy position vacancies).

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<sup>8</sup> VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A peer review is a confidential, non-punitive process for evaluating the quality of health care provided by an individual, designed to promote patient safety, organizational improvements, and optimal patient outcomes. The peer review committee is responsible for "ensuring that formal discussions regarding a peer review" during committee "meetings are recorded in formal meeting minutes" and is required to review initial assignments, provide final level assignments, and make recommendations to improve the quality of health care delivered.

<sup>9</sup> VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. "Level 1 is the level at which most experienced and competent clinicians would have managed the case in a similar manner. Level 2 is the level at which most experienced and competent clinicians might have managed the case differently but it remains within the standard of care. Level 3 is the level at which most experienced and competent clinicians would have managed the case differently."

<sup>10</sup> VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

## Patient B: Wrong Site Surgery for a Toe Amputation

Patient B, who was in their 80s, with a medical history of [paraplegia](#), [diabetes](#), and a fifth digit (toe) amputation of the right foot presented to the facility's Emergency Department with blackened areas on the tips of the right toes. The radiologist's CT scan interpretation report cited bone destruction of the fourth toe, "strongly suggestive of osteomyelitis of the fourth toe." A facility [vascular](#) surgeon completed a consult and noted the patient's right fourth toe had osteomyelitis and needed to be amputated.<sup>11</sup> The patient agreed to the surgical amputation.

A review of the patient's electronic health record revealed that all documentation prior to the surgical procedure, including radiological imaging, pre-operative planning, and informed consent, consistently identified osteomyelitis in, and the vascular surgeon's plan to amputate, the right fourth toe. The patient signed an informed consent for the removal of the fourth toe on the right foot and the surgical team conducted a time-out verifying and marking the right fourth toe for removal. However, at the operating table the vascular surgeon directed a surgical [resident](#) to amputate the patient's right third toe.

The OIG substantiated that Patient B's amputation of the third toe was a wrong site surgery, overseen by a vascular surgeon, resulting in an adverse clinical outcome.

The OIG found that, although removal of the patient's third toe was clinically indicated due to infection, the surgeon failed to acknowledge and discuss the deviation from the informed consent and pre-operative plan with the patient and surgical team. These omissions are inconsistent with VHA policy and VHA's culture of safety embodied in the goals of a high reliability organization. Additionally, the vascular surgeon did not complete an operative report immediately following the surgery as required.

Although facility and service line leaders completed an initial review of the vascular surgeon's care, for unknown reasons, leaders failed to address the vascular surgeon's disregard for patient safety protocols and the undermining of high reliability organization principles.<sup>12</sup> Facility and service line leaders had not taken measures to ensure the vascular surgeon's future compliance with these protocols and principles.

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<sup>11</sup> *Merriam-Webster.com Dictionary*, "osteomyelitis," accessed October 26, 2021, <https://www.merriam-webster.com/dictionary/osteomyelitis>. An infectious usually painful inflammatory disease of bone often of bacterial origin that may result in the death of bone tissue.

<sup>12</sup> VHA Directive 1026.01, *VHA Systems Redesign and Improvement Program*, December 12, 2019. Per VHA, a high reliability organization "is an organization with a goal of achieving "zero harm" in an environment where accidents are expected due to complexity or risk factors."

## **Patient C: Complication from a Robotic-Assisted Laparoscopic Hemicolectomy**

Patient C, who was in their 60s, was referred for a surgical consult after a colonoscopy identified a [cecal polyp](#). After evaluation, a facility surgeon scheduled the patient for and oversaw a surgical resident's completion of a robotic-assisted laparoscopic right hemicolectomy to remove the polyp. Following the procedure, the patient was treated for an elevated blood pressure. Subsequently, the patient became [hypotensive](#), did not respond to intravenous fluid, and required a blood transfusion. The patient's mental status progressively decreased, and the patient was emergently intubated and prepared for an exploratory laparotomy. The surgeon and the cardiology service critical care team determined that the patient was likely experiencing an intrabdominal bleed.

The OIG substantiated that the patient experienced an adverse clinical outcome related to complications following a robotic-assisted laparoscopic hemicolectomy. However, the OIG found the patient's treatment team, that included the surgeon, surgical residents, and nursing staff, immediately identified, closely monitored, and managed the surgical complication. The treatment team's continuous monitoring, coordination of care, and timely return to the operating room to address post-operative complications, contributed to the patient's successful recovery.

## **Other Findings: Deficiencies Identified in Patient Consent and Time-out Protocols**

The OIG identified deficiencies in facility [practitioners'](#) and surgical nurses' compliance with patient safety procedures. When reviewing the three patients' six surgical or invasive procedures, the OIG identified that neither an informed consent nor a time-out was completed for one procedure and found a pattern of failing to confirm applicable radiological imaging on the time-out checklists. Although medical imaging is not applicable to all surgical and invasive procedures, the pattern of marking "not applicable" to the time-outs reviewed (one time-out for Patient A, one time-out for Patient B, and three time-outs for Patient C) raised concern. VHA requires the completion of patient safety protocols to ensure the correct surgical or invasive procedure is performed on the correct patient and at the correct site.

The OIG made one recommendation to the Veterans Integrated Service Network Director related to facilitating a comprehensive review of Patient A's episode of care. The OIG made six recommendations to the Facility Director related to admitting and transferring medically-complex patients, peer review for quality management practices, timeliness of institutional disclosures and root cause analysis, the vascular surgeon's disregard of patient safety protocols, and informed consent and time-out practices.

## Comments

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



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## Abbreviations

CT	computerized tomography
EHR	electronic health record
FPPE	focused professional practice evaluation
OIG	Office of Inspector General
RCA	root cause analysis
tPA	tissue plasminogen activator
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



## Introduction

The VA Office of Inspector General (OIG) conducted an inspection to review allegations of adverse clinical outcomes related to surgical procedures at the Columbia VA Health Care System (facility) in South Carolina.<sup>1</sup>

### Background

The facility, part of Veterans Integrated Service Network (VISN) 7, consists of the Wm. Jennings Bryan Dorn VA Medical Center located in Columbia, South Carolina, and seven community-based outpatient clinics. The facility provides comprehensive health care “through primary care, tertiary care and long-term care in areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, cardiology, neurology, oncology, dentistry, geriatrics and extended care.” From October 1, 2020, through September 30, 2021, the facility served 86,913 patients. The facility is classified as a 1b high-complexity facility with 112 hospital beds and 94 community living center beds.<sup>2</sup> The facility is affiliated and co-located with the University of South Carolina School of Medicine.

### Allegations and Related Concerns

On July 2, 2021, the OIG received a complaint alleging that patients experienced adverse clinical outcomes related to surgical procedures performed at the facility. The OIG received three patient case examples.

During the inspection, the OIG identified concerns regarding facility quality management processes and facility leaders’ responses to the adverse clinical outcomes for two of the three patients. These concerns are addressed directly within the inspection results related to the specific patient.

The OIG also identified concerns regarding facility staff’s compliance with patient informed consent and time-out protocols. As these concerns are not specific to one patient, they are listed separately.

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<sup>1</sup> In the context of this report, the OIG defines an adverse clinical outcome as any incident, complication, or adverse event related to an invasive procedures or surgical intervention, regardless of the incident, complication, or adverse event being a known risk or leading to an increased level of care.

<sup>2</sup> VHA Office of Productivity, Efficiency and Staffing, accessed July 27, 2021. The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex.

## Scope and Methodology

The OIG initiated the inspection on July 29, 2021, and conducted a virtual site visit from September 13–16, 2021. Virtual interviews were conducted prior to, during, and following the site visit.

The OIG team interviewed leaders from VHA's National Surgery Office and the VISN 7 Chief Surgical Consultant. Additional interviews included select members of the facility's executive leadership team (facility leaders); the Chiefs of Quality Management, Radiology, and Surgical Services; and quality management, nursing, medicine, infectious disease, and surgical staff who were familiar with one or more of the patients' episode(s) of care.<sup>3</sup> The OIG team also interviewed non-VHA staff, including a former surgical [resident](#) and a medical student.

The OIG team reviewed relevant VHA and facility policies, internal quality and administrative reviews, peer review reports, and relevant committee meeting minutes from September 2020 through October 2021. The OIG team also reviewed the electronic health records (EHRs) of the three identified patients during the time frame specific to each surgical procedure and one patient's autopsy report.

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

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1101, 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.

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<sup>3</sup> Facility leaders interviewed included the Facility Director, Chief of Staff, and Associate Director for Patient Care Services.

## Patient Case Summaries

### Patient A: Chest Tube Placement

Patient A, who was in their 50s, had a complex medical history that included [nasopharyngeal carcinoma](#) treated with [chemotherapy](#) and [radiation therapy](#) resulting in a severe radiation injury to the jaw.<sup>4</sup> Consequently, the patient had limited mouth opening (approximately one centimeter), vocal cord paralysis, difficulty swallowing, and a low functioning thyroid.

In early summer 2021 (day 1), the patient presented to the facility's Emergency Department with a one-week history of right upper abdominal and right-sided [pleuritic chest pain](#) associated with shortness of breath. Laboratory results revealed an elevated white blood cell count and a low [hemoglobin](#) level. The patient had low blood pressure that was treated with intravenous fluids but did not improve. A [computerized tomography](#) (CT scan) of the abdomen and pelvic region showed a large right [pleural effusion](#). The patient was admitted to the intensive care unit for further evaluation and management.

On day 2, at 4:48 a.m., the intensive care unit attending physician documented that the patient was stable and would need [thoracentesis](#) and possible [chest tube](#) placement to treat the pleural effusion. At 8:56 a.m., a facility medical [intensivist](#) entered a procedure note documenting the placement of a [pigtail catheter](#) (catheter). The procedure note reflected that the patient was placed in an upright position, and an ultrasound was used to identify and locate the right-sided pleural effusion. A large needle was inserted into the patient's [pleural cavity](#) (space between the layers of [pleura](#)). The medical intensivist noted that "no fluid was obtained but there appeared to be clotted blood trying to enter the syringe."<sup>5</sup> The medical intensivist placed a guidewire through the needle and placed a catheter over the guidewire. No fluid was obtained through the catheter. The medical intensivist ordered [tissue plasminogen activator](#) (tPA), [dornase alfa](#), and a chest x-ray and documented "no immediate complications."<sup>6</sup> Following the procedure, a chest x-ray was obtained at 8:55 a.m., to verify the correct placement of the catheter. The radiology report stated, "A right pigtail catheter is noted. A PA [[posteroanterior](#)] and lateral view of the chest obtained to evaluate the position of the right pigtail catheter." The report's diagnostic code was "ABNORMALITY, ATTN. [attention] NEEDED." The position of the catheter could not be verified.

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<sup>4</sup> The OIG uses the singular form of they (their) in this instance for privacy purposes. The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

<sup>5</sup> ClinicalKey, "Chest Tube Placement," accessed December 29, 2021, [https://www.clinicalkey.com/#!/content/medical\\_procedure/19-s2.0-mp\\_GS-066](https://www.clinicalkey.com/#!/content/medical_procedure/19-s2.0-mp_GS-066). When the chest tube enters the pleural cavity, a "pop may be felt and a rush of air or fluid may occur."

<sup>6</sup> For purposes of this report, the OIG will use tPA when referring to the combination of tPA and dornase alfa.

The medical intensivist documented administering tPA into the patient's pleural space at 10:30 a.m. At 12:45 p.m., the medical intensivist returned to withdraw the tPA and pleural fluid and drew back "pure blood." The medical intensivist noted that, approximately 10 minutes after withdrawing the tPA, the patient became [hypotensive](#); and that the patient "has rapidly become unstable. Most likely cause at this point is [hemorrhagic shock](#)." The medical intensivist noted calling a facility thoracic surgeon to evaluate the patient's condition for "possible [hemothorax](#)." The medical intensivist placed a thoracic surgery consult at 12:57 p.m., and entered a note at 1:24 p.m., emphasizing that the patient's instability required immediate blood transfusion and intravenous vasopressors (drugs used to elevate the blood pressure).

At 1:32 p.m., a radiology technician documented the patient's nurse was contacted and informed that the radiology department was ready to perform the patient's CT scan (ordered by the medical intensivist at 12:55 p.m., for pleural effusion and possible hemothorax). The patient's nurse informed the technician that the patient was receiving blood emergently and the nurse would contact the radiology department when the patient was ready. Over the next four hours, the patient received six units of blood.

A repeat chest x-ray, completed at 2:47 p.m. showed the "pigtail catheter [was located in the] right quadrant [of the abdomen] and a larger right pleural effusion." At approximately 3:52 p.m., the thoracic surgeon initiated a right chest tube placement procedure in a second attempt to drain the patient's pleural effusion. After placement, no fluid returned via the chest tube. According to the thoracic surgeon's note, the post procedure chest x-ray revealed the tube to "be in good position" with no [pneumothorax](#), the right pleural effusion was unchanged, and there was no fluid returning in the chest tube. The thoracic surgeon documented that the consult was completed at 5:15 p.m.

At 8:29 p.m., a CT scan taken of the patient's chest and abdomen yielded critical results revealing the catheter placed by the medical intensivist was not located in the pleural space, and the catheter tip was not visible; further, the chest tube inserted by the thoracic surgeon was not in the pleural space but located in the [subcutaneous](#) space tracking to the patient's back. Intrabdominal fluid was noted, presumptively blood. Throughout the night, volume resuscitation continued using blood products.

On the morning of day 3, a critical care intensivist noted the vasopressor requirements had decreased from the day prior and that the patient continued to have abdominal pain. The patient's abdomen was distended and there was evidence of shock liver (very high liver enzymes in the blood). The plan was to obtain a CT scan of the patient's abdomen and pelvis to evaluate for active bleeding, and if so, the patient would be transferred to a hospital that had interventional radiology. If not actively bleeding, the patient's care would be managed at the facility.<sup>7</sup>

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<sup>7</sup> The OIG team did not find evidence that a CT scan of the patient's abdomen and pelvis was ordered or completed on July 1, 2021.

Later that morning, the thoracic surgeon rereviewed the patient's earlier images, noted the catheter "skirts the edge of the liver" and because of the large amount of blood in the peritoneal cavity determined the best course of treatment was to bring the patient "straight to the OR [operating room]." The patient was taken to the operating room at approximately 1:00 p.m. for an exploratory [thoracoscopic](#) exam and [laparotomy](#) to determine the cause and possible intervention for the bleeding and the pleural effusion. Because of the patient's jaw injury from radiation therapy and limited mouth opening, the surgical team planned to manage the patient's airway by conducting an awake nasal [intubation](#) with a [tracheostomy](#), if needed. In the operating room, while the [anesthesiologist](#) was dilating the nostrils, the patient began bleeding profusely from the nose and eventually became unresponsive. The surgical team attempted manual [ventilation](#). The patient went into [ventricular fibrillation](#) and the surgical team began [cardiopulmonary resuscitation](#). The thoracic surgeon proceeded with an emergent tracheostomy. The surgical team inserted a tracheostomy tube to ventilate the patient. The patient received six rounds of medications to restore cardiac rhythm but the surgical team was unable to revive the patient.

## **Patient B: Toe Amputation**

Patient B, who was in their 80s, had a medical history of [paraplegia](#), [diabetes](#), and a fifth digit (toe) amputation of the right foot. In early fall 2020 (day 1), the patient presented to the facility's Emergency Department because of blackened areas on the tips of the toes on the right foot (second, third, and fourth toe). The patient had a CT scan of the right foot. The radiologist's CT scan interpretation report cited soft tissue swelling throughout the foot and bone destruction of the fourth toe, "strongly suggestive of [osteomyelitis](#) of the fourth toe." Internal medicine providers admitted the patient to the medicine floor and consulted with a [vascular](#) surgeon.

The vascular surgeon completed a history and physical consult on day 3, noting the patient's right fourth toe had osteomyelitis and needed to be amputated. The vascular surgeon noted that the patient's other toes were scabbed with dried blood, [macerated](#), and stuck together.

An infectious disease [fellow](#) and supervising infectious disease physician (supervising physician) saw the patient and documented the patient's right foot was swollen with [necrotic](#) tips on the four toes, macerated skin between the third and fourth toe web space, and had a foul-smelling discharge. The fellow reviewed the CT scan of the right foot with the radiologist and noted that there was no osteomyelitis in the third toe, only the fourth toe. The fellow discussed the patient with the vascular surgeon and documented that the vascular surgeon thought the fourth toe amputation was reasonable and attributed the necrotic area on the tips of the toes were likely the result of friction injuries. The fellow's supervising physician added an addendum to the note agreeing with the plan to amputate the fourth toe. The patient signed an informed consent, presented by the vascular surgeon, for a right fourth toe amputation.

On day 4, a surgical nurse documented a time-out noting that the site of the operation, the patient's right fourth toe, was correctly marked with the physician's initials. The vascular surgeon and the surgical resident, with a medical student in attendance, performed the surgical procedure. Post-surgery, the vascular surgeon documented a brief operative note citing both the pre- and post-operative diagnosis of "osteomyelitis right fourth toe" and the operation to be a "right toe amputation and bone culture." The removed toe was sent from the operating room to the pathology department; the [pathologist's](#) report evaluated a specimen labeled as the patient's right fourth toe and found [coagulative necrosis](#) of the skin and chronic osteomyelitis of the bone.

On day 8, the infectious disease fellow and supervising physician saw the patient to evaluate the patient's right foot. The fellow initially noted the patient's fourth toe was amputated but later amended the EHR note documenting that the patient's third toe was amputated and that the fourth toe "which had radiological osteomyelitis, but no clinical overlying ulcer or cellulitis, has not been amputated." The fellow and supervising physician documented discussion about the patient's case and no clinical signs indicating the fourth toe needed further treatment.

In mid-spring 2021, facility leaders became aware that the vascular surgeon amputated the patient's third, versus fourth, toe. Nearly eight months after the surgical procedure, the vascular surgeon completed the patient's operative report and documented the pre- and post-diagnosis as "[o]steomyelitis right toe/foot..." and referred to the amputated toe as "digit of the right foot..." The Chief of Staff and other facility and service leaders completed an [institutional disclosure](#) with the patient. The institutional disclosure noted, "This is a wrong site surgery, which took place in [early fall], 2020, where the right 3rd toe instead of the right 4th toe was mistakenly amputated."

## **Patient C: Robotic-Assisted Laparoscopic Hemicolectomy**

Patient C, who was in their 60s, underwent a colonoscopy in late 2020; at that time, a large flat [cecal polyp](#) was discovered. The [gastroenterologist](#) placed a surgical consult, and after further evaluation, the patient was scheduled for a robotic-assisted [laparoscopic](#) right [hemicolectomy](#). Approximately two months later (day 1), a surgeon oversaw a resident's completion of the patient's hemicolectomy. The surgeon completed the operative summary and indicated the patient had minimal blood loss. During the procedure, the patient was checked for bleeding and no immediate complications were present. Following the procedure, the patient was treated for elevated blood pressure; subsequently, the patient became hypotensive and did not respond to intravenous fluid. The patient received a blood transfusion due to low hemoglobin levels. The patient's mental status progressively decreased, and the patient was emergently intubated and prepared for an exploratory laparotomy. During exploration, the surgeon did not find vessels or a source of bleeding, evacuated clots and blood, performed intra-abdominal packing, and placed a wound vacuum-assisted closure machine. A blood clotting issue was considered as a factor in the cause for the bleed. The patient remained intubated in anticipation for a return to the operating room for re-exploration and abdominal wound closure. On day 3, the patient returned to the

operating room; the surgeon found the patient's bleeding had resolved and removed the abdominal packing and closed the abdominal wound. The patient had a rapid recovery and was discharged on day 7.

## Inspection Results

### 1. Adverse Clinical Outcomes

The OIG substantiated three patients experienced adverse clinical outcomes related to the surgical or invasive procedure(s):

- Patient A—incorrect placement of chest catheter and tube
- Patient B—wrong site surgery for a toe amputation
- Patient C—complication from a robotic-assisted laparoscopic hemicolectomy

#### Patient A: Incorrect Placement of Chest Catheter and Tube

The OIG identified several clinical care deficiencies made by a medical intensivist and a thoracic surgeon that led to a series of unplanned events and contributed to Patient A's death.

Additionally, the OIG identified that the lack of facility specialty resources (an ear, nose, and throat physician and interventional radiologist) limited the clinical interventions needed for Patient A's care.

#### *Methods for Draining Pleural Collections*

Patients who develop an excess collection of fluid (pleural effusion), pus ([empyema](#)), gas or air (pneumothorax) in their pleural cavity may require a medical [practitioner](#) to insert a drain into the pleural cavity to drain the collection. Two common drains are a pigtail catheter (catheter) and a chest tube. Each drain has advantages and disadvantages and is preferred under certain conditions. Catheters are smaller in size, more flexible, and easier to insert than chest tubes and are associated with lower complication rates; however, catheters are ineffective in draining thick fluid and have a higher likelihood of clogging, kinking, and obstruction. Chest tubes are larger in diameter allowing for collections to be drained more rapidly and are effective in draining thick fluid; however, chest tube insertions are more painful, create more tissue damage, and are more likely to cause injury to adjacent structures such as arteries, nerves, and lungs. The choice of drainage method depends on the type of fluid needing removal.<sup>8</sup>

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<sup>8</sup>Alla Elsayed, et al, "Implication of pigtail catheter vs chest tube drainage," *International Journal of Community Medicine and Public Health* 5; 9 (September 2018), 3686-3690.

### *Medical Intensivist*

The OIG found that a medical intensivist administered tPA into the catheter prior to verification that the catheter was correctly located within the patient's pleural space.

The facility's Chief of Staff reported that the standard practice is for a practitioner to obtain a chest x-ray following the placement of a chest catheter or tube to verify correct placement. VHA policy requires ordering practitioners to initiate appropriate clinical action and follow up on abnormal results.<sup>9</sup>

During an OIG interview, the medical intensivist recalled reporting for duty in the intensive care unit at 8:00 a.m. on day 2 of Patient A's hospitalization. Upon arrival, the medical intensivist and the outgoing intensive care unit physician discussed the patient's condition, which they thought would benefit from a chest tube.

According to EHR documentation, the medical intensivist placed a catheter that morning in an attempt to drain the patient's pleural effusion. After inserting the catheter, the medical intensivist did not obtain a return of fluid as expected but rather noted the appearance of clotted blood. The medical intensivist ordered tPA (to dissolve the clotted blood) and noted that a chest x-ray was pending.

In an interview with the OIG team, the medical intensivist explained that after placing the catheter there was minimal fluid return and attributed this to the fluid being too thick to return through the catheter. After a period of observation without fluid return, the medical intensivist administered the tPA. When the OIG team asked if the medical intensivist was confident the catheter tip was in the pleural effusion, the intensivist stated, "that was my assumption."

Per EHR documentation, the medical intensivist administered the tPA at 10:30 a.m.; subsequently, the patient's medical status rapidly became unstable requiring blood transfusions and vasopressors for low blood pressure. At approximately 12:55 p.m., the medical intensivist placed an order for a CT scan, spoke with a facility thoracic surgeon, and placed a thoracic surgery consult.

The radiologist's impression of the single view chest x-ray noted a large pleural effusion and the presence of a catheter. The radiologist recommended further imaging to determine the position of the catheter and marked the exam as "ABNORMALITY, ATTN. [attention] NEEDED."<sup>10</sup> The OIG team did not find evidence in the EHR that the medical intensivist obtained the suggested additional imaging or acknowledged the radiologist's documentation of an abnormality needing

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<sup>9</sup> VHA Directive 1088(1), *Communicating Test Results to Providers and Patients*, October 7, 2015, amended January 24, 2022.

<sup>10</sup> Although the radiologist did not clearly state that additional imaging was needed to verify the position of the catheter, based on the documentation, the OIG would have expected a provider to understand the recommendation for a posteroanterior and lateral x-ray.

attention. When asked why neither the abnormal results were addressed nor additional images obtained, the medical intensivist did not recall the radiology report suggesting further imaging. However, the medical intensivist reported independently reviewing the imaging results and thought the catheter was placed correctly.

The OIG found that because the medical intensivist incorrectly assumed that the catheter was placed in the patient's pleural cavity and the lack of fluid return was due to clotted blood, tPA was administered prior to receiving radiological imaging to verify proper catheter placement. Although the medical intensivist initially ordered a chest x-ray to verify catheter placement, after the x-ray did not confirm the catheter's location the medical intensivist failed to address the "abnormal" imaging results and the radiologist's recommendation for further imaging. The patient's medical status rapidly declined following the medical intensivist's administration of tPA into the catheter.

### *Thoracic Surgeon*

The OIG found that after being consulted to evaluate the patient's rapid decline and possible hemothorax, the thoracic surgeon focused efforts on treating the patient's pleural effusion. The thoracic surgeon placed a chest tube in a second attempt to drain the patient's pleural effusion; however, the effusion was not relieved. Diagnostic images showed the chest tube was also misplaced and not in the patient's pleural cavity.

VA defines quality care as providing the right type of care for a patient's health condition, that keeps the patient safe from hazards and harm, and results in the best possible outcome.<sup>11</sup>

The patient's EHR indicates the thoracic surgeon responded to and completed the medical intensivist's consult on the day it was entered noting 240 minutes of "face-to-face" time spent with the patient. The consult for a possible hemothorax noted the patient's low blood pressure indicated possible hemorrhagic shock without a clear source of bleeding.

During an interview, the thoracic surgeon stated that the medical intensivist called after the patient became hypotensive and had a rapid heart rate. The medical intensivist was uncertain why the chest catheter had not relieved the patient's pleural effusion. The thoracic surgeon reported reviewing the patient's chest x-ray and thought the catheter was positioned low in the chest or abdominal cavity but stated that the pleural effusion was also low. Furthermore, although a CT scan of the chest was needed to determine the location of the catheter and to determine why the pleural effusion had not been relieved, the patient was not medically stable for transport to the radiology department.

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<sup>11</sup> "Quality of Care," VA Benefits and Health Care, accessed September 30, 2021, <https://www.va.gov/QUALITYOFCARE/>.

At approximately 3:52 p.m., the thoracic surgeon placed a chest tube in a second attempt to drain the patient's pleural effusion. The thoracic surgeon documented the completed consult at 5:15 p.m., noting that although the post procedure chest x-ray showed the chest tube was "in good position," the effusion did not drain. When queried, the thoracic surgeon informed the OIG team that they (medical intensivist and thoracic surgeon) could not determine why the patient's hemoglobin kept dropping. Although the patient appeared to be bleeding, the source was not found until approximately four hours later when a CT scan was completed and the results indicated bleeding in the abdominal cavity.

The patient was taken for a CT scan that evening, which revealed a "critical abnormality" misplacement of both the catheter and the chest tube. At 8:23 p.m., the interpreting tele-radiologist verbally communicated the findings to the medical intensivist, who then conveyed the results to the thoracic surgeon. After receiving multiple blood transfusions and vasopressors overnight the patient's blood pressure stabilized but hematocrit remained low and heart rate remained elevated.

The morning of day 3, a critical care intensivist documented the plan was for the patient to have a CT scan of the abdomen and pelvis to determine whether the patient was actively bleeding, and if so, the patient would be transferred to a hospital that had interventional radiology. If not actively bleeding, the patient's care would be managed at the facility.<sup>12</sup> Shortly thereafter, the thoracic surgeon reviewed the images and documented in the patient's EHR that the catheter "just skirts the edge of the liver" and due to the large amount of intra-abdominal bleeding the best treatment plan would be to bring the patient "straight to the OR [operating room]" for an exploratory laparotomy and biopsy of the pleural tissue.

The EHR documentation reflected the patient was taken to surgery for the exploratory laparotomy with nasal intubation at approximately 1:00 p.m. During an OIG interview, the anesthesiologist stated that because of the pre-existing significant radiation injury to the neck and limited mouth opening during the operative procedure it was necessary to secure the patient's airway by either nasal intubation or a tracheostomy. The anesthesiologist explained that the facility did not have an ear, nose, and throat surgeon to consult and added that having an ear, nose, and throat evaluation to determine the amount of scar tissue on the patient's trachea, evaluate for nasal tumors, and provide guidance on the best course of intubation would have been helpful. The OIG reviewed surgical meeting minutes from September 2020 through October 2021 and found the lack of and need to recruit ear, nose, and throat physicians to be a standing agenda item.

According to the thoracic surgeon, the decision to wait until the following day to operate was made in collaboration with the Chief of Anesthesia and the Chief of Surgery. The decision was

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<sup>12</sup> The OIG team did not find evidence that a CT scan of the patient's abdomen and pelvis was ordered or completed on day 3 of Patient A's hospitalization.

based on the patient “clinically responding to the [increased] volume [blood transfusions and]...coming off of the [vaso]pressors,” and “was not unstable.” The thoracic surgeon explained that the patient’s medical history and anticipation of a difficult airway in the operating room factored into the decision to operate the following day when full operating room support would be available.

The OIG concluded that the medical intensivist placed a catheter in the patient’s abdomen, instead of the pleural space, and without ensuring proper catheter placement injected a clot-dissolving enzyme into the catheter after which the patient’s [hemodynamic](#) status deteriorated. The thoracic surgeon failed to place a chest tube in the patient’s pleural space; consequently, the pleural fluid did not drain. Further, the lack of an ear, nose, and throat physician impaired the operative team’s ability to properly secure the patient’s airway in preparation for abdominal surgery to control the bleeding. The OIG found that the facility lacked the resources, specifically, interventional radiologists; ear, nose, and throat physicians; and full evening operative room support needed to address the patient’s complex, dynamic medical needs. The patient’s acute illness superimposed with the pharyngeal cancer had surgical demands that exceeded the facility’s capabilities.

### **Related Concern: Deficiencies in Quality Management Processes**

On the day of Patient A’s death, Surgical Services staff completed a [critical incident tracking notification](#) and an [issue brief](#) notifying facility leaders, quality management staff, VISN staff, and the National Surgery Office of the patient event. Although quality management staff and facility leaders immediately began reviewing Patient A’s death, the OIG found several deficiencies in the quality management processes including insufficient peer reviews; lowering peer review finding levels; and delays in the initiation of an institutional disclosure and completion of a [root cause analysis](#) (RCA).

#### *Peer Review for Quality Management*

The OIG determined that there were deficiencies in the peer review process related to Patient A’s surgical procedures and death. The OIG found that the thoracic surgeon, who did not fully assess the patient, incorrectly placed the patient’s chest tube, and was the patient’s attending surgeon in the operating room on the day of the patient’s death, was not peer reviewed. The OIG found the facility’s final peer review of the medical intensivist failed to identify critical areas for improvement and the peer review committee meeting minutes did not include individualized rationale for the final rating.

A peer review for quality management purposes is a confidential, non-punitive process for evaluating health care provided by an individual, designed to promote patient safety, organizational improvements, and optimal patient outcomes. VHA policy requires that certain clinical events, such as major [morbidity](#)s related to surgical care, are evaluated to determine

whether a peer review is indicated. Additionally, patient deaths associated with an adverse event, complication of treatment, and during a surgical or invasive procedure require a peer review. Identifying areas for improvement by one or multiple clinicians is achieved through systematic and credible peer reviews. Peer reviews are completed and rated a Level 1, 2, or 3 by a practitioner with similar practices and privileges; the rating is based on what the reviewer would have done with the same set of clinical circumstances as the provider under review.<sup>13</sup> All Level 2 and 3 initial peer reviews are evaluated and discussed by the peer review committee to determine a final peer review level. The peer review committee is responsible for “ensuring that formal discussions regarding a peer review” during committee “meetings are recorded in formal meeting minutes.”<sup>14</sup> The peer review committee is required to review initial assignments, provide final level assignments, and make recommendations to improve the quality of health care delivered.

The OIG learned that following Patient A’s death, two risk managers completed a clinical review of the adverse event and made the recommendation for peer reviews to be conducted for four practitioners involved in the patient’s episode of care; however, neither risk manager recommended that a peer review be completed for the thoracic surgeon.<sup>15</sup> When the OIG inquired why a peer review was not recommended nor conducted on the thoracic surgeon, a risk manager cited a lack of documentation indicating the thoracic surgeon’s awareness that the chest tube had been incorrectly placed. The OIG did not find that VHA policy provides exceptions for conducting peer reviews based upon a provider’s lack of awareness.

The peer review committee’s meeting minutes revealed that the committee assigned the medical intensivist a final rating without documenting the committee’s discussion specific to the case or rationale used to arrive at the rating. The OIG had concerns with the committee’s rating and was unable to evaluate the rationale for the decision since the discussion was not captured in the meeting minutes.

The OIG reviewed the peer review committee minutes from September 2, 2020, through August 16, 2021, and found that 16 initial peer review ratings of either Level 2 or 3 were lowered by the committee to a final rating of Level 1. For 8 of the 16 peer reviews, meeting minutes documentation failed to describe the committee’s decision-making process in determining that the initial peer review was incorrectly rated and should be lowered. Instead, the peer review committee minutes reflected use of a generic, standardized statement, such as “Committee members discussed case and took into consideration the written input of the provider. Committee

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<sup>13</sup> VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. “Level 1 is the level at which most experienced and competent clinicians would have managed the case in a similar manner. Level 2 is the level at which most experienced and competent clinicians might have managed the case differently but it remains within the standard of care. Level 3 is the level at which most experienced and competent clinicians would have managed the case differently.”

<sup>14</sup> VHA Directive 1190.

<sup>15</sup> For the purposes of this report, the OIG refers to the patient’s episode of care as the day of admission to the facility through the day of the patient’s death.

members determined that standard of care was met by the provider and that most providers would have managed the case similarly.” The statement varied by one to two words depending upon whether the committee considered written and verbal input of the provider.

The OIG identified deficiencies in the facility’s completion of peer reviews, specifically failing to complete a peer review for the thoracic surgeon. In addition, the OIG was concerned about the peer review committee’s rating decision regarding the medical intensivist and found the committee’s discussion was not documented in committee meeting minutes. Furthermore, the facility’s peer review committee documented a generic statement in lieu of case-specific committee discussion when reviewing and reducing initial Level 2 and Level 3 peer reviews to a Level 1 rating. These deficiencies weaken the peer review process and its overarching purpose of ensuring patient safety.

### *Delay of an Institutional Disclosure*

The OIG determined that facility leaders delayed the initiation of an institutional disclosure with Patient A’s family. The OIG found that quality management staff followed an inherited practice of waiting for the completion of an autopsy before determining whether an institutional disclosure would be conducted.

VHA policy directs facilities to disclose adverse events to a patient or their personal representative when there are unanticipated outcomes of care. VHA defines an adverse event as “untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers.”<sup>16</sup> Facility leaders and clinicians collaboratively complete an institutional disclosure to inform a patient or their personal representative of their rights and recourse when an adverse event, regardless if in error, resulted in or was reasonably expected to result in death or serious injury. The disclosure of an adverse event may not always be “a singular event, but may involve a series of conversations,” particularly if additional information is learned regarding the event.<sup>17</sup> Institutional disclosures are intended to be ongoing (allowing for communication of new information about the incident as it is obtained) and timely (generally as soon as possible or within seventy-two hours). When institutional disclosures are not completed as required, patients and their representatives may inadvertently be denied their rights.<sup>18</sup>

During an interview, the Chief of Quality Management informed the OIG team that the facility was waiting for the autopsy results prior to determining whether to conduct an institutional disclosure with the patient’s family. When questioned why, the Chief of Quality Management stated that the practice of awaiting autopsy results prior to reviewing the event for an institutional

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<sup>16</sup> VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

<sup>17</sup> VHA Directive 1004.08.

<sup>18</sup> VHA Directive 1004.08.

disclosure was not formal guidance through VHA policy but rather an inherited practice from a previous leader in quality management who had since retired. The Facility Director confirmed the practice of postponing institutional disclosures until receiving autopsy results when specifics about a death were unclear. The Facility Director admitted that the autopsy did not provide additional details and, based on the information they originally had, they would do an institutional disclosure. The facility received the autopsy results approximately four months after Patient A's death. The day after receiving the autopsy results, facility leaders initiated the institutional disclosure process.<sup>19</sup>

The OIG concluded that facility leaders did not conduct an institutional disclosure as soon as possible or within 72 hours but waited nearly four months after the death to initiate contact with the patient's family. The OIG learned that the Chief of Quality Management and quality management staff maintained a practice of postponing institutional disclosures until an autopsy, when applicable, was completed. The OIG found that the practice of waiting for autopsy results was not based in policy and resulted in the delay of patients or their representatives being advised of their rights and resources.

### *Delayed RCA*

The OIG determined that the Facility Director and patient safety staff did not complete an RCA for Patient A within the required 45-day time frame, delaying the opportunity for facility leaders to identify and address system vulnerabilities.

VHA has implemented approaches to improve patient safety, including the reporting of patient safety incidents. An RCA is one of the processes used to identify the contributing factors to adverse events or close calls.<sup>20</sup> An RCA must be initiated, completed, and signed by the Facility Director within 45-days of the facility becoming aware that a review is required.<sup>21</sup> A delay in investigating and correcting system vulnerabilities allows opportunities for patient harm to persist.<sup>22</sup>

On the day of Patient A's death, facility leaders were notified. According to patient safety records, an anesthesiologist entered the patient incident into the Joint Patient Safety Reporting system the next day.<sup>23</sup> Four days after the report was entered, patient safety staff finalized the incident report and found that the incident met criteria for an RCA. However, the Facility Director did not sign the RCA charter until 65 days later. The Facility Director gave final

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<sup>19</sup> The autopsy confirmed an acute intrabdominal hemorrhage and that the catheter was in the upper central abdomen.

<sup>20</sup> VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, March 4, 2011.

<sup>21</sup> VHA Handbook 1050.01.

<sup>22</sup> VHA National Center for Patient Safety, *Guide to Performing a Root Cause Analysis*, Revision 02/05/2021.

<sup>23</sup> VHA National Center for Patient Safety, *2020 JPSR Business Rules and Guidebook*, July 2020. The Joint Patient Safety Reporting System is the VHA patient safety event reporting system and database.

concurrence for the RCA team's findings and action plan 108 days after the need for an RCA was identified. In an OIG interview, the facility's Quality Manager attributed the RCA delay to competing priorities and staff shortages (staff detailed to other services to assist with COVID-related needs, staff retirements, and lengthy position vacancies).

The OIG concluded that the Facility Director and patient safety staff did not complete the RCA within the 45-day requirement. The delay prevented facility leaders from identifying and addressing system vulnerabilities at an earlier date.<sup>24</sup>

### **Patient B: Wrong Site Surgery for a Toe Amputation**

The OIG substantiated that Patient B's wrong site surgery, overseen by a vascular surgeon, was an adverse clinical outcome. The OIG noted the patient signed an informed consent for the removal of the fourth toe on the right foot and the surgical team conducted a time-out verifying the removal of the fourth toe; however, at the operating table the vascular surgeon directed a surgical resident to amputate the patient's third toe. Although removal of the patient's third toe was clinically indicated; the OIG found that, the surgeon failed to acknowledge and discuss the deviation from the informed consent and pre-operative plan with the patient and surgical team. This omission is inconsistent with VHA policy and VHA's culture of safety embodied in the goals of a high reliability organization (HRO). Additionally, the vascular surgeon did not complete an operative report immediately following the surgery as required.

After removal of the third toe the patient recovered without complications. The OIG opined that had the third toe not been removed, healing of a surgical wound would have been difficult due to the existing infection thus, the removal of the third toe appears to have been the correct clinical action.

On July 1, 2004, The Joint Commission introduced the Universal Protocol as a mandatory quality standard to ensure the correct surgeries and nonsurgical invasive procedures are performed on the correct patient and site.<sup>11</sup> In alignment with this protocol, VHA standardized the required steps practitioners and procedure team members must complete to ensure that correct surgeries and invasive procedures are performed on the correct patient and site.<sup>11</sup> VHA requires a practitioner obtain an informed consent and conduct a time-out prior to the initiation of an invasive or surgical procedure.<sup>25</sup> The time-out must include the practitioner and requires members of the surgical team to verbally concur with each item on the time-out checklist, to include the correct site and correct marking of the surgical site for the procedure.<sup>26</sup> Additionally, VHA policy states, "if there is a significant deviation from the treatment plan to which the

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<sup>24</sup> The RCA concluded that the facility's limited access to interventional radiology may have been a contributing factor that limited clinical options requiring surgical intervention in the operating room with general anesthesia.

<sup>25</sup> VHA Directive 1039(2); VHA Handbook 1004.01 (4).

<sup>26</sup> VHA Directive 1039(2).

patient originally consented,” an informed consent discussion must be repeated, and when required, a new signed consent must be obtained.<sup>27</sup>

VHA’s journey to become an HRO began in 2019. Per VHA, an HRO “is an organization with a goal of achieving “zero harm” in an environment where accidents are expected due to complexity or risk factors.”<sup>28</sup> Three key pillars of an HRO are leadership commitment, safety culture, and continuous process improvement.<sup>29</sup> One way VHA promotes a culture of safety is through the VHA wide “Stop the Line” initiative that encourages employees to speak up and report any behaviors, actions, or inactions that could lead to error or patient harm.<sup>30</sup> The initiative protects employees from retribution when they report concerns to supervisors, team members, and VHA leaders.<sup>31</sup>

VHA policy states that “the author of the health record entry is responsible for completing, authenticating and correcting any health record deficiencies within the timeframe” stated by facility policies and by-laws.<sup>32</sup> Facility medical staff by-laws require the operating surgeon to complete an operative report “immediately following surgery. Immediately means upon completion of the operation or procedure, before the patient is transferred to the next level of care.”<sup>33</sup>

The OIG team reviewed the patient’s EHR and noted that documentation prior to the surgical procedure, including radiological imaging, pre-operative planning, and informed consent, consistently identified osteomyelitis in, and the vascular surgeon’s plan to amputate, the fourth toe. The history and physical, completed by the vascular surgeon, along with the EHR documentation reflecting the marking of, and patient’s concurrence with the site markings, all referenced the fourth toe of the right foot. The vascular surgeon confirmed the proper marking of the amputation site on the pre-procedural checklist, and the surgical team further confirmed the markings during the time-out. The vascular surgeon completed the brief operative note following the procedure and documented the pre-operative and post-operative diagnosis as “osteomyelitis

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<sup>27</sup> VHA Handbook 1004.01(4).

<sup>28</sup> VHA Directive 1026.01, *VHA Systems Redesign and Improvement Program*, December 12, 2019.

<sup>29</sup> VHA Directive 1003, *VHA Veteran Patient Experience*, April 14, 2020.

<sup>30</sup> “Stop the Line for Patient Safety Initiative,” Quality, Safety, and Value, <https://www.qualityandsafety.va.gov/stoptheline/stoptheline.asp>, accessed October 7, 2021. “Stop the Line” is a VA-wide initiative that empowers VHA employees to speak up immediately if they see a risk to patient safety.” As of March 15, 2022, this website has been removed.

<sup>31</sup> “Stop the Line for Patient Safety Initiative.”

<sup>32</sup> VHA Handbook 1907.1, *Health Information Management and Health Records*, rescinded March 19, 2015. This handbook was in effect for a portion of this timeframe of the events discussed in this report. It was rescinded and replaced by VHA Directive 1907.01, *VHA Health Information Management and Health Records*, April 5, 2021. The 2021 directive has the same or similar language as the 2015 handbook related to health information management and health records.

<sup>33</sup> Facility Memorandum 544-11-81, *2018 Bylaws and Rules of the Medical Staff*, August 3, 2018.

right 4th toe;" however, when documenting the operation performed and specimen removed, the vascular surgeon did not specify the number of the toe removed but stated "right toe amputation." The vascular surgeon did not complete an operative report at the time of the surgery.

The patient's EHR reflected that an infectious disease fellow and supervising physician evaluated the patient prior to and following surgery. Before surgery the infectious disease physicians noted the condition of the patient's toes on the right foot and documented discussing concerns regarding the patient's third toe with the radiologist and vascular surgeon. Following these discussions, the supervising physician added an addendum to the EHR note documenting agreement to proceed with the vascular surgeon's plan to amputate the patient's fourth toe. Four days after the surgery, the infectious disease physicians noted unwrapping the patient's right foot bandages and discovered that the third versus the fourth toe had been amputated. The documentation reflected that the fourth toe did not require further clinical intervention.

During an OIG interview, the supervising infectious disease physician reported evaluating the patient's right foot prior to the surgical procedure and making the assessment that the third toe was significantly infected and may need to be removed. The supervising physician shared the assessment with the vascular surgeon who reiterated the plan to amputate the patient's fourth toe shown to have osteomyelitis in the radiological images. Following the procedure, the supervising physician recalled evaluating the patient with the infectious disease fellow when they noted that the patient's third toe was amputated. The supervising physician did not consider that the event may have been a surgical error and, as such, did not inform facility leaders. The supervising physician attributed the amputation of the clinically infected third toe as an intraoperative decision.

The OIG found that subsequent to the surgery, with the exception of the infectious disease physicians' EHR notes, the majority of EHR entries completed by staff from various disciplines continued to incorrectly state that the patient's fourth toe had been amputated. Further, no EHR documentation from the vascular surgeon or surgical team members acknowledged a deviation from the original surgical plan or noted that the third toe had been amputated until discovered by facility leaders nearly eight months after the procedure.

In mid-spring 2021, during an unrelated administrative investigation, the quality management team was informed that during the investigation a surgical resident reported concerns regarding a wrong site surgery that occurred in the fall of 2020 for the patient.<sup>34</sup> Ten days after the surgical

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<sup>34</sup> Of note, the OIG learned that the facility identified the wrong site surgery while conducting an unrelated administrative investigation board that was reviewing allegations, many of which were substantiated, of inappropriate behavior and a hostile work environment from an attending surgeon towards a resident. Although the subject of the investigation was a surgical attending physician who is no longer at the facility, the investigation identified an incidental finding that surgical residents were alleging the "surgery department lack[ed] a culture of safety."

resident reported concerns, the patient was seen by a wound care provider who identified the third toe was amputated and the fourth toe remained intact and alerted the Chief of Surgery. An x-ray was performed, which confirmed the findings. After the Chief of Surgery's direction, the vascular surgeon completed the operative report 236 days after the surgery, and listed the pre-operative and post-operative diagnosis as "osteomyelitis right toe/foot with DJD [[degenerative joint disease](#)]." Of note, the vascular surgeon's brief operative note completed the day of the surgery provided diagnostic particulars specifying the fourth toe.

The OIG team interviewed the vascular surgeon, surgical resident, and medical student who were present for the surgical procedure. The surgical resident reported reviewing the radiological images, the radiologist's interpretation reflecting that the patient's fourth toe should be removed, and marked the fourth toe as the surgical site, prior to surgery. During the surgical procedure, the vascular surgeon conducted a clinical exam of the patient's toes, identified an infection, and directed the resident to remove the infected toe (later formally identified as the third toe). The resident told the OIG of questioning the vascular surgeon about the discrepancy between the toe identified in the radiological imaging and marked for removal and the toe identified during the operative clinical exam. The resident amputated the toe, as instructed. The vascular surgeon did not recall the resident questioning the removal of the infected toe. The OIG determined that a conversation did not occur to discuss the difference between the x-ray and informed consent reflecting the fourth toe removal, and the clinical exam which suggested the third toe should be removed.

The OIG concluded that the patient's wrong site surgery was an adverse clinical outcome. The OIG determined that the vascular surgeon deviated from the pre-operative plan (the x-ray and the informed consent reflecting the fourth toe for removal) when identifying the third toe to be amputated based on the surgeon's clinical evaluation of the patient's toes during the procedure. However, the surgeon failed to have a forthright acknowledgment and discuss the discrepancies with the surgical staff and patient. Additionally, the vascular surgeon failed to complete the operative report immediately following the surgery and did not do so until eight months later after being prompted by the Chief of Surgery. The less than straightforward documentation of the removal of the third toe and lack of discussion with surgical staff and the patient placed doubt on the integrity of the processes in place designed to promote quality medical care.

## **Facility Leaders' Response**

The OIG determined that facility and service line leaders failed to address the vascular surgeon's disregard for patient safety protocols and the undermining of HRO principles. Further, the OIG found that facility and service line leaders had not taken measures to ensure the vascular surgeon's future compliance.

VHA utilizes a management review process when the purpose of the review is to provide a basis for actions that may affect clinical privileges or personnel status. Management reviews include focused clinical care reviews and focused professional practice evaluations (FPPEs) for cause.<sup>35</sup>

A focused clinical care review is “a clinician-specific comprehensive clinical care review of a specific area of practice, a specific time period of practice, or both, when there is an identified concern or issue.” The focused clinical care review retrospectively reviews a clinician’s practice and determines what actions, if any, will be taken. One such action may include an FPPE for cause.<sup>36</sup>

An FPPE for cause is a structured process giving a privileged provider an opportunity to improve.<sup>37</sup> This is for a time-limited period that provides leaders an opportunity to assess a provider’s performance and determine if any action should be taken regarding the provider’s privileges. An FPPE for cause should be customized to the specific provider and the unique clinical concern. An FPPE for cause must include clearly-defined expectations that are linked to the identified deficiencies, and expected outcomes that are to be maintained during ongoing practice.<sup>38</sup>

The day after a surgical resident reported concerns regarding a wrong site surgery, Quality Management staff completed a clinical review that proposed several actions be completed including a peer review, a focused clinical care review, and an RCA. Ten days later, facility leaders used radiology imaging to confirm that a wrong site surgery had occurred. At that time quality management staff referred the incident to the Chief of Surgery to conduct a focused clinical care review.

The Chief of Surgery reviewed Patient B’s EHR, followed by a retrospective review of the 27 amputation procedures conducted by the vascular surgeon over a six-month period starting in late 2020. The Chief of Surgery did not identify a trend of wrong site amputations. The review found documentation deficiencies. The vascular surgeon completed four operative notes and the remainder were completed by residents. Out of the vascular surgeon’s four operative notes, one was completed on time and included clinical findings and a brief description of the procedure. The Chief of Surgery recommended that the vascular surgeon be placed on a 90-day FPPE for cause with a focus on correct site procedures and timely operative notes. The Chief of Surgery also indicated there was a potential “system failure on multiple levels” and recommended reinforcing the importance of the time-out protocol and culture of safety Stop the Line.

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<sup>35</sup> VHA Directive 1190.

<sup>36</sup> VHA Directive 1190.

<sup>37</sup> VHA Directive 1190.

<sup>38</sup> VHA Medical Staff Affairs Quality, Safety, and Value, Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE [focused professional practice evaluation] for Cause Guidance, Revision 3, January 2018.

During an interview with the OIG, the Chief of Surgery indicated that the Chief of Staff encouraged placing the vascular surgeon on an FPPE for cause and that the evaluation had been approved by the credentials committee. The OIG found the vascular surgeon had been placed on a 90-day FPPE for cause, and that the 90-day evaluation was successfully completed and signed by the Chief of Surgery 133 days after initiation. The FPPE for cause did not address the concerns identified in the focused clinical care review, which included late documentation, limited information in operative notes, and ensuring the correct surgical site.

During an OIG interview, the Chief of Staff acknowledged that the vascular surgeon was aware of and chose to proceed with the amputation of the patient's third versus the consented fourth toe. When asked what the vascular surgeon should have done in the operating room after determining that the third toe, rather than the fourth, required amputation, the Chief of Staff stated the vascular surgeon should have stopped the procedure and obtained a new patient consent identifying the removal of the third toe. Neither the focused clinical care review nor the FPPE for cause addressed the vascular surgeon's decision to proceed with removing the patient's third versus fourth toe despite this action being a violation of VHA policy. Neither the Chief of Surgery nor the Chief of Staff identified any further action specific to the vascular surgeon regarding the reinforcement of the importance of the time-out, culture of safety, and Stop the Line, as identified and recommended in the focused clinical care review.

The Facility Director chartered an RCA in the summer of 2021, which concluded 43 days later. The OIG concluded that for unknown reasons the Chief of Staff and Chief of Surgery failed to hold the vascular surgeon accountable for choosing not to follow patient safety protocols and undermining the culture of safety.

### **Patient C: Complication from a Robotic-Assisted Laparoscopic Hemicolectomy**

The OIG substantiated that the patient experienced an adverse clinical outcome following a robotic-assisted laparoscopic hemicolectomy. However, the OIG found the patient's treatment team that included the surgeon, surgical residents, and nursing staff immediately identified, closely monitored, and managed the surgical complication.

VA defines quality care as providing the right type of care for a patient's health condition that results in the best possible outcome.<sup>39</sup>

An OIG review of the EHR revealed the patient was scheduled for a robotic-assisted laparoscopic right hemicolectomy to remove a large cecal polyp in early 2021. Per the surgeon's operative report, the patient did not experience complications during the procedure; however, approximately three hours later, the patient's blood pressure and heart rate became elevated.

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<sup>39</sup> VA, Health Care, *Quality of Care*, accessed September 30, 2021, <https://www.va.gov/QUALITYOFCARE/>.

Following an administration of [labetalol](#) to treat the hypertension, the patient experienced a drop in blood pressure. The nursing staff notified the surgical resident and continued to monitor the patient's blood pressure. Despite receiving medication and intravenous fluids, the patient remained hypotensive. Nursing staff initiated an emergency response to assist with stabilizing the patient's low blood pressure. The patient was transferred to the intensive care unit.

The EHR documentation further reflected the cardiology service, critical care team, and the surgeon determined that the patient was likely experiencing an intrabdominal bleed. The surgeon and surgical resident returned the patient to the operating room the day after the surgery for an exploratory laparotomy. Blood clots were evacuated and the patient's abdomen was packed; however, the source of the bleeding was not identified. The following day the surgeon and surgical resident removed the abdominal packing and closed the patient's wound. The patient remained in the hospital for one week until discharged. Per an interview with the surgeon, the patient fully recovered, and returned to daily exercise activities such as swimming. Additionally, documentation in the patient's EHR supports that the patient recovered from the procedure.

The OIG concluded that the patient experienced a complication from the robotic-assisted laparoscopic surgical procedure. The OIG found that the treatment team's continuous monitoring, coordination of care, and timely return to the operating room to address post-operative complications, contributed to the patient's successful recovery.

## **2. Other Findings: Deficiencies Identified in Patient Consent and Time-out Protocols**

The OIG determined there were deficiencies in facility practitioners' and surgical nurses' compliance with patient safety procedures to ensure the correct surgical or invasive procedure was completed on the correct patient and at the correct site, as required by VHA policy. Specifically, when reviewing the three patients' six surgical or invasive procedures, the OIG identified that neither an informed consent nor a time-out procedure was completed for one procedure and found a pattern of failing to confirm applicable radiological imaging on time-out checklists.

VHA requires a practitioner to obtain an informed consent and conduct a time-out prior to the initiation of a surgical or invasive procedure.<sup>40</sup> The practitioner performing the procedure is responsible for ensuring the informed consent is obtained.<sup>41</sup> Prior to beginning the surgical procedure, the practitioner and a member of the nursing staff must complete a time-out using a checklist, which includes the confirmation of pertinent medical images, when applicable, by two

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<sup>40</sup> VHA Directive 1039(2).

<sup>41</sup> VHA Handbook 1004.01(4).

members of the surgical team prior to beginning the surgical procedure. “The physician performing the surgical procedure bears the primary responsibility for image verification.”<sup>42</sup>

While reviewing Patient A’s EHR, the OIG team did not find that the medical intensivist conducted an informed consent and a time-out prior to placing the chest catheter. During an interview, the medical intensivist recalled completing a time-out prior to the procedure but could not remember when an informed consent was completed. When asked, neither the medical intensivist nor quality management staff could locate or provide documented evidence that the consent or time-out was completed. In a follow-up email, the medical intensivist conveyed that if the patient’s informed consent and time-out could not be located in the EHR, then the medical intensivist failed to complete the documentation in the medical record.

The OIG team reviewed time-out documentation for the three patients’ surgical procedures and found that on each time-out checklist, surgical nursing staff had marked the confirmation of pertinent medical images as “not applicable.” In a response to the OIG team’s inquiry, the Associate Director for Patient Care Services and a nurse manager reviewed the procedures and noted multiple reasons nursing staff would mark “not applicable” on the checklist. The reasons included surgeons

- marking ‘not applicable’ on the pre-operative checklist statement that two providers were needed to confirm radiologic images;
- not identifying the need for or requesting the images;
- not bringing the images to the operating room; and
- not requiring imaging for the surgical procedure.<sup>43</sup>

The OIG team asked the facility’s Chief of Staff about the time-out concerns related to pertinent medical images. The Chief of Staff answered that for Patient A, the x-rays and CT scan were not critical information to be displayed in the operating room. Regarding Patient B, the Chief of Staff noted that hard copies of the medical images were not present or displayed on the computer within the operating room as the surgeon felt this was not clinically necessary. The Chief of Staff noted that for Patient C, displaying the pre-operative imaging was not crucial for the planned procedure. The Chief of Staff summarized that when hard-copy images are not present in the holding area, the answer on the checklist is “not applicable” as there is nothing to confirm. The Chief of Staff noted hard-copy films are rarely brought to the holding area to be confirmed prior to a surgery and that nursing staff could access images on the operating room computers, if needed.

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<sup>42</sup> VHA Directive 1039(2).

<sup>43</sup> Of note, the facility Chief of Staff stated that all surgical cases (with the exception of oral, plastic, and orthopedic) have digital images embedded in EHRs and, when needed, the circulating nurse could obtain and display the images at the computer station inside the operating room.

Although the OIG recognizes that medical imaging is not applicable to all surgical and invasive procedures, the pattern of marking “not applicable” to the time-outs reviewed (one time-out for Patient A, one time-out for Patient B, and three time-outs for Patient C) raised concerns. The facility leaders' response to the identified pattern is troublesome, especially considering Patient B's wrong site toe amputation was based on the imaging results that identified osteomyelitis in the fourth toe, the resident questioning the vascular surgeon about the imaging on the fourth versus the third toe, and the subsequent wrong toe amputation.

The OIG concluded that critical surgical and invasive procedure protocols were circumvented by multiple staff, and that facility leaders failed to recognize and address these patient safety deficiencies.

## Conclusion

The OIG substantiated three patients experienced adverse clinical outcomes related to surgical or invasive procedure(s). However, the OIG found concerns with the quality of care for Patients A and B but did not find concerns related to the quality of care for Patient C. The OIG identified multiple deficiencies in facility quality management processes and facility leaders' response to the adverse clinical outcomes for two of the three patients. The OIG also identified concerns regarding facility staff's compliance with patient informed consent and time-out protocols.

The OIG found that several clinical care deficiencies made by a medical intensivist and a thoracic surgeon contributed to Patient A's medical deterioration and led to a series of unplanned events and death. The medical intensivist placed a catheter in the patient's abdomen, instead of the pleural space, and without ensuring proper catheter placement, injected a clot-dissolving enzyme into the catheter after which the patient's hemodynamic status deteriorated. The thoracic surgeon failed to place a chest tube in the patient's pleural space; consequently, the pleural fluid did not drain. Further, the lack of ear, nose, and throat physicians impaired the operative team's ability to properly secure the patient's airway in preparation for abdominal surgery to control the bleeding. The OIG found that the facility lacked the resources, specifically, interventional radiologists; ear, nose, and throat physicians; and full evening operative room support needed to address the patient's complex, dynamic medical needs. The patient's acute illness superimposed with the pharyngeal cancer had surgical demands that exceeded the facility's capabilities.

Although quality management staff and facility leaders immediately began reviewing Patient A's death, the OIG found several deficiencies in quality management processes including insufficient peer reviews and peer review committee practices and delays in the initiation of an institutional disclosure and completion of an RCA.

The OIG substantiated that Patient B experienced an adverse clinical outcome. The OIG noted the patient signed an informed consent for the removal of the fourth toe on the right foot and the surgical team conducted a time-out verifying the fourth toe for removal; however, at the

operating table, the vascular surgeon directed the surgical resident to amputate the patient's third toe. Although removal of the patient's third toe was clinically indicated, the OIG found that the surgeon failed to acknowledge and discuss the deviation from the informed consent and pre-operative plan with the patient and surgical team.

The Chief of Surgery's management reviews and actions completed after the wrong site surgery, including a focused clinical care review and an FPPE, failed to hold the vascular surgeon accountable for violating patient safety protocols and undermining the culture of safety.

The Chief of Staff acknowledged that the vascular surgeon knowingly deviated from the surgical plan and stated that the surgeon should have stopped the procedure and obtained a new informed consent identifying the third toe requiring amputation. Despite this acknowledgment, neither the Chief of Surgery nor the Chief of Staff identified any further action being taken to address the vascular surgeon's noncompliance with, and ensuring future adherence to, the time-out, culture of safety, and Stop the Line principles.

The OIG substantiated that Patient C experienced an adverse clinical outcome following a robotic-assisted laparoscopic hemicolectomy. Although the patient experienced a surgical complication, the surgeon, surgical residents, and nursing staff promptly identified the patient's medical decline, closely monitored the patient's status, and provided timely intervention to stabilize the patient's condition. The OIG found that the treatment teams' continuous monitoring, coordination of care, and timely return to the operating room to address post-operative complications, led to the patient's full recovery.

Facility practitioners' and surgical nurses' compliance with patient safety procedures is required to ensure the correct surgical or invasive procedure is completed on the correct patient and at the correct site. When reviewing the three patients' surgical and invasive procedures, the OIG identified that neither an informed consent nor a time-out was completed before one procedure and found a pattern of failing to confirm applicable radiological imaging on time-out checklists.

The Associate Director for Patient Care Services and the Chief of Staff provided multiple reasons why the review of medical images was marked as not applicable on the time-out checklists or why the review of medical images was not necessary for the surgical procedures. However, the OIG found the leaders' response to the identified pattern to be concerning, especially considering that Patient B's wrong site toe amputation was based on the imaging results that identified osteomyelitis in the fourth toe, the resident questioning the vascular surgeon about the imaging on the fourth versus the third toe, and the subsequent wrong toe amputation. The OIG concluded that multiple staff circumvented critical surgical and invasive procedure protocols, and that facility leaders failed to recognize and address these patient safety deficiencies.

## Recommendations 1–7

1. The Southeast Network Director facilitates a comprehensive review of Patient A's episode of care, from the time and date of the patient's hospitalization through the date and time of the patient's death, to identify practitioner and process improvements that may reduce the potential for future incidents, and takes appropriate actions.
2. The Columbia VA Health Care System Director ensures providers carefully consider facility resources when evaluating medically-complex patients for admission and when determining whether admitted patients' medical complexities exceed the facility's capabilities to meet patients' needs.
3. The Columbia VA Health Care System Director ensures that the peer review committee record the committee members formal discussions specific to the peer review in meeting minutes, and monitors ongoing compliance.
4. The Columbia VA Health Care System Director evaluates quality management practices that impede the timeliness of institutional disclosures, ensures current practices are in alignment with Veterans Health Administration policy, and takes action as warranted.
5. The Columbia VA Health Care System Director ensures that root cause analyses are completed within the required 45-day time frame to promptly identify and address system vulnerabilities.
6. The Columbia VA Health Care System Director facilitates a comprehensive administrative review of the vascular surgeon's disregard of surgical and invasive procedure protocols and Stop the Line principles, consults with the Office of Regional Counsel and human resource specialists, and takes administrative actions, as appropriate.
7. The Columbia VA Health Care System Director evaluates facility staff's informed consent and time-out practices, to include the review of pertinent medical images, and ensures practices are consistent with correct surgery and invasive procedure requirements, takes action as appropriate, and monitors compliance.

## Appendix A: VISN Director Memorandum

### Department of Veterans Affairs Memorandum

Date: July 15, 2022

From: Director, Southeast Network (10N7)

Subj: Healthcare Inspection—Surgical Adverse Clinical Outcomes and Leaders' Responses at the Columbia VA Health Care System in South Carolina

To: Director, Office of Healthcare Inspections (54HL04)  
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. I have had the opportunity to review the Draft Report: Healthcare Inspection—Surgical Adverse Clinical Outcomes and Leaders' Responses at the Columbia VA Health Care System in South Carolina.
2. I concur with VISN 7 and Columbia VA Health Care System's action plan and ongoing implementation for recommendations 1-7.
3. I appreciate the opportunity for this review as part of a continuing process to improve the care of our Veterans.
4. If you have any questions or require further information, please contact the VISN 7 Quality Management Officer.

*(Original signed by:)*

Rakisha Hunter  
Chief Operations Officer  
For  
David M. Walker, MD, MBA  
Network Director

## VISN Director Response

### Recommendation 1

The Southeast Network Director facilitates a comprehensive review of Patient A's episode of care, from the time and date of the patient's hospitalization through the date and time of the patient's death, to identify practitioner and process improvements that may reduce the potential for future incidents and takes appropriate actions.

Concur.

Target date for completion: January 2023

### Director Comments

The Southeast Network Director will facilitate the following comprehensive review of Patient A's episode of care:

1. VISN Surgical Chief Consultant and Intensive Care Unit lead Review of care provided to Patient A
2. Facility Surgical Workgroup Discussion to address:
  - a. Aspects of care facility is able to provide 24/7 given current staffing levels
  - b. Aspects of care facility is unable to provide 24/7 given current staffing levels  
Include Ear, Nose, and Throat surgeon availability, Interventional Radiology availability, Operating Room Staffing availability.
3. Review of peer review committee structure, peer review process, and committee documentation of the process and discussion during annual Chief Medical Officer/Patient Safety Manager site visit.
4. VISN-wide education and discussion about Institutional Disclosures with all VISN7 facilities at Executive Leadership Council meeting.

## Appendix B: Facility Director Memorandum

### Department of Veterans Affairs Memorandum

Date: July 14, 2022

From: Director, Columbia VA Health Care System (544/00)

Subj: Healthcare Inspection—Surgical Adverse Clinical Outcomes and Leaders' Responses at the Columbia VA Health Care System in South Carolina

To: Director, Southeast Network (10N7)

1. The Columbia VA Health Care System is committed to quality health care and continues to build an organization focused on improving patient safety. I reviewed the draft report and concur with the recommendations and action plan as submitted.
2. If you have any additional questions, please contact the Chief, Quality Management.

*(Original signed by:)*

David L. Omura, DPT, MHA, MS  
Director

## Facility Director Response

### Recommendation 2

The Columbia VA Health Care System Director ensures providers carefully consider facility resources when evaluating medically-complex patients for admission and when determining whether admitted patient's medical complexities exceed the facility's capabilities to meet patient's needs.

Concur.

Target date for completion: September 2022

### Director Comments

The Columbia VA Health Care System transitioned to a new Chief of Staff in January 2022. Since assuming the role, the Chief of Staff has strengthened oversight of providers and clinical processes. The Chief of Staff currently reviews admission practices and patient complexity. To strengthen processes, staff will be educated on determining resources and expertise available prior to performing complex or high-risk procedures through a multidisciplinary huddle. Outside of an emergency situation, the case will be reviewed by the Chief of Surgery and Chief of Staff before proceeding with the surgical case or transferring the patient to a higher level of care. This includes establishing, in advance, appropriate arrangements, if and as needed in a manner consistent with legal authorities, to ensure that emergency care transfers and/or care is made available to patients when the facility is unable to provide the needed level of care.

The Chief of Staff will determine a method of identifying cases that require review (e.g., utilizing American Society of Anesthesiology (ASA) classification, probable exhaustion of resources or supplies, backup, or support staff not available, etc.), determine huddle members required, and develop a process of reviewing and documenting the results of the review in the Computerized Patient Record System (CPRS) including review and concurrence by the Chief of Surgery and Chief of Staff.

### Recommendation 3

The Columbia VA Health Care System Director ensures that the peer review committee record the committee members formal discussions specific to the peer review in meeting minutes and monitors ongoing compliance.

Concur.

Target date for completion: December 2022

## Director Comments

The Columbia VA Health Care System concurs that documentation in the Peer Review Committee Minutes does not always reflect the extensive case-specific discussion that occurs during peer reviews; however, the peer review process, to include formal discussions, does occur and decisions by the committee members are based on thorough review of the case and formal case-specific discussion. The Chief of Staff will ensure that the formal discussions regarding peer review occurring during the Peer Review Committee meeting are recorded and minutes accurately reflect case-specific discussion. The Peer Review Committee Minutes will be reviewed by the Chief, Quality Management prior to being submitted to the Chief of Staff for review and signature. Peer Review Minutes will be monitored for documented case-specific discussion for  $\geq 90\%$  compliance for 6 consecutive months.

## Recommendation 4

The Columbia VA Health Care System Director evaluates quality management practices that impede the timeliness of institutional disclosures, ensures current practices are in alignment with Veterans Health Administration policy, and takes action as warranted.

Concur.

Target date for completion: April 2022

## Director Comments

The Columbia VA Health Care System concurs with the recommendation. In retrospect, the facility acknowledges that in this unique circumstance in which the family immediately requested an autopsy, the facility decision to wait on results of the autopsy to determine the need for institutional disclosure was not in alignment with the intent of the Veterans Health Administration Directive 1004.08. When an adverse event occurs during the patient's care that may warrant an Institutional Disclosure, Clinical Executive Leadership and Quality Management will meet immediately to discuss the adverse event and ensure timely initiation of the Institutional Disclosure as prescribed in the Veterans Health Administration Directive 1004.08. Quality Management will report Institutional Disclosures quarterly through Executive Leadership to the VISN. Reporting will include date of adverse event and date of disclosure in addition to other case-specific information. We kindly request closure of this recommendation.

## OIG Comments

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

## Recommendation 5

The Columbia VA Health Care System Director ensures that root cause analyses are completed within the required 45-day time frame to promptly identify and address system vulnerabilities. Concur.

Target date for completion: August 2022

### Director Comments

The Columbia VA Health Care System prioritizes patient safety and the processes established to ensure safe patient care. While we concur with this recommendation and acknowledge that the Root Cause Analysis (RCA) for patient A exceeded the 45-day time frame, the facility notes this case occurred in the midst of a surge from the ongoing COVID-19 pandemic, with critical staffing shortages that were compounded by details of staff to clinical areas in support of direct patient care. The facility delayed in chartering this RCA to ensure the appropriate staff would have the needed time to complete a focused systems review with thoughtful recommendations for improvement. The facility notes that the delay in the RCA is an anomaly and not our standard practice. Moving forward, RCAs will be completed within 45 days of the facility becoming aware that an RCA is required in accordance with VHA Handbook 1050.01. Quality Management will report RCAs to the National Center for Patient Safety through Executive Leadership to include timeliness of completion.

## Recommendation 6

The Columbia VA Health Care System Director facilitates a comprehensive administrative review of the vascular surgeon's disregard of surgical and invasive procedure protocols and Stop the Line principles, consults with the Office of Regional Counsel and human resource specialists, and takes administrative actions, as appropriate.

Concur.

Target date for completion: January 2023

### Director Comments

The Chief of Staff will complete a comprehensive review of the charges and corrective actions previously taken with the vascular surgeon as a result of this case (Patient B). Employee Relations/Labor Relations (ER/LR) will be consulted to compare the list of previous charges with the deficiencies identified in this report. The Chief of Staff will generate an evidence file and route through ER/LR and the Office of General Counsel, Office of District Counsel for recommendation and corrective action.

The Chief of Staff and Chief of Surgery will monitor the vascular surgeon's performance and compliance since the previous corrective actions were taken. This review will include an audit of

the Operating Room (OR) checklist data for 6 months to include History and Physical, consent, pre-operative checklist, timeout, and debrief checklists, poll of OR staff to ensure vascular surgeon's active participation in the timeout and debrief, audit brief operative note, operative report, and the OR nurse's intraoperative notes to ensure the procedure performed matches the procedure posted and consented.

## **Recommendation 7**

The Columbia VA Health Care System Director evaluates facility staff's informed consent and time-out practices, to include the review of pertinent medical images, and ensures practices are consistent with correct surgery and invasive procedure requirements, takes action as appropriate, and monitors compliance.

Concur.

Target date for completion: January 2023

### **Director Comments**

The Columbia VA Health Care System concurs with the recommendation. The Chief of Staff and the Associate Director, Patient Care/Nursing Services will conduct collaborative, combined training for provider and nursing staff on acute care units regarding informed consent and time-out in person, via Teams, or in the Talent Management System (TMS), and maintain rosters.

To eliminate the 'not applicable' option that is currently in the template, the preoperative checklist will be revised. The revised checklist will provide options including a. radiographs needed in Operating Room; b. radiology images reviewed prior to surgery; and c. radiology images not pertinent to procedure.

Compliance will be monitored via chart reviews reported to the Medical Executive Board. The chart reviews will include review of History and Physical, consent, time-out, and review of pertinent medical images (when indicated). The facility will monitor compliance for  $\geq 90\%$  compliance for 6 consecutive months.

## Glossary

*To go back, press "alt" and "left arrow" keys.*

**anesthesiologist.** A physician specializing in anesthesiology.<sup>1</sup>

**cardiopulmonary resuscitation.** A procedure designed to restore normal breathing after cardiac arrest that includes the clearance of air passages to the lungs, mouth-to-mouth method of artificial respiration, and heart massage by the exertion of pressure on the chest.<sup>2</sup>

**cecum polyp.** "The cecum is the beginning of the colon, where the small intestine empties into the large intestine." A polyp is a "projection (growth) of tissue from the inner lining of the colon into the lumen (hollow center) of the colon."<sup>3</sup>

**chemotherapy.** A therapeutic use of chemical agents to treat disease.<sup>4</sup>

**chest tube.** A hollow, flexible, tube placed in the chest that acts as a drain. "Chest tubes drain blood, fluid, or air from around [the] lungs, heart, or esophagus."<sup>5</sup>

**coagulative necrosis.** A common form of necrosis (dead tissue) that can occur in most organs. "Following devitalisation, the cells retain their outline as their proteins coagulate and metabolic activity ceases."<sup>6</sup>

**computerized tomography.** A radiography in which a three-dimensional image of a body structure is constructed by computer from a series of plane cross-sectional images made along an axis.<sup>7</sup>

**critical incident tracking notification.** Intended to notify key stakeholders when a critical event occurs in surgery such as death in the operating room, death from hemorrhage within 24 hours of leaving the operating room, wrong patient, wrong site/side, wrong implant, or retained foreign body.<sup>8</sup>

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<sup>1</sup> Merriam-Webster.com Dictionary, "anesthesiologist," accessed November 10, 2021, <https://www.merriam-webster.com/dictionary/anesthesiologist>.

<sup>2</sup> Merriam-Webster.com Dictionary, "cardiopulmonary resuscitation," accessed November 17, 2021, <https://www.merriam-webster.com/dictionary/cardiopulmonary%20resuscitation>.

<sup>3</sup> American Cancer Society, "Understanding Your Pathology Report: Colon Polyps (Sessile or Traditional Serrated Adenomas)," accessed November 5, 2021, <https://www.cancer.org/content/dam/CRC/PDF/Public/7947.00.pdf>.

<sup>4</sup> Merriam-Webster.com Dictionary, "chemotherapy," accessed October 28, 2021, <https://www.merriam-webster.com/dictionary/chemotherapy>.

<sup>5</sup> MedlinePlus, "Chest tube insertion," accessed October 19, 2021, <https://medlineplus.gov/ency/article/002947.htm>.

<sup>6</sup> Elsevier Clinical Key, "Coagulative Necrosis," accessed November 5, 2021, <https://www.clinicalkey.com#!/content/book/3-s2.0-B9780702072123000050?scrollTo=%23hl0000509>.

<sup>7</sup> Merriam-Webster.com Dictionary, "computed tomography," accessed October 22, 2021, <https://www.merriam-webster.com/dictionary/computerized%20tomography>.

<sup>8</sup> VHA Deputy Under Secretary for Health for Operations and Management (10N) memo.

**degenerative joint disease.** “Also referred to as osteoarthritis (OA), is a common ‘wear and tear’ disease that occurs when the cartilage that serves as a cushion in the joints deteriorates.”<sup>9</sup>

**diabetes.** A group of diseases that affect how the body uses blood sugar (glucose: an important source of energy for the cells that make up muscles and tissue).<sup>10</sup>

**dornase alfa.** A medication that breaks up thick mucus around the lungs and helps make breathing easier specifically in cystic fibrosis patients. Additionally, dornase alfa, in combination with tPA, has shown to be effective for treating empyema.<sup>11</sup>

**empyema.** The presence of pus in a bodily cavity.<sup>12</sup>

**fellow.** A person appointed to a position granting a stipend and allowing for advanced study or research.<sup>13</sup>

**gastroenterology.** A branch of medicine concerned with the structure, functions, disease, and pathology of the stomach and intestines.<sup>14</sup>

**hemicolectomy.** A surgical excision of part of the colon.<sup>15</sup>

**hemodynamic.** Relating to or functioning in the mechanics of blood circulation.<sup>16</sup>

**hemoglobin.** A protein in red blood cells that acts as a carrier; carrying oxygen to the body's organs and tissues and carbon dioxide to the lungs.<sup>17</sup>

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<sup>9</sup> American Academy of Physical Medicine and Rehabilitation, "Degenerative Joint Disease," accessed November 30, 2019, <https://www.aapmr.org/about-physiatry/conditions-treatments/pain-neuromuscular-medicine-rehabilitation/degenerative-joint-disease>.

<sup>10</sup> Mayo Clinic, “diabetes,” accessed October 26, 2021, <https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444>.

<sup>11</sup> Mayo Clinic, “dornase alfa (inhalation route),” accessed November 15, 2021, <https://www.mayoclinic.org/drugs-supplements/dornase-alfa-inhalation-route/side-effects/drg-20063509?p=1>. V. Bobek, et al. “Intrapleural administration of DNase alone for pleural empyema,” *International Journal of Clinical Experimental Medicine*. 15, (November 2015):22011-22015.

<sup>12</sup> *Merriam-Webster.com Dictionary*, “empyema,” accessed November 15, 2021, <https://www.merriam-webster.com/dictionary/empyema>.

<sup>13</sup> *Merriam-Webster.com Dictionary*, “fellow,” accessed October 29, 2021, <https://www.merriam-webster.com/dictionary/fellow>.

<sup>14</sup> *Merriam-Webster.com Dictionary*, “gastroenterology,” accessed November 5, 2021, <https://www.merriam-webster.com/dictionary/gastroenterologist>.

<sup>15</sup> *Merriam-Webster.com Dictionary*, “hemicolectomy,” accessed October 26, 2021, <https://www.merriam-webster.com/medical/hemicolectomy>.

<sup>16</sup> *Merriam-Webster.com Dictionary*, “hemodynamic,” accessed November 17, 2021, <https://www.merriam-webster.com/dictionary/hemodynamic>.

<sup>17</sup> Mayo Clinic, “hemoglobin test,” accessed October 28, 2021, <https://www.mayoclinic.org/tests-procedures/hemoglobin-test/about/pac-20385075>.

**hemorrhagic shock.** “A form of hypovolemic shock in which severe blood loss leads to inadequate oxygen delivery at the cellular level. If hemorrhage continues unchecked, death quickly follows.”<sup>18</sup>

**hemothorax.** Blood in the pleural cavity.<sup>19</sup>

**hypotensive.** Causing low blood pressure or a lowering of blood pressure.<sup>20</sup>

**institutional disclosure.** A formal process by which VA medical facility leader(s), together with clinicians, inform the patient or the patient’s personal representative that an adverse event has occurred during the patient’s care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient’s rights and recourse.<sup>21</sup>

**intensivist.** A physician who specializes in the care and treatment of patients in intensive care.<sup>22</sup>

**intubation.** The introduction of a tube into a hollow organ or part, especially to maintain an open passage or gain access to the interior.<sup>23</sup>

**issue brief.** A document “drafted to provide specific information to leadership within the organization, working through the appropriate chain of command, regarding a situation/event/issue.”<sup>24</sup>

**labetalol.** A medication “used to treat severe high blood pressure (hypertension).”<sup>25</sup>

**laparoscopic.** The visual examination of the abdomen by means of a laparoscope.<sup>26</sup>

**laparotomy.** A surgical incision of the abdominal wall.<sup>27</sup>

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<sup>18</sup> Jeremy W. Cannon, “hemorrhagic shock,” *The New England Journal of Medicine* 378; (January 25, 2018), 370-379, <https://www.nejm.org/doi/full/10.1056/nejmra1705649>, accessed November 4, 2021.

<sup>19</sup> Merriam-Webster.com Dictionary, “hemothorax,” accessed November 16, 2021, <https://www.merriam-webster.com/medical/hemothorax>.

<sup>20</sup> Merriam-Webster.com Dictionary, “hypotensive,” accessed October 26, 2021, <https://www.merriam-webster.com/medical/hypotensive>.

<sup>21</sup> VHA Directive 1004.08.

<sup>22</sup> Merriam-Webster.com Dictionary, “intensivist,” accessed October 20, 2021, <https://www.merriam-webster.com/dictionary/intensivist>.

<sup>23</sup> Merriam-Webster.com Dictionary, “intubation,” accessed November 15, 2021, <https://www.merriam-webster.com/dictionary/intubation>.

<sup>24</sup> Deputy Secretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs*, March 29, 2018.

<sup>25</sup> Mayo Clinic, “labetalol,” accessed November 10, 2021, <https://www.mayoclinic.org/drugs-supplements/labetalol-intravenous-route/description/drg-20071176>.

<sup>26</sup> Merriam-Webster.com Dictionary, “laparoscopy,” accessed October 26, 2021, <https://www.merriam-webster.com/dictionary/laparoscopic>.

<sup>27</sup> Merriam-Webster.com Dictionary, “laparotomy,” accessed November 5, 2021, <https://www.merriam-webster.com/dictionary/laparotomy>.

**macerated.** To soften (as tissue) to separate.<sup>28</sup>

**morbidities.** A complication or undesirable side effect following surgery or medical treatment.<sup>29</sup>

**nasopharyngeal carcinoma.** A cancer that occurs behind the nose and above the back of the throat.<sup>30</sup>

**necrosis.** Death of living tissue.<sup>31</sup>

**osteomyelitis.** An infectious usually painful inflammatory disease of bone often of bacterial origin that may result in the death of bone tissue.<sup>32</sup>

**paraplegia.** Partial or complete paralysis of the lower half of the body with involvement of both legs that is usually due to injury or disease of the spinal cord in the thoracic or lumbar region.<sup>33</sup>

**pathologist.** A physician who interprets and diagnoses the changes caused by disease in tissues and body fluids.<sup>34</sup>

**pigtail catheter.** A type of catheter used to drain pleural collections.<sup>35</sup>

**pleura.** “Thin layer of tissue that covers the lungs and lines the interior wall of the chest cavity.” “This tissue secretes a small amount of fluid that acts as a lubricant, allowing the lungs to move smoothly in the chest cavity while breathing.”<sup>36</sup>

**pleural cavity.** A space that is formed when the two layers of the pleura spread apart.<sup>37</sup>

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<sup>28</sup> Merriam-Webster.com Dictionary, “macerated,” accessed March 31, 2022, <https://www.merriam-webster.com/dictionary/macerated>.

<sup>29</sup> Merriam-Webster.com Dictionary, “morbidity,” accessed November 15, 2021, <https://www.merriam-webster.com/dictionary/morbidity>.

<sup>30</sup> Mayo Clinic, “nasopharyngeal carcinoma,” accessed November 1, 2021, <https://www.mayoclinic.org/diseases-conditions/nasopharyngeal-carcinoma/symptoms-causes/syc-20375529>.

<sup>31</sup> Merriam-Webster.com Dictionary, “necrosis,” accessed October 29, 2021, <https://www.merriam-webster.com/dictionary/necrosis>.

<sup>32</sup> Merriam-Webster.com Dictionary, “osteomyelitis,” accessed October 26, 2021, <https://www.merriam-webster.com/dictionary/osteomyelitis>.

<sup>33</sup> Merriam-Webster.com Dictionary, “paraplegia,” accessed October 26, 2021, <https://www.merriam-webster.com/dictionary/paraplegia>.

<sup>34</sup> Merriam-Webster.com Dictionary, “pathologist,” accessed October 29, 2021, <https://www.merriam-webster.com/dictionary/pathologist>.

<sup>35</sup> Alla Elsayed, et al, “implication of pigtail catheter vs chest tube drainage,” *International Journal of Community Medicine and Public Health* 5; 9 (September 2018), 3686-3690, <https://www.ijcmph.com/index.php/ijcmph/article/download/3602/2335>, accessed November 8, 2021.

<sup>36</sup> National Cancer Institute, “pleura,” accessed May 19, 2022, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/pleura>.

<sup>37</sup> Merriam-Webster.com Dictionary, “pleural cavity,” accessed December 28, 2021, <https://www.merriam-webster.com/medical/pleural%20cavity>.

**pleural effusion.** A build-up of excess fluid between the layers of the pleura that line the outside of the lungs.<sup>38</sup>

**pleuritic chest pain.** A pain “characterized by sudden and intense sharp, stabbing, or burning pain in the chest when inhaling or exhaling.”<sup>39</sup>

**pneumothorax.** A condition in which air or other gas is present in the pleural cavity and which occurs spontaneously because of disease or injury of lung tissue, rupture of air-filled pulmonary cysts, or puncture of the chest wall or is induced as a therapeutic measure to collapse the lung.<sup>40</sup>

**posteroanterior.** Involving or produced in a direction from the back toward the front (as of the body or an organ).<sup>41</sup>

**practitioner.** A “health care professional granted specific clinical privileges to perform the treatment or procedure.”<sup>42</sup>

**radiation therapy.** “A type of cancer treatment that uses beams of intense energy to kill cancer cells.”<sup>43</sup>

**resident.** A doctor who is training at a hospital to become a specialist in a particular field of medicine.<sup>44</sup>

**root cause analysis.** “A process for identifying the basic or contributing casual factors that underlie variations in performance associated with adverse events or close calls.”<sup>45</sup>

**subcutaneous.** A term referring to under the skin.<sup>46</sup>

**tissue plasminogen activator.** A clot-dissolving enzyme.<sup>47</sup>

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<sup>38</sup> Veterans Health Library, “pleural effusion,” accessed July 27, 2021, <https://www.veteranshealthlibrary.va.gov/Search/3,40414>.

<sup>39</sup> Reamy, Brian V., Pamela M. Williams, and Michael R. Odom, “Pleuritic Chest Pain: Sorting Through the Differential Diagnosis,” *American Family Physician* 96, no. 5 (September 1, 2017): 306-312, accessed October 28, 2021, <https://www.aafp.org/afp/2017/0901/p306.html>.

<sup>40</sup> *Merriam-Webster.com Dictionary*, “pneumothorax,” accessed November 16, 2021, <https://www.merriam-webster.com/dictionary/pneumothorax>.

<sup>41</sup> *Merriam-Webster.com Dictionary*, “posteroanterior,” accessed November 16, 2021, <https://www.merriam-webster.com/medical/posteroanterior>.

<sup>42</sup> VHA Handbook 1004.01 (4).

<sup>43</sup> Mayo Clinic, “radiation therapy,” accessed October 28, 2021, <https://www.mayoclinic.org/tests-procedures/radiation-therapy/about/pac-20385162>.

<sup>44</sup> *Merriam-Webster.com Dictionary*, “resident,” accessed October 29, 2021, <https://www.merriam-webster.com/dictionary/resident>.

<sup>45</sup> VHA Handbook 1050.01.

<sup>46</sup> *Merriam-Webster.com Dictionary*, “subcutaneous,” accessed December 21, 2021, <https://www.merriam-webster.com/dictionary/subcutaneous>.

<sup>47</sup> *Merriam-Webster.com Dictionary*, “tissue plasminogen activator,” accessed October 20, 2021, <https://www.merriam-webster.com/dictionary/tissue%20plasminogen%20activator>.

**thoracentesis.** A procedure to remove fluid from the chest.<sup>48</sup>

**thoracoscopic.** An endoscope that is inserted through a puncture of the chest wall in an intercostal space (as for the visual examination of the chest cavity).<sup>49</sup>

**tracheostomy.** A surgical formation of an opening into the trachea through the neck to allow the passage of air.<sup>50</sup>

**vascular.** A channel for the conveyance of a body fluid.<sup>51</sup>

**ventilation.** The circulation and exchange of gases in the lungs.<sup>52</sup>

**ventricular fibrillation.** Rapid uncoordinated fluttering contractions of the ventricles of the heart resulting in loss of synchronization between heartbeat and pulse beat.<sup>53</sup>

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<sup>48</sup> Merriam-Webster.com Dictionary, "thoracentesis," accessed November 16, 2021, <https://www.merriam-webster.com/medical/thoracentesis>.

<sup>49</sup> Merriam-Webster.com Dictionary, "thoracoscopic," accessed November 17, 2021, <https://www.merriam-webster.com/medical/thoracoscopic>.

<sup>50</sup> Merriam-Webster.com Dictionary, "tracheostomy," accessed November 16, 2021, <https://www.merriam-webster.com/dictionary/tracheostomy>.

<sup>51</sup> Merriam-Webster.com Dictionary, "vascular," accessed October 26, 2021, <https://www.merriam-webster.com/dictionary/vascular>.

<sup>52</sup> Merriam-Webster.com Dictionary, "ventilation," accessed December 22, 2021, <https://www.merriam-webster.com/dictionary/ventilation>.

<sup>53</sup> Merriam-Webster.com Dictionary, "ventricular fibrillation," accessed November 17, 2021, <https://www.merriam-webster.com/medical/ventricular%20fibrillation>.

## OIG Contact and Staff Acknowledgments

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