US DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Heart Transplant Program Review: Facility Leaders Failed to Ensure a Culture of Safety and the Section Chief Engaged in Unprofessional Conduct at the Richmond VA Medical Center in Virginia

Healthcare Inspection | **23-03526-07** | **October 24, 2024**

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to review allegations regarding the heart transplant program and the performance and behavior of the cardiothoracic section chief (section chief) at the Richmond VA Medical Center (facility) in Virginia.[1] Specifically, the OIG reviewed the section chief's surgical complications, patient outcomes, and reports of unprofessional behavior. The OIG also reviewed the temporary inactivation of the heart transplant program and factors associated with reactivation, and Veterans Integrated Service Network (VISN) and facility leaders' responses to staff concerns about the heart transplant program.

From March 16–August 11, 2023, the OIG received multiple complaints related to the section chief's unprofessional conduct, cardiac surgical patient outcomes, and patient care practices. The OIG initiated the inspection in September 2023. The OIG reviewed additional allegations that were not substantiated, or the OIG was unable to determine whether an alleged event or action took place. The additional allegations are documented in appendix A.[2]

In early 2022, prior to the OIG's inspection, the Facility Director requested VISN review of cardiac surgical program data in response to staff's patient safety concerns. In late 2022, the VISN Chief Medical Officer (CMO) requested National Surgery Office (NSO) assistance in reviewing the facility's heart transplant and cardiac surgery programs.[3] Two NSO site visits were conducted (February 2023 and August 2023), with reports and recommendations made to VISN, facility, and surgery leaders. VISN leaders initiated an action plan to address and track the NSO recommendations. The VISN CMO told the OIG that due to concerns about increased cardiac and heart transplant surgery patient safety event reports in summer 2023, the Facility Director

[1] The facility is one of six Veterans Health Administration (VHA) facilities that provide heart transplant services, and one of two that perform the transplants in-house; "Cardiothoracic" is relating to, involving, or specializing in the heart and chest. *Merriam-Webster.com Dictionary*, "cardiothoracic," accessed February 29, 2024, https://www.merriam-webster.com/dictionary/cardiothoracic.

[2] The OIG received a complaint in November 2023 further alleging the section chief's poor surgical outcomes; The underlined terms are hyperlinks to another section of the report. To return to the point of origin, press and hold the "alt" and "left arrow" keys together.

[3] The National Surgery Office (NSO) is VHA's national program office that provides "operational oversight of the VHA Surgery Program including the VA transplant program" and "monitors surgical quality and outcomes data and quality improvement activities at the national, regional, and local level." VHA Directive 1102.01(2), *National Surgery Office*, April 24, 2019, amended April 19, 2022.

notified the Organ Procurement and Transplantation Network (OPTN) of a voluntary and temporary inactivation of the heart transplant program, effective August 15, 2023.[4]

Facility Heart Transplant Program

When the OIG initiated this inspection in September 2023, the section chief was the only surgeon privileged to perform heart transplants and was responsible for heart transplant program oversight and management.[5]

Veterans Health Administration (VHA) transplant centers must comply with VHA and OPTN policies; they also voluntarily comply with Centers for Medicare and Medicaid Services regulations pertaining to organ transplantation.[6] The OPTN allows facilities to inactivate transplant programs on a short- or long-term basis, and requires that transplant programs in a long-term inactive status reapply and be approved by the OPTN prior to the transplant program's reactivation.[7] VISN and facility leaders told the OIG the decision to reactivate the facility heart transplant program will be made jointly as the VISN action plan progresses.

Evaluation of Cardiac Surgery Quality Outcomes

The NSO established the Veterans Affairs Surgical Quality Improvement Program (VASQIP) to meet legal mandate and serve "as the primary tool for measurement of the quality of surgical outcomes."[8] Facility surgical quality nurses collect the data and NSO staff then analyze and compare facility data to VHA national metrics. The NSO issues quarterly reports to VISN,

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[4] Patient safety event reports are "an event, incident or condition, directly associated with care or services provided to a patient, that could have resulted or did result in unintentional harm." VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023; The OPTN was established by the United States Congress through the National Organ Transplant Act in 1984 to maintain a national registry for organ matching and has been administered by the United Network for Organ Sharing since 1986. "History & NOTA [National Organ Transplant Act]," US Department of Health and Human Services Organ Procurement and Transplantation Network, accessed January 24, 2024, https://optn.transplant.hrsa.gov/about/history-nota; "About," US Department of Health and Human Services Organ Procurement and Transplantation Network, accessed September 21, 2023, https://optn.transplant.hrsa.gov/about/. The facility heart transplant program remained on pause as of April 22, 2024.

[5] VHA defines "privileged" as a description "of the specific scope and content of patient care services for which a [licensed independent practitioner] is qualified and expected to actively perform." VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was rescinded and replaced by VHA Directive 1100.21(1), *Privileging*, March 2, 2023, amended April 26, 2023. The policies contain similar language related to privileging. The section chief began employment at the facility in August 2020. The former cardiothoracic section chief served as section chief from May 2008 through August 2019.

[6] VHA Directive 1101.03, *Solid Organ, Tissue and Eye Donation*, August 21, 2021; Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants, 72 Fed. Reg. 61, 15,197–15,198 (Mar. 30, 2007) (to be codified at 442 C.F.R. pts. 405, 482, 488, and 498).

[7] OPTN, *Bylaws*, December 5, 2022; OPTN, *Bylaws*, December 5, 2023.

[8] VHA Directive 1102.01(2).

facility, and surgical leaders that reflect metrics such as morbidity (complications) and mortality outcomes. Outcomes that deviate significantly from national averages are further reviewed by the NSO to determine interventions dependent on the degree of persistence or concern.[9]

The OIG reviewed NSO quarterly reports for the period of October 1, 2018–September 30, 2023, and found that the facility did not have statistically significant variations in cardiac surgery morbidity and mortality outcome rates when compared to national data. The OIG did not substantiate that the section chief's morbidity (complication) and mortality rates were "much worse than the previous cardiothoracic surgeons."

The OIG did not substantiate that the facility has a high readmission rate following cardiothoracic surgery. The NSO quarterly reports indicated that cardiac surgery 30-day all-cause inpatient readmission rates were not significant enough to elicit further NSO assessment, and readmission rates have improved since the second quarter of fiscal year 2022.

Heart Transplant Survival Rates

The OIG reviewed data provided by the Scientific Registry of Transplant Recipients (SRTR) for the period of January 1, 2018–June 30, 2023, to assess for any significant increases in heart transplant mortality prior to and during the section chief's employment.[10] The SRTR provides statistical and analytical support and prepares aggregate bi-annual reports but does not provide surgeon-specific patient survival rates.[11] The OIG reviewed one-year survival rate data associated with heart transplants as a representative quality measure.

The OIG reviewed the SRTR reports and noted no patient deaths within one year of transplantation until late 2021, when two patient deaths contributed to higher-than-expected rates for transplanted organ failures.[12] The OIG identified the two patients during the inspection and reviewed the respective electronic health records (EHRs) and other relevant documents. The OIG found one transplant surgery was performed by the section chief and the second by another surgeon who was no longer employed by VHA. The OIG found that both surgeries were

[9] VHA Directive 1102.01(2). Interventions may include VISN chief surgical consultant review; site visits from the VISN chief surgical consultant, NSO, or VA Central Office; a facility action plan; or an audit of surgical deaths.

[10] The SRTR provides statistical and analytical support, including policy, performance metrics, economic analysis, and preparation of reports to the OPTN and other government agencies. The SRTR operates "under contract from the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), US Department of Health and Human Services (HHS)."

[11] The SRTR operates "under contract from the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), US Department of Health and Human Services (HHS)." "Driven to Make a Difference," SRTR, accessed March 6, 2024, https://www.srtr.org/about-srtr/mission-vision-and-values/; "About SRTR Reports," SRTR, accessed March 6, 2024, https://www.srtr.org/reports/about-srtr-reports/. The OIG reviewed SRTR reports released from January 5, 2021, through January 9, 2024. The reports cover one-year survival rates for transplants from October 2018 through June 2023.

[12] The April 2023 SRTR report included data from January 1–March 1, 2020, and June 13–30, 2022.

discussed in the NSO August 2023 site visit report and reviewed through the facility peer review process per VHA policy.[13] The OIG did not find evidence that disclosure of adverse events was warranted or conducted for either transplant patient's death.

Cardiopulmonary Bypass Time

The OIG was unable to determine whether the section chief had "incredibly long" cardiopulmonary bypass (CPB) times. When a patient is on CPB, a machine takes over for a patient's heart and lungs, typically during heart surgery. This allows the surgeon to work on or around the heart while it is temporarily paused, not beating, and empty of blood.[14] The OIG acknowledges the cardiac surgical research consensus that a shorter CPB duration is preferred. While there is no universally agreed-upon threshold of CPB duration after which a patient is at higher risk of mortality or morbidity, it is an accepted principle in cardiac surgery that a patient's time on CPB should be minimized. One hundred and eighty minutes is commonly cited as a marker of "long" CPB pump time duration.[15]

During interviews, staff reported concerns regarding the section chief's longer CPB times and "poor outcomes," and identified two patients with notable CPB times. The OIG found the CPB times for both patients significantly exceeded the NSO's average length of expected total surgical time for their planned principal procedures (approximately five hours). However, the OIG cannot draw a direct causal relationship between the prolonged CPB times and the outcomes experienced by those two patients, nor can the OIG generalize about the surgeon's average CPB times based on those two cases. The OIG found no evidence of a peer review or joint patient safety report for one of the two patients.

The chief of surgery reported reviewing 12 years of facility CPB data, which did not support the staff's concern of longer CPB times during the section chief's tenure compared to historical data. The section chief told the OIG that facility leaders and a surgical quality nurse provided facility

[13] Specific and detailed information, including individual patient information, related to NSO consultative site visits and VHA peer reviews are not discussed further in this report as these are quality management activities that can generate confidential records and documents under 38 U.S.C. § 5705. A peer review is a "a critical review of care performed by a peer" "to promote confidential and non-punitive assessments of care at the individual clinician level." VHA Directive 1190*, Peer Review for Quality Management*, November 21, 2018; VHA Directive 1102.01(2).

[14] "What is Cardiopulmonary Bypass," Cleveland Clinic, accessed December 12, 2023, https://my.clevelandclinic.org/health/treatments/24106-cardiopulmonary-bypass.

[15] The OIG interviewed members of the facility cardiac surgery team, including a surgeon, who referred to 180 minutes as the duration of CPB after which they have concerns for CPB-related complications. Juha Nissinen et al., "Safe Time Limits of Aortic Cross-Clamping and Cardiopulmonary Bypass in Adult Cardiac Surgery," *Perfusion* 24 no. 5 (September 2009): 297–305, https://journals.sagepub.com/doi/10.1177/0267659109354656; Diyar Jamil, Aram Baram, and Bashar Saqat, "Impact of Prolonged Cardiopulmonary Bypass and Operative Exposure Time on the Incidence of Surgical Site Infections in Patients Undergoing Open Heart Surgery: Single Center Case Series," *International Journal of Surgery Open*, no. 22 (2020): 52–56, https://doi.org/10.1016/j.ijso.2019.12.001.

CPB time data to the NSO during both site visits, and "it was not an outlier."

The OIG is unable to draw a conclusion regarding current versus historical CPB times based on the chief of surgery's facility bypass time data, as the methodology of the data collection could not be validated.

The Heart Transplant Program Had Consistently Low Patient Volume

The Centers for Medicare and Medicaid Services recommends a facility heart transplant program have a clinical experience of 10 heart transplants over a 12-month period. This minimum volume target is to maintain the team's surgery-related proficiency and clinical expertise.[16] The OPTN also requires heart transplant programs to remain functionally active by performing at least one heart transplant within 3 consecutive months.[17]

The OIG reviewed data retrieved from the VA Corporate Data Warehouse and learned that facility staff performed 17 heart transplants from August 1, 2020–September 30, 2023; all but one surgery was performed by the section chief. The transplant program director noted the program's "struggle to maintain" the required volume, citing a change in the primary heart transplant surgeon, staff vacancies, and insufficient number of referrals for transplant. The Chief of Staff also acknowledged this concern, citing the need for volume growth.

The OIG believes that extended periods of inactive status and low transplant volumes would lessen opportunities for the many specialized professionals involved in the complex process of transplantation to maintain clinical experience and team proficiency, possibly contributing to variations in outcomes. The OIG expects facility and service leaders to continue rigorous surveillance of quality measures if the heart transplant program is reactivated. VISN and facility leaders should ensure attainable program target volumes would meet clinical experience requirements.

The Section Chief Engaged in Unprofessional Conduct

The OIG substantiated that the section chief repeatedly exhibited unprofessional conduct, including four specific instances in which the section chief was unprofessional in communications to other staff. For example, the OIG heard multiple staff members report that the section chief displayed unprofessional behaviors, including rudeness and a threat to tape a

[16] Centers for Medicare and Medicaid Services Decision Memo CAG-00061N, "Transplant Centers: Re-Evaluation of Criteria for Medicare Approval," July 26, 2000; Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants, 72 Fed. Reg. at 15,197–15,198.

[17] OPTN, *Bylaws*, December 5, 2022; OPTN, *Bylaws*, December 5, 2023.

staff member's mouth shut. The OIG also found that facility staff had filed multiple disruptive behavior reports regarding the section chief's unprofessional behaviors.[18]

The section chief expressed awareness of the staff complaints and indicated a need to improve interpersonal communication and reported engaging in leadership counseling. The chief of surgery reported witnessing the unprofessional behavior firsthand and that complaints of unprofessionalism were addressed through verbal counseling; however, the OIG is concerned that complaints were still being made as of fall 2023. The OIG found that the chief of surgery should have considered these communications as either repeated unprofessional behaviors or unacceptable employee behaviors and should have utilized options described in facility policies such as a focused professional practice evaluation for cause or progressive disciplinary action.[19]

Through an interview, the OIG learned that NSO representatives also reported similar concerns and VISN leaders added a specific item to the VISN action plan requiring the chief of surgery to address the section chief's unprofessional conduct.

Facility Leaders Failed to Ensure a Culture of Safety

The OIG determined facility and surgical leaders failed to incorporate the VHA High Reliability Organization (HRO) pillar of creating a culture of safety to ensure staff felt comfortable reporting concerns.[20] For example, surgical staff told the OIG of not reporting threats or concerns due to fear of retaliation and feeling that the complaints were "turned around on us," as well as some staff seeking other employment opportunities.

In addition, the facility's medical bylaws recognize behaviors that undermine a culture of safety, including "foul language; rude, loud, or offensive comments; and intimidation of staff, patients and family members." The bylaws further note that these behaviors are "commonly recognized as detrimental to patient care."[21]

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[18] Disruptive behavior reports "alert the [disruptive behavior committee] or [employee threat assessment team] about behaviors that cause a safety concern, and about disruptive or violent events occurring within the health care setting." VHA Directive 1160.08(1), *VHA Workplace Violence Prevention Program*, amended February 22, 2022.

[19] Central Virginia VA Health Care System, MCM 00-031, *Behavioral Code of Conduct*, September 5, 2019. This MCP was rescinded and replaced with Central Virginia VA Health Care System, MCP-000-031, *Behavioral Code of Conduct*, December 7, 2022. The two policies contain similar language related to promoting a culture of safety, unacceptable employee behaviors, and progressive disciplinary actions; Central Virginia VA Health Care System MCP-011-104, *Focused Professional Practice Evaluation/Ongoing Professional Practice Evaluation (FPPE/OPPE)*, June 2, 2021; VHA Handbook 1100.19; VHA Directive 1100.21(1). The two policies contain similar language related to focused professional practice evaluations. The directive explains that a focused professional practice evaluation for cause is a time-limited period providing an opportunity for improvement after a clinical concern has been triggered, and states that "it is not a restriction or limitation on the ability to practice."

[20] VHA, "VHA High Reliability Organization (HRO) Reference Guide" April 2023, Pre-Decisional Deliberative Document - Internal VA Use Only.

[21] Central Virginia VA Health Care System, *Bylaws and Rules of the Medical Staff*, March 17, 2023.

The OIG found facility leaders conducted leadership rounding and provided psychological safety and conflict resolution discussions. After the NSO report was issued in October 2023, the Facility Director requested additional team training from VHA's National Center for Organization Development.[22]

VISN Oversight

The OIG evaluated VISN leaders' oversight and response to concerns raised regarding the facility's heart transplant program. While the OIG found that VISN leaders failed to ensure a timely quality of care review, the VISN CMO, after being hired in April 2022, identified further concerns regarding the transplant program and addressed those concerns promptly, including requesting an NSO review of the cardiac surgery and heart transplant programs, and supporting NSO site visits.

The OIG found that VISN leaders did not provide timely follow-up to the Facility Director's February 2022 request to review specific surgical complications. The OIG found that instability in VISN leadership may have contributed to the delay in responding to the Facility Director's request for clinical review.

The VISN Deputy CMO requested assistance with the clinical reviews from leaders of two VA medical facilities with active heart transplant programs. The OIG found two occasions when the VISN Deputy CMO delayed responding to leaders of the VA medical facilities who agreed to provide the clinical review but needed additional information, thus delaying the clinical review.[23] Ultimately, four heart transplant surgery reviews were completed in November 2022.[24]

The VISN Deputy CMO noted barriers to the review as (1) the small number of VA medical centers with heart transplant programs with subject matter expertise, and (2) the inability to exert pressure on another VA facility's provider who volunteered to complete the reviews.

The OIG made two recommendations to the Under Secretary for Health related to a comprehensive review of the facility transplant program and oversight of transplant program quality measures, including ensuring clinical experience targets are met; one recommendation to the VISN Director on completion of facility leaders' requests for clinical care reviews; and three

[22] VHA's National Center for Organization Development "collaboratively works with leaders throughout VA to improve organizational outcomes by supporting the development of an engaged workforce" using planned assessment and intervention. "Homepage," VHA National Center for Organization Development, accessed February 7, 2024, https://dvagov.sharepoint.com/sites/VHANationalCenterforOrganizationDevelopment/SitePages/Home.aspx. (This site is not publicly accessible.)

[23] The OIG found that risk managers were diligent in following up with VISN leaders and the Facility Director on the request for reviews of the cardiothoracic cases, requesting numerous status updates from April through November.

[24] The OIG identified no additional concerns following the VISN reviews of these four heart transplant surgeries.

recommendations to the Facility Director regarding a clinical care review for a patient with an extended CPB time, review of the section chief's conduct and staff's concerns, and development of a culture of safety.

VA Comments and OIG Response

The Under Secretary for Health and the Veterans Integrated Service Network and Facility Directors concurred with recommendations 1–6 and provided acceptable action plans (see appendixes C, D, and E for memorandums and appendix C for action plans). The OIG will follow up on the planned actions until they are completed.

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Contents

Abbreviations

CMO	Chief Medical Officer
CMS	Centers for Medicare and Medicaid Services
CPB	cardiopulmonary bypass
EHR	electronic health record
HRO	high reliability organization
NSO	National Surgery Office
O/E	observed to expected outcomes
OIG	Office of Inspector General
OPTN	Organ Procurement and Transplantation Network
SRTR	Scientific Registry of Transplant Recipients
VASQIP	Veterans Affairs Surgical Quality Improvement Program
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to review allegations regarding the heart transplant program at the Richmond VA Medical Center (facility) in Virginia, and the performance and behavior of the section chief for cardiac surgery (section chief). Specifically, the OIG reviewed the section chief's surgical complications and patient outcomes, and reports of unprofessional behavior. The OIG also reviewed the temporary inactivation of the heart transplant program and factors associated with reactivation. Further, the OIG reviewed Veterans Integrated Service Network (VISN) and facility leaders' responses to concerns raised about the heart transplant program.[1]

Facility Background

The Central Virginia VA Health Care System consists of the Richmond VA Medical Center and six outpatient clinics that are part of VA Mid-Atlantic Health Care Network, VISN 6.[2] The facility provides a comprehensive range of services including general medicine and primary, surgical, behavioral health, spinal cord injury, nursing home, palliative, and dental care. From October 1, 2022–September 30, 2023, the facility served 80,114 patients. The Veterans Health Administration (VHA) classifies the facility as a level 1a–highest complexity.[3] At the time of the inspection, the facility maintained an *inpatient complex* procedure complexity designation and reported completion of 4,649 invasive procedures in fiscal year 2023.[4] The facility offers many surgical specialties including cardiac, thoracic, and vascular.[5]

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[1] VA administers healthcare services through a nationwide network of 18 regional systems referred to as Veterans Integrated Service Networks.

[2] The facility's outpatient clinics are located in Charlottesville, Emporia, Fredericksburg (3), and Henrico, Virginia.

[3] VHA Office of Productivity, Efficiency and Staffing, "Facility Complexity Model Fact Sheet." The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, and educational and research missions. Complexity levels include 1a, 1b, 1c, 2, and 3. Level 1a facilities are considered the most complex and level 3 facilities are the least complex.

[4] "Inpatient complex invasive procedures require a dedicated critical care service providing 24/7 coverage and daily multidisciplinary rounds, specialized technology and board-certified specialists depending on the approved invasive programs, dedicated in-house 24/7 coverage of invasive patients and a readily available OR [operating room] call team for emergency and salvage procedures." VHA Directive 1220(1), *Facility Procedure Complexity Designation Requirements to Perform Invasive Procedures in Any Clinical Setting*, May 13, 2019, amended February 11, 2020; fiscal year 2023 represents the time frame of October 1, 2022–September 30, 2023.

[5] "Heart (cardiac) and chest (thoracic) surgeons diagnose and surgically treat conditions of the heart, lungs and chest." "Experts in complex heart surgery," Mayo Clinic, accessed February 27, 2024, https://www.mayoclinic.org/departments-centers/cardiovascular-surgery/sections/overview/ovc-20123422; The term "vascular" refers to the blood vessels. *Merriam-Webster.com Dictionary*, "vascular," accessed May 29, 2024, https://www.merriam-webster.com/dictionary/vascular.

Facility Heart Transplant Program

The facility has clinical programs in heart and liver transplantation and is a member of the Organ Procurement and Transplantation Network (OPTN).[6] The OPTN was established by the United States Congress through the National Organ Transplant Act in 1984 to maintain a national registry for organ matching, and has been administered by the United Network for Organ Sharing since 1986.[7] All transplant facilities must be independent members of and report organ-specific data to the OPTN. Additionally, facilities must meet the qualifications and requirements to obtain United Network for Organ Sharing membership designation and maintain ongoing compliance with network bylaws.[8] Failure to do so will result in membership revocation.[9]

VHA transplant centers, as members of the OPTN, voluntarily comply with OPTN policies and Centers for Medicare and Medicaid Services (CMS) regulations pertaining to organ transplantation.[10] CMS does not review or approve VA transplant programs but recognizes that quality of care and outcomes are "are a function of many elements of the facility and transplant team, and not solely determined by the individuals performing the procedure."[11]

The facility heart transplant program is one of six VHA facilities that provide heart transplant services, and one of two that perform the transplants in-house. Patients in the other four programs receive transplants at non-VA facilities and receive pre- and post-transplant services at the VHA facility under dual care or primary care agreements.[12]

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[6] The facility liver transplantation program functions as an "affiliate" transplant program, whereby pre- and post-transplant care is done at the facility, but the actual surgical procedure is performed at an affiliated non-VA facility.

[7] "History & NOTA [National Organ Transplant Act]," US Department of Health and Human Services Organ Procurement & Transplantation Network, accessed January 24, 2024, https://optn.transplant.hrsa.gov/about/history-nota; "About," US Department of Health & Human Services Organ Procurement & Transplantation Network, accessed September 21, 2023, https://optn.transplant.hrsa.gov/about/. For the purposes of this report, the OIG will refer to the OPTN as representing both the OPTN and United Network for Organ Sharing.

[8] OPTN, *Bylaws*, December 5, 2022. Replaced by OPTN, *Bylaws*, December 5, 2023. Unless otherwise specified, the 2023 bylaws contain the same or similar language as the 2022 bylaws regarding requirements for primary heart transplant surgeons who are not eligible for certification by the American Board of Thoracic Surgery.

[9] United Network for Organ Sharing, "Appendix A to Bylaws," March 23, 2007.

[10] VHA Directive 1101.03, *Solid Organ, Tissue and Eye Donation*, August 23, 2021; Federal Register, *Department of Health and Human Services, Centers for Medicare & Medicaid Services*, Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants, 72 Fed. Reg. 61, 15,198–15,280 (Mar. 30, 2007).

[11] CMS Memo CAG-00061N, "National Coverage Policy Request," July 26, 2000.

[12] William Gunnar, "The VA Transplant Program: A Rebuttal to Criticism and a Look to the Future," *American Journal of Transplantation* 19, no. 5 (May 2019): 1288–1295, https://doi.org/10.1111/ajt.15295; The Michael E. DeBakey VA Medical Center in Houston, Texas, is the other VHA facility that provides in-house heart transplants. "Houston VA Performs First Multi-Organ Transplant Involving the Heart," accessed February 23, 2024, https://www.va.gov/houston-health-care/stories/houston-va-performs-first-multi-organ-transplant-involving-the-heart/#:~:text=In%20July%2C%20Air%20Force%20Veteran%20Walter%20Pinkney%20was,and%20has%20performed%20simultaneous%20liver%2Fkidney%20transplants%20since%202014.

On September 13, 2019, the OPTN granted facility leaders' request for voluntary inactive status as there was no primary transplant surgeon.[13] The OPTN reactivated the program in September 2020, and designated the section chief as the primary heart transplant surgeon. The section chief also serves as the surgical director of cardiac transplantation. The VISN Chief Medical Officer (CMO) told the OIG that on August 10, 2023, due to concerns about increased cardiac and heart transplant surgery patient safety event reports from summer 2023, the decision was made to pause the heart transplant program. The Facility Director notified the OPTN of a voluntary and temporary inactivation of the heart transplant program, effective August 15, 2023.[14] As of April 2024, the program remained paused.

When the OIG initiated this inspection in September 2023, the section chief was the only surgeon privileged to perform heart transplants and was responsible for heart transplant program oversight and management.[15] A second full-time heart transplant surgeon entered employment at the facility in fall 2023. From summer 2022 to fall 2023, the majority of cardiac surgeries—including heart transplants—were performed and managed by the section chief, while a part-time cardiothoracic surgeon provided periodic on-call coverage.

National Surgery Office

The National Surgery Office (NSO) is VHA's national program office that "provides operational oversight of the VHA Surgery Program including the VA transplant program" and "monitors surgical quality and outcomes data and quality improvement activities at the national, regional, and local level."[16] Components of NSO oversight include performing consultative facility site visits as requested by facility or VISN leaders, reviewing concerns related to quality outcomes, and rendering expert opinions.[17]

Prior to the initiation of this inspection, the VISN CMO requested NSO assistance in reviewing the facility's heart transplant and cardiac surgery programs, which resulted in two consultative site visits. The VISN CMO told the OIG the first NSO site visit occurred in February 2023, and a

[13] During this inactive period, the facility entered into a sharing agreement with the affiliate Virginia Commonwealth University Medical Center, whereby pre- and post-cardiac transplantation care was provided by a part-time cardiac surgeon, but the actual surgical procedure was performed at an affiliated non-VA facility.

[14] Patient safety reports are "an event, incident or condition, directly associated with care or services provided to a patient, that could have resulted or did result in unintentional harm." VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023.

[15] VHA defines "privileged" as a description "of the specific scope and content of patient care services for which a [licensed independent practitioner] is qualified and expected to actively perform." VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was rescinded and replaced by VHA Directive 1100.21(1), *Privileging*, March 2, 2023, amended April 26, 2023. The policies contain similar language related to privileging. According to the chief of surgery, the section chief was not responsible for providing thoracic care. The former cardiothoracic section chief served as section chief from May 2008 through August 2019.

[16] VHA Directive 1102.01(2), *National Surgery Office*, April 24, 2019, amended April 19, 2022.

[17] VHA Directive 1102.01(2).

report containing findings and recommendations was provided to VISN and facility leaders in April 2023. The second visit occurred in August 2023, and the resulting report was given to VISN and facility leaders in October 2023.

The two NSO site visit reports included multiple recommendations related to this inspection. The first report recommended reviewing locally collected cardiac surgery outcome data for comparison to the Veterans Affairs Surgical Quality Improvement Program (VASQIP) and completing surgeon recruitment efforts. The second report recommended supplementing team-building efforts, assessing staff concerns, and sharing quality and safety data reports with staff.

Veterans Affairs Surgical Quality Improvement Program

VASQIP is a quality assurance program used by the NSO that "serves as the primary tool for measurement of the quality of surgical outcomes" and was established to meet legal mandate.[18] VASQIP data are collected locally at VHA facilities by surgical quality nurses, who log all cardiac cases for inclusion in the NSO data analytic process.[19] NSO staff then analyze and compare facility data to VHA national metrics and provide quarterly reports to VISN, facility, and surgical leaders that reflect morbidity (complication) and mortality outcomes, critical safety events, and procedural compliance.[20] VASQIP data is neither surgeon- nor patient-specific, and is presented in the report in an aggregate format by facility surgical specialty for quality assurance purposes.[21] Facility surgical programs with morbidity and mortality outcomes that deviate significantly from national averages are further reviewed by the NSO to determine interventions dependent on the degree of persistence or concern.[22]

Allegations

From March through August 2023, the OIG received multiple complaints related to the section chief's unprofessional conduct, cardiac surgery outcomes, and patient care practices. Several allegations focused on the heart transplant program and the section chief's clinical skills. In

[18] VHA Directive 1102.01(2).

[19] VHA Directive 1102.01(2); Facilities are required to have a dedicated surgical quality nurse lead who serves as a subject matter expert for VASQIP data collection and member of the facility surgical workgroup. VA NSO, *VA Surgical Quality Improvement Program (VASQIP) Operations Manual for Surgical Outcomes Data Transfer, Validation and Risk Assessment*, version 4.5, March 2016.

[20] VHA Directive 1102.01(2).

[21] NSO, *VA Surgical Quality Improvement Program (VASQIP) Operations Manual for Surgical Outcomes Data Transfer, Validation and Risk Assessment*, v 4.5, March 2016. The manual states "as an established medical quality assurance database, VASQIP data meet the requirements for confidentiality as mandated in title 38 U.S.C. § 5705 and its implementing regulations." Confidentiality of medical quality assurance records requires that identifiable information is not included in documents disclosed, and as such, identifiable surgeon-specific data are not entered into the VASQIP database. 38 C.F.R. § 5705.

[22] VHA Directive 1102.01(2). Interventions may include VISN chief surgical consultant review; site visits from the VISN chief surgical consultant, NSO, or VA Central Office; a facility action plan; or an audit of surgical deaths.

November 2023, during the inspection, the OIG team received a complaint alleging additional concerns regarding the section chief's poor surgical outcomes.

The OIG received many similar or duplicative allegations. The OIG identified the following allegations as relevant to this inspection, and representative of similar allegations:

- The section chief had "much worse" cardiac surgical outcomes than previous cardiac surgeons employed at the facility, including higher cardiac surgery morbidity and mortality rates; "many patients readmitted after CT [cardiothoracic] surgery"; and patients with "incredibly long" cardiac surgery cardiopulmonary bypass (CPB) times.[23]
- The section chief engaged in disruptive and unprofessional behaviors in the workplace.

During the inspection, the OIG identified the following additional concerns: (1) heart transplant volume was not consistent with OPTN and CMS targets to ensure clinical competencies, (2) facility leaders failed to ensure a culture of safety in response to staff's concerns, and (3) VISN leaders did not provide timely follow-up to the Facility Director's February 2022 request to review cardiac surgery complications, returns to the operating room, and episodes of care when chest incisions were left open.

Additional allegations were reviewed that the OIG did not substantiate or was unable to determine whether an alleged event or action took place. The OIG acknowledges the complainants' willingness to bring these concerns to the OIG, even when reporting concerns about retaliation for doing so. The OIG exercised due diligence and conducted a comprehensive review of the additional allegations, the results of which are briefly summarized in appendix A.[24]

Scope and Methodology

The OIG initiated the inspection on September 25, 2023, and conducted an on-site visit November 14–16, 2023. The OIG conducted additional virtual interviews through December 21, 2023. The OIG interviewed available complainants, NSO leaders and subject matter experts, VISN and facility executive leaders, the acting VISN chief surgical consultant, the VISN quality management officer, the facility chief of surgery, the section chief of cardiac surgery, former and current facility surgeons, nursing leaders, surgical quality nurses, current and

[23] "Cardiothoracic" is relating to, involving, or specializing in the heart and chest. "Cardiopulmonary bypass," Cleveland Clinic, accessed December 28, 2023, https://my.clevelandclinic.org/health/treatments/24106-cardiopulmonary-bypass; *Merriam-Webster.com Dictionary*, "cardiothoracic," accessed February 29, 2024, https://www.merriam-webster.com/dictionary/cardiothoracic. Also described as being "on the pump," "cardiopulmonary bypass" occurs when a heart-lung machine takes over for a patient's heart and lungs during surgery. The patient's blood is directed away from the heart and lungs to a machine outside of the body, which allows the surgeon to work on those organs while they are paused. During this time, the blood is continually circulated back to the rest of the patient's body from the machine.

[24] The underlined terms are hyperlinks to another section of the report. To return to the point of origin, press and hold the "alt" and "left arrow" keys together.

former heart transplant program clinical and administrative staff, a quality management leader, risk managers, and operating room clinical staff.[25]

The OIG reviewed relevant VHA directives, handbooks, and guidelines as well as applicable OPTN policies, and CMS regulations pertaining to organ transplantation.[26] The review also included facility policies and procedures related to cardiothoracic care, the heart transplant program, clinic management, and physician clinical responsibilities; medical staff bylaws; and committee meeting minutes. The OIG also examined NSO reports, OPTN reviews, and related facility action plans. The OIG analyzed cardiac and transplant surgery program outcomes published in NSO and Scientific Registry of Transplant Recipients (SRTR) reports, assessed facility data regarding CPB times and facility quality management reports, and reviewed patient electronic health records (EHRs).[27] The OIG did not independently verify VHA data for accuracy or completeness, nor provide an analysis of the methodologies used by NSO to report VASQIP data. The OIG retrieved cardiac surgery data from VA's Corporate Data Warehouse and reviewed to determine the numbers and types of surgeries performed at the facility.[28]

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

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. The OIG reviews

[25] The OIG did not interview one confidential complainant. Given the duplicative nature of many of the allegations, the OIG concluded additional interviews would likely not provide additional information required for the analysis.

[26] VHA Directive 1101.03, *Solid Organ, Tissue and Eye Donation*, August 23, 2021; Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants, 72 Fed. Reg. 61 at 15,262–15,280.

[27] The SRTR operates "under contract from the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), US Department of Health and Human Services (HHS)." SRTR bi-annual reports are publicly available, program-specific, and provide comparative outcomes data against all transplant centers in the US. "Driven to Make a Difference," SRTR, accessed March 6, 2024, https://www.srtr.org/about-srtr/mission-vision-and-values/; "About SRTR Reports," SRTR, accessed March 6, 2024, https://www.srtr.org/reports/about-srtr-reports/; "Program-Specific Reports," SRTR, accessed March 6, 2024, https://www.srtr.org/reports/program-specific-reports/.

[28] The Corporate Data Warehouse is made up of four regional data warehouses to standardize, consolidate, and streamline clinical data systems to provide a high-performance business intelligence infrastructure. "Corporate Data Warehouse (CDW)," VA Health Services Research, accessed on March 5, 2024, https://www.hsrd.research.va.gov/for_researchers/vinci/cdw.cfm.

available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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

Inspection Results

1. Evaluation of Cardiac Surgery Quality Outcomes

Morbidity and Mortality

The OIG did not substantiate that the section chief's morbidity (complication) and mortality rates were "much worse than the previous [cardiothoracic] surgeons." The OIG reviewed NSO quarterly reports for the period of October 1, 2018–September 30, 2023, and found that the facility did not have statistically significant increases in cardiac surgery morbidity and mortality outcome rates when compared to national data.

The NSO measures morbidity and mortality outcomes as the ratio of "observed" occurrences divided by "expected" occurrences (O/E), with an associated confidence level as an indicator of statistical significance. The NSO describes expected mortality as "the number (or percentage) of patient deaths that may be anticipated to occur during a reported time period, based upon the patient population's associated risk factors."[29] Observed mortality "is the number (or percentage) of actual patient deaths during the time period being reported." This same formula is used for morbidity calculations.[30]

The OIG found that observed facility cardiac surgery morbidity rates were not significantly different than expected rates and therefore did not indicate the need for further review by the VISN chief surgical consultant or NSO. The OIG did not note any concerning differences in the facility's morbidity rates prior to versus during the section chief's employment with the facility.

Aggregated facility and specialty-specific VASQIP data indicated that during the time period when the section chief was the sole full-time cardiothoracic surgeon, the cardiac surgery program did not have any significantly higher O/E ratios for mortality compared to previous levels reviewed.

[29] The NSO defines "surgical mortality" to include deaths within 30 days of surgery. National Surgery Office, *NSO Quarterly Report Interpretation Document*, December 19, 2023.

[30] National Surgery Office, *NSO Quarterly Report Interpretation Document,* December 19, 2023.

The OIG reviewed NSO quarterly reports and found 13 reported patient deaths in the 22 months prior to the section chief's employment and 3 patient deaths in a one-year period under the section chief's leadership (fiscal year 2022). No data in the NSO quarterly reports indicated a need for further review of facility cardiac surgery mortality rates by the VISN chief surgical consultant or NSO.

The OIG found that a surgical quality nurse reviewed mortality data, and the results were shared with the Chief of Staff and surgical leaders during the majority of Surgical Work Group meetings and the newly established Cardiothoracic Surgery Program Quality Assessment Performance Improvement Committee. The OIG concluded that the current mortality and morbidity review structure included monitoring surgical outcomes.

Heart Transplant Survival Rates

The OIG reviewed SRTR data for the period of January 1, 2018–June 30, 2023, to assess for any significant variation in mortality prior to and during the section chief's employment.[31] The OIG reviewed one-year survival rate data associated with heart transplants as a representative quality measure.[32]

The SRTR provides statistical and analytical support including policy, performance metrics, economic analysis, and preparation of reports to the OPTN and other government agencies.[33] SRTR reports reflect facility heart transplant patient and organ survival rates at specific postoperative intervals in comparison to all other heart transplant programs nationally. The one-year reporting period covered a key portion of the section chief's tenure at the facility.

The OIG reviewed the SRTR reports and noted no patient deaths within one year of transplantation until late 2021, when two patient deaths contributed to higher-than-expected rates for transplanted organ failures.[34] SRTR program data does not disclose specific patient identifying information; however, the OIG identified the two patients during the inspection and reviewed the respective EHRs and other relevant documents.

The OIG found one transplant surgery was performed by the section chief and the second by another surgeon who is no longer employed by VHA. The OIG found that both surgeries were discussed in the NSO August 2023 site visit report and reviewed through the facility peer review

[31] The OIG reviewed SRTR reports released from July 6, 2021, through January 9, 2024. The reports cover one-year survival rates for transplants from October 2018 through June 2023. The SRTR data for the review period excluded data beginning on March 13, 2020, the date of the declaration of the COVID-19 national public health emergency, through June 12, 2020. Further, the facility program was inactive between September 13, 2019, and September 24, 2020, following the departure of the former cardiothoracic section chief.

[32] SRTR reports reflect aggregated facility data and do not provide surgeon-specific patient survival rates.

[33] "Driven to Make a Difference," SRTR; "About SRTR Reports," SRTR; "Program-Specific Reports," SRTR.

[34] The April 2023 SRTR report included data from January 1–March 1, 2020, and June 13–30, 2022.

process per VHA policy.[35] The OIG did not find evidence that disclosure of adverse events was warranted or conducted for either transplant patient's death.

Cardiac Surgery Postoperative Readmission Rates

The OIG did not substantiate that the facility has "had many patients readmitted after CT [cardiothoracic] surgery."[36] The OIG found that the facility's cardiac surgery 30-day all-cause readmission rates were not significant enough to elicit further NSO assessment.[37]

The OIG reviewed NSO quarterly reports from October 1, 2018–September 30, 2023. The NSO quarterly reports use the 30-day all-cause readmission rate, which includes "any acute hospital admission to the same hospital or another VA hospital within 30 days of discharge from the inpatient surgical admission."[38] The OIG found no quarterly reports when cardiac surgery inpatient all-cause readmission rates were double the national average, the threshold for further NSO or VISN review.

A surgical quality nurse told the OIG that readmission rates were below the national average, which the OIG confirmed from the fiscal year 2023 second through fourth quarter NSO reports. The surgical quality nurse told the OIG that readmissions may not be specifically related to the cardiac surgical care provided to the patient and that the readmission rate can be affected by comorbidities and the length of time the patient remained in the hospital after surgery.

The OIG's review found that inpatient readmission rates were not double the national average and had improved since the second quarter of fiscal year 2022. The OIG also found that a surgical quality nurse was aware of facility readmission trends and potential contributing factors to this outcome measure.

Cardiopulmonary Bypass Time

The OIG was unable to determine whether the section chief had "incredibly long" CPB times. The OIG learned through interviews and literature review that the duration of CPB can vary widely depending on many factors, including the specific type of surgery, and is not universally accepted as a metric of quality or skill. Additionally, the OIG could not verify the CPB data

[35] A peer review is a "a critical review of care performed by a peer" "to promote confidential and non-punitive assessments of care at the individual clinician level." VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018; VHA Directive 1102.01(2). Specific and detailed information, including individual patient information, related to NSO consultative site visits and VHA peer reviews are not discussed further in this report as these are quality management activities that can generate confidential records and documents under 38 U.S.C. § 5705. VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

[36] The OIG was unable to ascertain what the complainant referred to by using the term "many." The OIG used VASQIP and the resulting NSO analysis for quantitative interpretations.

[37] The NSO advises surgical leaders to focus on quarters with more than 100 surgeries for statistical relevance. National Surgery Office, "NSO Quarterly Report Tutorial Summary and Outcome Chapters," September 2022.

[38] NSO, *Quarterly Report Interpretation Document*, December 19, 2023.

collected by the chief of surgery, as the methodology for collection and interpretation was unclear and the data did not identify the surgeon or specific patient information.

When a patient is on CPB, a machine takes over for the heart and lungs, typically during heart surgery. The CPB machine temporarily provides oxygen, removes carbon dioxide, and returns the blood to the patient's aorta, supplying circulation and blood pressure to the rest of the patient's body. This allows the surgeon to work on or around the heart while it is temporarily paused, not beating, and empty of blood.[39]

There are a number of variables that may contribute to the adverse effects of CPB, including the length of time a patient spends on the machine (known as "pump time").[40] Technical difficulties executing the planned operation, due to unfavorable anatomy or unforeseen complications, may extend the time on CPB during heart operations.[41] While there is no universally agreed-upon threshold of CPB duration after which a patient is at higher risk of mortality or morbidity, it is an accepted principle in cardiac surgery that a patient's time on CPB should be minimized. One hundred and eighty minutes is commonly cited as a marker of "long" CPB pump time duration.[42]

The chief of surgery told the OIG about being unaware of any national quality benchmark for CPB times. Additionally, the chief of surgery, a perfusionist, and two cardiac surgeons told the OIG that CPB times vary by case, and may not be a reliable indicator of quality, performance, or

[39] "What is Cardiopulmonary Bypass," Cleveland Clinic, accessed December 12, 2023, https://my.clevelandclinic.org/health/treatments/24106-cardiopulmonary-bypass; While cardiac surgical literature cites associations between the use of CPB and complications after heart surgery, CPB continues to be an important part of how many procedures can be done; Stefano Salis et al., "Cardiopulmonary Bypass Duration Is an Independent Predictor of Morbidity and Mortality After Cardiac Surgery," *Journal of Cardiothoracic and Vascular Anesthesia* 22, no. 6 (December 2008): 814–822, https://doi.org/10.1053/j.jvca.2008.08.004.

[40] Salis et al., "Cardiopulmonary Bypass Duration Is an Independent Predictor of Morbidity and Mortality After Cardiac Surgery"; Shijun Xu et al., "Cardiopulmonary Bypass Time is an Independent Risk Factor for Acute Kidney Injury in Emergent Thoracic Aortic Surgery: A Retrospective Cohort Study," *Journal of Cardiothoracic Surgery*, no. 14 (May 7, 2019): https://doi.org/10.1186/s13019-019-0907-x.

[41] Salis et al., "Cardiopulmonary Bypass Duration Is an Independent Predictor of Morbidity and Mortality After Cardiac Surgery"; Diyar Jamil, Aram Baram, and Bashar Saqat, "Impact of Prolonged Cardiopulmonary Bypass and Operative Exposure Time on the Incidence of Surgical Site Infections in Patients Undergoing Open Heart Surgery: Single Center Case Series," *International Journal of Surgery Open*, no. 22 (2020): 52–56, https://doi.org/10.1016/j.ijso.2019.12.001. Unfavorable anatomy refers to anticipated or unexpected variations in characteristics of the body structures or tissues encountered during the planned surgical procedure that make the steps of the procedure more challenging or time consuming.

[42] The OIG interviewed members of the facility cardiac surgery team, including a surgeon, who referred to 180 minutes as the duration of CPB after which they have concerns for CPB related complications. Juha Nissinen et al., "Safe Time Limits of Aortic Cross-Clamping and Cardiopulmonary Bypass in Adult Cardiac Surgery," *Perfusion* 24, no. 5 (September 2009): 297–305, https://journals.sagepub.com/doi/10.1177/0267659109354656; Diyar Jamil, Aram Baram, and Bashar Saqat, "Impact of Prolonged Cardiopulmonary Bypass and Operative Exposure Time on the Incidence of Surgical Site Infections in Patients Undergoing Open Heart Surgery: Single Center Case Series."

outcomes.[43] Neither VASQIP nor the Society of Thoracic Surgeons Adult Cardiac Surgery Database include CPB times as part of their cardiac surgery quality or reporting processes.[44]

During the OIG inspection, facility staff members described concerns of prolonged CPB times during the section chief's cardiac surgeries. The chief of surgery reported reviewing 12 years of facility CPB data, which did not support the staff's concern of longer CPB times during the section chief's tenure compared to historical data. The section chief told the OIG that facility leaders and a surgical quality nurse provided facility CPB time data to the NSO during both site visits, and "it was not an outlier." This was supported by the NSO National Director of Surgery, who told the OIG that the NSO's team evaluated CPB times during their consultative site visit and did not note patterns of deviations.

The OIG found that in response to NSO site visit recommendations to share quality and safety data with clinical team members, facility leaders discussed CPB times and improvement strategies in the Cardiothoracic Surgery Program Quality Assessment Performance Improvement Committee.

The OIG reviewed two of the section chief's patients cited by facility staff as examples of patients who had prolonged CPB times during cardiac surgery and "poor outcomes." The OIG found the two patients' CPB times were approximately eight hours, significantly exceeding the five-hour average total surgical time cited by the NSO for their planned principal procedures. Patient 1 died hours after surgery and patient 2 died just over one month post-operatively. However, the OIG cannot draw a causal relationship between the prolonged CPB times and the two patients' outcomes, nor can the OIG generalize about the surgeon's average CPB times based on those two cases. Patient 1's episode of care was peer reviewed, but the OIG found no evidence of a peer review or joint patient safety report for patient 2.

The OIG is unable to draw a conclusion regarding current versus historical CPB times based on the chief of surgery's facility bypass time data, as the methodology of the data collection and interpretation could not be validated.

[43] A perfusionist is a certified medical technician responsible for operation of the heart and lung machine that oxygenates the blood equipment during open-heart surgery. *Merriam-Webster.com Dictionary*, "perfusionist," accessed March 26, 2024, https://www.merriam-webster.com/dictionary/perfusionist.

[44] Karen Kim et al., "The Society of Thoracic Surgeons Adult Cardiac Surgery Database: 2022 Update on Outcomes and Research," *Annals of Thoracic Surgery* 115, no. 3 (March 1, 2023): 566–574, https:/doi.org/10.1016/j.athoracsur.2022.12.033; The Society for Thoracic Surgery Database is the "gold standard for [cardiothoracic] CT surgery clinical outcomes registries, with nationally recognized quality performance measures." "About STS," Society for Thoracic Surgery, accessed March 7, 2024, https://www.sts.org/about/about-sts. A VA chief of cardiac surgery reported VHA does not participate in STS data collection, but this analysis is included to reflect the omission of CPB as a quality measure in the STS National Database.

2. The Heart Transplant Program Had Consistently Low Patient Volume

Although facility cardiac transplant surgery outcomes data did not indicate further NSO or VISN evaluation, the OIG noted that the program was operating below target volumes, in part due to periods of inactive status from September 2019–December 2020 and August 2023–April 2024. Higher volumes would likely support greater statistical resolution for outcomes data.[45]

CMS recommends a facility heart transplant program to perform 10 heart transplants over a 12-month period. This minimum volume requirement is to maintain the team's surgery-related proficiency and clinical expertise.[46] Clinical literature supports the opinion that mortality and morbidity rates may not be "statistically reliable" metrics for less-frequent, high-risk procedures.[47]

As previously noted, facility leaders temporarily inactivated the heart transplant program in August 2023 and notified the OPTN, VHA leaders, and national program offices. The OPTN allows facilities the discretion to inactivate transplant programs on a short- or long-term basis. The OPTN requires heart transplant programs to remain active by performing at least one heart transplant "in three consecutive months."[48]

The OIG reviewed data retrieved from the VA Corporate Data Warehouse and learned that facility staff performed 17 heart transplants from August 1, 2020–September 30, 2023; all but one surgery was performed by the section chief. CMS would have expected approximately 30 heart transplants to have occurred during this period if the facility program was considered active. Further, the OIG found the heart transplant program had become "functionally inactive" according to OPTN bylaws by twice failing to perform at least 1 transplant in a three-month period (see figure 1).[49]

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[45] Bradley Reames et al., "Hospital Volume and Operative Mortality in the Modern Era," *Annals of Surgery* 260, no. 2 (August 2014): 244–251, https://doi:10.1097/SLA.0000000000000375.

[46] CMS Decision Memo CAG-00061N, "Transplant Centers: Re-Evaluation of Criteria for Medicare Approval," July 26, 2000; Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants, 72 Fed. Reg. 61, 15198–15280 (Mar. 30, 2007) (to be codified at 42 C.F.R. pts. 405, 482, 488, and 498).

[47] Bradley Reames et al., "Hospital Volume and Operative Mortality in the Modern Era."

[48] OPTN, *Bylaws*, December 5, 2022; OPTN, *Bylaws*, December 5, 2023. Short-term inactivity for a transplant program is defined as no more than 14 consecutive days. "Long-term inactivity occurs when a transplant program is inactive for 15 or more consecutive days." For long-term inactivation, a facility must provide written notification to OPTN and inform patients currently involved with the facility's heart transplant program.

[49] The OIG does not consider the period from August 2020 through the first heart transplant in December 2020 to be a period of functional inactivity, as this was used to gain OPTN approval for the section chief to perform as the primary heart transplant surgeon.

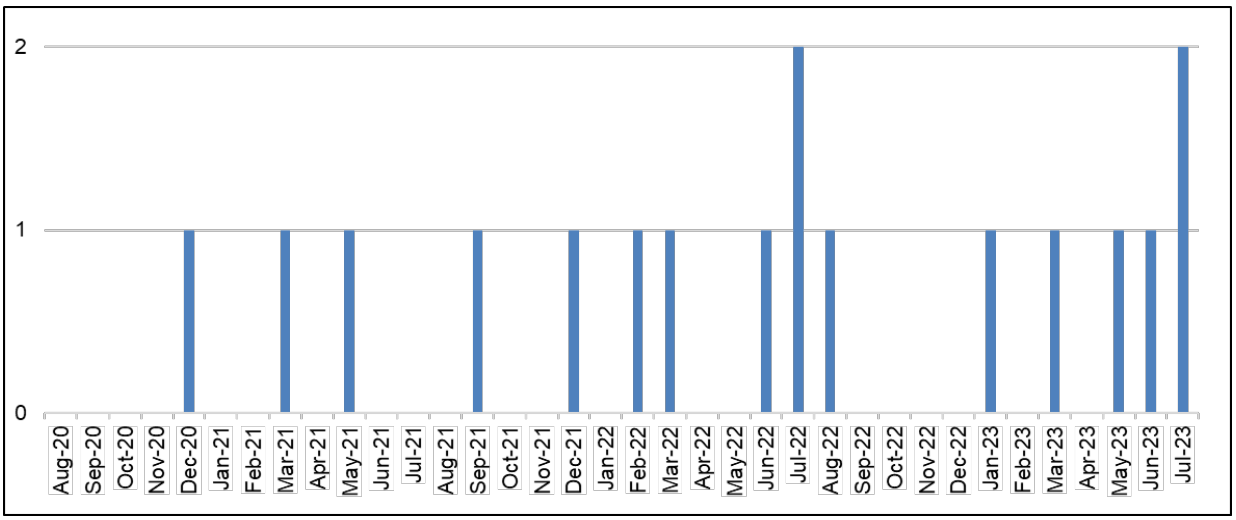

Figure 1. *Number of heart transplants completed at the facility.*
Source: VA Corporate Data Warehouse
Note: This graph shows the time period in which the section chief began employment at the facility (August 2020) through temporary inactivation of the facility heart transplant program (August 2023).

The facility transplant program director acknowledged recent "bad outcomes," explaining that it is "impossible to have 100% survival" in a heart transplant program. The transplant program director also identified the program's goal of a minimum of 10 transplants a year and cited reasons behind the program's "struggle to maintain" that volume, including a change in the primary heart transplant surgeon, staff vacancies, and insufficient number of referrals for transplant. The Chief of Staff also acknowledged this concern, citing the need for volume growth.

During this three-year period, the OIG found two patient deaths occurred within 30 days of transplantation.[50] Given the low volume of transplants performed at the facility per year, these two patient deaths had a noticeable impact on heart transplant program mortality rates. Further, the OIG believes that extended periods of inactive status and low transplant volumes would lessen opportunities for the many specialized professionals involved in the complex process of transplantation to maintain clinical experience and team proficiency, possibly contributing to variations in outcomes. The OIG expects facility and service leaders to continue rigorous surveillance of quality measures if the heart transplant program is reactivated. VISN and facility leaders should ensure attainable program target volumes would meet clinical experience requirements.

[50] These two patients were previously discussed in the "Heart Transplant Survival Rates" section.

3. The Section Chief Engaged in Unprofessional Conduct

The OIG substantiated that the section chief engaged in unprofessional behavior toward staff. The OIG found four specific instances in which the section chief was unprofessional in communications to other staff.

Incivility has been described as behavior that is "bred in toxic work and learning environments" and may be rude, disrespectful, belittling, or cause psychological or physical distress.[51] Studies show that those most affected by incivility in the workplace may be those most committed to their work.[52]

The Joint Commission recognizes that failure to address intimidating behavior in health care may lead to medical errors, staff attrition, and patient dissatisfaction.[53] In addition, the Accreditation Council for Graduate Medical Education guidance states, "Professionalism is at the core of being a physician" and further demonstrates the importance of a physician's non-technical skills by including professionalism and interpersonal and communication skills as two of the six core competencies.[54]

Further, The Joint Commission recognizes that staff may be afraid to report a colleague or perceive that leaders disregard complaints against certain providers who bring in more revenue or when there may be consequences for reporting them.[55] Literature recommends that leaders foster positive learning environments and recognize and mitigate incivility in the surgical setting to cultivate high-functioning teams. Additionally, leaders should engage and support retention of employees who are most negatively affected by unprofessional conduct.[56]

The facility's behavioral code of conduct states that it "seeks to promote a culture of safety by addressing behaviors which threaten the performance of the health care team by optimizing

[51] Katherine B. Santosa et al., "Incivility, Work Withdrawal, and Organizational Commitment Among US Surgeons," *Annals of Surgery* 277, no. 3 (March 2023): 416–422, https://doi.org/10.1097/SLA.0000000000005186; Katherine B. Santosa and Gurjit Sandhu, "Physician Mistreatment and Toxic Teams: Incivility in Clinical Learning Environments," *American Journal of Surgery* 220, no. 2 (August 1, 2020): 274–275, https://doi.org/10.1016/j.amjsurg.2020.05.017.

[52] Katherine B. Santosa et al., "Incivility, Work Withdrawal, and Organizational Commitment Among US Surgeons"; Katherine B. Santosa and Gurjit Sandhu, "Physician Mistreatment and Toxic Teams: Incivility in Clinical Learning Environments."

[53] The Joint Commission, "Behaviors that Undermine a Culture of Safety," *Sentinel Event Alert*, no. 40, July 9, 2008, updated June 18, 2021.

[54] Accreditation Council for Graduate Medical Education, *Guide to the Common Program Requirements (Residency)*, revised July 2023.

[55] The Joint Commission, "Behaviors that Undermine a Culture of Safety," *Sentinel Event Alert*.

[56] Katherine Santosa and Gurjit Sandhu, "Physician Mistreatment and Toxic Teams: Incivility in Clinical Learning Environment"; Katherine Santosa et al., "Incivility, Work Withdrawal, and Organizational Commitment Among US Surgeons."

respectful communication and interpersonal effectiveness."[57] Per the facility's behavioral code of conduct, unacceptable employee behaviors include

- "shouting or yelling,"
- "profane or disrespectful language," and
- "other behavior demonstrating disrespect, dishonesty, intimidation, or disruption to the work environment."[58]

Another facility policy explains that service chiefs have the responsibility to "identify when performance does not meet expectations, and initiate appropriate action to improve performance."[59] Facility policy provides two options to address unprofessional or disruptive behavior.[60] Under the first option, "repeated or egregious unprofessional behavior" by licensed providers is a trigger for a focused professional practice evaluation for cause.[61] The second option recognizes that "a pattern of disruptive behavior is generally considered more serious and may require progressive disciplinary action" such as admonishment, reprimand, or suspension.[62]

The OIG heard multiple staff members report that the section chief displayed unprofessional communication and behaviors, including rudeness and a threat to tape a staff member's mouth shut. The OIG reviewed disruptive behavior reports and found that facility staff had filed multiple disruptive behavior reports regarding the section chief's unprofessional behaviors,

[57] Central Virginia VA Health Care System, MCM 00-031, *Behavioral Code of Conduct*, September 5, 2019. This document was rescinded and replaced with Central Virginia VA Health Care System, MCP-000-031, *Behavioral Code of Conduct*, December 7, 2022. The two policies contain similar language related to promoting a culture of safety, unacceptable employee behaviors, and progressive disciplinary actions.

[58] Central Virginia VA Health Care System MCM 00-031; Central Virginia VA Health Care System MCP-000-031.

[59] Central Virginia VA Health Care System, MCP-011-104, *Focused Professional Practice Evaluation/Ongoing Professional Practice Evaluation (FPPE/OPPE)*, June 2, 2021.

[60] Central Virginia VA Health Care System MCP-011-104; Central Virginia VA Health Care System MCM 00-031; Central Virginia VA Health Care System MCP-000-031.

[61] Central Virginia VA Health Care System MCP-011-104; VHA Handbook 1100.19; VHA Directive 1100.21(1). The two policies contain similar language related to focused professional practice evaluations. The directive explains that a focused professional practice evaluation for cause is time-limited period providing an opportunity for improvement after a clinical concern has been triggered. "It is not a restriction or limitation on the ability to practice."

[62] Central Virginia VA Health Care System MCM 00-031; Central Virginia VA Health Care System MCP-000-031; Progressive disciplinary action is "using the least severe action which, in the supervisor's judgment, will most likely correct the employee's misconduct . . . The facts of the case, degree of willfulness of the employee's violation of VA conduct rules, and the seriousness of the misconduct and its resultant impact on VA operations, may be examples of reasons for necessitating consideration of more severe discipline." An admonishment is "an official letter of censure to an employee for minor act(s) of misconduct or deficiency in competence;" a reprimand is "a more severe disciplinary action;" a suspension is the "involuntary placement of an employee, for disciplinary reasons, in a non-duty, non-pay status for a temporary period of time." VA Directive 5021, *Employee/Management Relations*, April 15, 2002.

which were forwarded to the chief of surgery.[63] The chief of surgery explained to the OIG that reported concerns were reviewed to determine what occurred and if the situation had been rectified. The chief of surgery further stated that the concerns were not close in occurrence and that there were "mitigating circumstances," such as a concern about noise in the operating room.

The section chief expressed awareness of staff complaints that indicated a need for improvement related to interpersonal communication and acknowledged two specific occurrences of unprofessional behavior, including an incident in the operating room in which the section chief told a staff member to be quiet in an unprofessional manner. The section chief told the OIG, "I'm learning. I'm improving" and that "whenever I know that I've done something, I've personally gone and apologized to the person . . . like with the promise that it's not going to happen again." Additionally, the section chief reported engaging in leadership counseling.

During an interview, the chief of surgery reported personally witnessing an incident where the section chief spoke disrespectfully to another staff member. In addition, the OIG reviewed a fall 2023 electronic communication from a staff physician to the chief of surgery reporting a concerning interaction and recalling three other episodes when the section chief "acted in a rather erratic, unprofessional manner, raising [their] voice, using condescending and abusive language." The chief of surgery responded to this message and indicated having a conversation with the section chief, who acknowledged the behavior.

Both the chief of surgery and the section chief reported that concerns related to interpersonal communication and unprofessionalism were addressed through verbal counseling.[64] Through an interview, the OIG learned that NSO representatives had similar concerns and these concerns were relayed to VISN and facility leaders during the second site visit exit brief. The OIG found that VISN leaders added a specific item to the VISN's action plan in response to the second NSO report and recommendations, which required the chief of surgery to address the section chief's unprofessional conduct.

The OIG substantiated that the section chief had repeatedly exhibited unprofessional conduct. While the OIG recognized that the section chief engaged in leadership counseling and the chief of surgery informally addressed concerns through verbal counseling, the OIG is concerned that as of fall 2023, this unprofessional conduct persisted. The OIG found that the chief of surgery should have considered these disrespectful communications by the section chief as either repeated unprofessional behaviors or unacceptable employee behaviors and utilized options

[63] The Disruptive Behavior Reporting System is a "VA-approved secure web-based reporting mechanism providing means for all VA employees to alert the [disruptive behavior committee] or [employee threat assessment team] about behaviors that cause a safety concern, and about disruptive or violent events occurring within the health care setting." VHA Directive 1160.08(1), *VHA Workplace Violence Prevention Program*, amended February 22, 2022. Eleven disruptive behavior reports were filed regarding the section chief's unprofessional behaviors; however, the OIG determined that several of the reports were filed for the same incident.

[64] Verbal counseling is not considered a disciplinary action. VA Directive 5021.

described in facility policies, such as a focused professional practice evaluation for cause or progressive disciplinary action.[65] Leading an effective transplant program requires strong interpersonal skills, diplomacy, and the ability to partner with all stakeholders involved.

4. Facility Leaders Failed to Ensure a Culture of Safety

The OIG determined facility and surgical leaders failed to incorporate the VHA High Reliability Organization (HRO) pillar of creating a culture of safety to ensure staff felt comfortable reporting concerns.[66] During interviews with staff, the OIG learned of a fear of retaliation by leaders if complaints were brought forward.

Since 2018, VHA has used the HRO framework to drive toward continuous improvement and zero harm.[67] The HRO culture of safety pillar refers to the importance of staff feeling comfortable reporting safety concerns because they trust leaders will communicate openly about meaningful improvements to prevent harm and learn from mistakes.[68]

In addition, the facility's medical bylaws recognize behaviors that undermine a culture of safety. These include "foul language; rude, loud, or offensive comments; and intimidation of staff, patients and family members." The bylaws further note that these behaviors are "commonly recognized as detrimental to patient care."[69]

During interviews, the OIG heard surgical staff

- did not report threats or concerns due to fear of retaliation,
- felt that the complaints were "turned around on us,"
- escalated concerns by making the complaints "louder than in the past where we were more fearful," and
- sought other employment opportunities to leave the situation.

The Facility Director received two complaints in spring 2022 from staff regarding the section chief's "blaming the staff, patient complications, outcomes and mortalities," and a "lack of psychological safety."

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[65] Central Virginia VA Health Care System MCM 00-031; Central Virginia VA Health Care System MCP-000-031. Central Virginia VA Health Care System MCP-011-104.

[66] VHA, "VHA High Reliability Organization (HRO) Reference Guide" April 2023, Pre-Decisional Deliberative Document - Internal VA Use Only.

[67] VHA, "VHA High Reliability Organization (HRO) Reference Guide" April 2023, Pre-Decisional Deliberative Document - Internal VA Use Only.

[68] VHA, "VHA High Reliability Organization (HRO) Reference Guide" April 2023, Pre-Decisional Deliberative Document - Internal VA Use Only; VHA, "VHA High Reliability Organization (HRO) Glossary of Terms" May 2023, Internal VA Use Only.

[69] Central Virginia VA Health Care System, *Bylaws and Rules of the Medical Staff*, March 17, 2023.

The OIG found the facility leaders took the following actions to address staff's concerns:

- In March, April, June, and July 2022, the acting Facility Director conducted HRO leadership rounding with surgical staff; however, the OIG was unable to confirm that the acting Facility Director met with employees who were assigned to the cardiothoracic surgery service at the time of the rounding.[70]
- In April, the chief experience officer facilitated a discussion with the cardiothoracic team about psychological safety.
- In August, the chief experience officer facilitated a cardiothoracic section staff meeting that focused on conflict resolution. The Facility Director advised that while staff were supportive of this effort, staff continued to report that the section chief did not take responsibility for contributing to the problem.[71]

According to the Facility Director, after the decision was made to pause heart transplants in August 2023:

- The Chief of Staff met with the cardiothoracic staff to discuss the status of the program, while encouraging "them to keep patient safety and quality at the forefront of what we do, reinforce that they are providing quality care, remind them that as an HRO organization we support a just culture and psychological safety and any serious issue should be reported to [the Chief of Staff] or [the chief of surgery] immediately."
- A version of HRO training was going to be provided to the cardiothoracic team in early August 2023; however, due to the NSO site visit, the training was postponed.
- The Facility Director met with cardiothoracic staff three times in September and October 2023.
- After the NSO report was issued in October 2023, the Facility Director requested additional team training from VHA's National Center for Organization Development.[72]

A staff member told the OIG that meetings involved the section chief, which did not allow staff to feel comfortable voicing concerns to leaders. Another cardiothoracic staff member stated that

[70] The Facility Director reported being detailed to serve as the Facility Director of another VISN 6 medical center from late January through early August 2022.

[71] The OIG found these reports were in addition to those made through the disruptive behavior reporting system discussed above.

[72] VHA's National Center for Organization Development "collaboratively works with leaders throughout VA to improve organizational outcomes by supporting the development of an engaged workforce" using planned assessment and intervention. "Homepage," VHA National Center for Organization Development, accessed February 7, 2024, https://dvagov.sharepoint.com/sites/VHANationalCenterforOrganizationDevelopment/SitePages/Home.aspx. (This site is not publicly accessible.) In May 2024, the chief experience officer reported National Center for Organization Development consultations were scheduled for May, June, and July 2024.

the complaints would not have gone to the OIG if facility leaders had been more receptive or listened to staff.

The Chief of Staff acknowledged that, looking back on leaders' reactions to the complaints, meeting with staff earlier may have influenced the staff's responses. The Chief of Staff reported encouraging cardiothoracic team members to voice concerns through a variety of mechanisms. However, the Chief of Staff also described challenges with asking clarifying questions to staff who lodged anonymous complaints. The chief of surgery also reported similar frustrations with follow-up on anonymous complaints, and further described difficulty determining whether a complaint was new or previously addressed. The chief of surgery also voiced concerns over delayed reporting by staff and interpreted the reports as personal attacks on the section chief rather than staff not feeling comfortable voicing concerns.

The OIG found that the section chief's behaviors undermined a culture of safety and facility leaders, including the chief of surgery, are responsible for addressing these behaviors. After hearing staff's concerns and reviewing documentation, the OIG determined that while facility leaders took several actions to address staff's concerns, the team continued to report fear of retaliation.

VISN leaders also had similar concerns, as the VISN CMO told the OIG, "I think they [facility leaders] underestimated the complaints from their staff." The VISN quality management officer described unease with the perceived lack of urgency from facility leaders and stated, "I don't know that that level of interaction and communication at the facility level occurred as it should have."

A former NSO Surgical Advisory Board member told the OIG, "It falls entirely on the leader of the Surgical Service to make sure that everybody understands that those behaviors are not tolerated. And my understanding was that this was not made clear at VA Richmond."

The OIG found that despite facility leaders' efforts to provide the cardiothoracic team with information regarding psychological safety and conflict management, staff members reported these efforts were not successful in creating a culture of safety where staff felt comfortable reporting concerns without fear of retribution.

5. VISN Leaders' Oversight of the Cardiac Surgery Program

The OIG evaluated VISN leaders' oversight and response to concerns raised regarding the facility's heart transplant program. The OIG found that VISN leaders did not provide timely follow-up to the Facility Director's February 2022 request to review surgical complications, returns to the operating room, and chest incisions that were left open. The OIG found that instability in VISN leadership may have contributed to the delay in responding to the Facility Director's request for clinical review.

However, the OIG determined that after being hired in April 2022, the newly-appointed VISN CMO identified further concerns regarding the transplant program and addressed those concerns promptly, including requesting an NSO review of the cardiac surgery and heart transplant programs, and supporting NSO site visits. After receiving and evaluating the clinical review results of four heart transplant cases, the VISN CMO voiced concerns about two of these cases, as well as the section chief's management of surgical complications, and requested assistance from the NSO in November 2022. The NSO completed a site visit in February 2023 and issued a report with seven recommendations to VISN and facility leaders in April. The CMO voiced concerns about facility leaders not addressing one of the NSO recommendations and stated, "What I found at that time is not a lot had been done and so I asked for a lot of very specific information from the facility."

The VISN CMO told the OIG of consulting with facility leaders and agreeing to pause the heart transplant program in August 2023, reportedly out of concern for patient safety, and described requesting another review by the NSO. A second NSO site visit occurred in August 2023, and the resulting report was issued to VISN and facility leaders in October with 12 recommendations. In November 2023, as part of the overall VISN response, VISN leaders—in consultation with NSO—developed an action plan (VISN action plan) to monitor facility leaders' responses to NSO recommendations and complaints received from staff regarding the section chief, facility leadership in general, and clinical concerns.

VISN Leaders Failed to Ensure a Timely Quality of Care Review

In an interview with the OIG, the Facility Director recalled requesting risk managers complete a review of cardiothoracic surgeries for calendar year 2021 after receiving anonymous concerns regarding cardiothoracic surgery in late 2021.[73] The facility risk managers' initial review in February 2022 prompted the Facility Director to consult with the VISN Chief Nursing Officer, who then coordinated the request for clinical review with the VISN Deputy CMO, former acting CMO, and quality management officer.[74] See appendix B for a full timeline of VISN leaders' actions taken as a result of the Facility Director's request for further clinical review.

The OIG found the Facility Director requested VISN assistance with reviewing 21 surgical cases in February 2022, including 4 heart transplant surgeries. The VISN's Deputy CMO described initially working with the prior acting CMO to review surgical cases and later seeking subject

[73] The facility has two risk managers who are registered nurses. This review was completed in February 2022 and included both cardiothoracic and heart transplants, which were performed by cardiothoracic surgeon 1 and the section chief. The risk managers reported 22 concerns regarding complications, deaths, readmissions, returns to the operating room, and chest incisions that were left open after surgery; however, the OIG counted 21 cases with complications documented by the risk managers.

[74] The OIG found that due to a temporary status, the acting VISN chief surgical consultant had limited participation in reviewing complaints and resulting actions.

matter support outside of the VISN.[75] However, the OIG was unable to determine why the Deputy CMO requested a review of less than a quarter of the cardiac surgery cases identified in the Facility Director's request. VISN leaders provided conflicting information regarding the decision to reduce the number of surgical reviews.

The OIG found that the Deputy CMO requested assistance with the clinical reviews from leaders of two VA medical facilities (VISNs 9 and 19) with heart transplant programs. The OIG found two occasions when the Deputy CMO delayed responding to leaders of the VA medical facilities who agreed to provide the clinical review but needed additional information, thus delaying the clinical review.[76] Ultimately a VISN 9 facility heart transplant cardiologist completed the reviews of the 4 heart transplant surgeries in November 2022.[77]

In discussions with the OIG, the Deputy CMO described barriers to completing the review: (1) the small number of VA medical centers that perform heart transplants with the subject matter expertise to provide the clinical reviews, and (2) an inability to exert pressure on other VA facility providers who volunteered to take on the additional reviews. When asked if the NSO was consulted for assistance in locating potential subject matter experts, the Deputy CMO expressed unawareness of being able to reach out to the NSO.[78]

The OIG found that from December 2021–April 2022, the VISN CMO role was held by three individuals; the permanent CMO told the OIG of being appointed on April 10, 2022. VISN leaders also told the OIG that in 2023, the VISN had an acting chief surgical consultant until the permanent chief surgical consultant was appointed in November 2023. The OIG has identified in other reports that frequent turnover and long-term use of leaders in interim positions have significant negative consequences for facility oversight and support.[79] The OIG believes that the changes in leadership may have contributed to the delays in obtaining subject matter expert review of the remaining 17 surgical cases.

[75] The Deputy CMO reported serving in the capacity of acting Deputy CMO starting August 2020 and subsequently acting CMO until permanent appointment as Deputy CMO in October 2022.

[76] The OIG found that risk managers were diligent in following up with VISN leaders and the Facility Director on the request for reviews of the cardiothoracic cases, requesting numerous status updates from April through November.

[77] The OIG identified no additional concerns following the reviews of these 4 heart transplant events.

[78] The OIG found one email to the Deputy CMO and Quality Management Officer that indicated "I don't think this merits elevation to the National Surgery Office."

[79] VA OIG, *Review of VISN 10 and Facility Leaders' Response to Recommendations from a VHA Office of the Medical Inspector Report, John D. Dingell VA Medical Center in Detroit, Michigan*, Report No. 22-04099-153, July 18, 2023; VA OIG, *Comprehensive Healthcare Inspection of Veterans Integrated Service Network 5: VA Capitol Health Care Network in Linthicum, Maryland*, Report No. 21-00239-180, July 14, 2022; VA OIG, *Descriptive Analysis of Select Performance Indicators at Two Healthcare Facilities in the Same Veterans Integrated Service Network*, Report No. 20-02899-22, November 16, 2021; VA OIG, *Leadership, Clinical, and Administrative Concerns at the Charlie Norwood VA Medical Center, Augusta, Georgia*, Report No. 19-00497-161, July 11, 2019.

The OIG found that VISN leaders failed to ensure the retrospective reviews of the 4 heart transplant cases were competed in a timely manner, and that the remaining 17 cases were also reviewed, as requested by the Facility Director. VHA guidance specifies the CMO has a level of "oversight of clinical processes and outcomes."[80] When asked about a plan to conduct a comprehensive review of the section chief's cases, the VISN CMO stated that VISN leaders were already aware of complication concerns and further retrospective review would not be helpful. The VISN's NSO action plan includes items related to clinical care and quality reviews of cardiac surgery cases beginning August 29, 2023, but does not indicate a requirement to complete the retrospective review of the remaining 17 cases discussed above.

Program Inactivation

As previously noted, facility leaders temporarily inactivated the heart transplant program in August 2023 and notified the OPTN, VHA leaders, and national program offices. The OPTN requires that transplant programs in a long-term inactive status submit application materials and be approved by the OPTN prior to the transplant program's reactivation.[81]

The OIG heard from VISN and facility leaders the decision to submit the application to reactivate the facility heart transplant program will be made in conjunction with VISN leaders as the action plan progresses. In addition to the clinical requirements to resume the facility heart transplant program, the VISN CMO stated, "there needs to be some evidence from the facility leadership that they've addressed the concerns appropriately raised by their staff related to the professionalism and conduct concerns about the [section chief]." The OIG expects VISN and facility leaders to provide oversight and accountability to the facility heart transplant program and consider making changes that will give the program the highest chance of sustainable success going forward.

The OIG found that the VISN CMO recognized the need for further subject matter expertise in addressing concerns about the facility heart transplant program, which included requesting additional NSO reviews and site visits and developing an action plan to address the NSO recommendations. The CMO ensured appropriate systems were in place to track and monitor the section chief's leadership, behavior towards staff, and surgical quality of care concerns.

The OIG concluded that VISN leaders were actively engaged in identifying and resolving concerns presented by facility staff regarding cardiac surgery services. The OIG expects that VISN leaders will continue to support facility leaders as they address the potential impacts on patient safety and implement corrective actions outlined in the VISN action plan in a timely manner before considering reactivation of the transplant program.

[80] *Department of Veterans Affairs (VA) Veterans Health Administration (VHA) Veterans Integrated Service Network (VISN) Chief Medical Officer (CMO) Playbook*, May 2022.

[81] OPTN, *Bylaws*, December 5, 2022; OPTN, *Bylaws*, December 5, 2023.

Conclusion

The OIG reviewed NSO quarterly reports for surgical morbidity and mortality outcomes. The OIG did not substantiate that the section chief's morbidity and mortality rates were "much worse" than those of prior surgeons. Facility VASQIP data did not indicate further review from the NSO or VISN. There were no statistically significant data outliers before or during the section chief's tenure.

Mortality rates were reviewed by a surgical quality nurse during Surgical Work Group meetings, and in the recently created Cardiothoracic Surgery Program Quality Assessment Performance Improvement Committee.

SRTR reports noted two patient deaths in late 2021, contributing to higher-than-expected rates for transplanted organ failures. Both episodes of care were discussed in the NSO August 2023 site visit report and reviewed through the facility peer review process per VHA policy.

The OIG did not substantiate that the facility "had many patients readmitted after CT [cardiothoracic] surgery." The facility's cardiac surgery 30-day all-cause readmission rates were not significant enough to elicit further NSO assessment.

The OIG was unable to determine whether the section chief had "incredibly long" CPB times. CPB duration is dependent on many factors, including the specific type of surgery, and is not universally accepted as an indicator of quality, performance, or outcomes. Further, while a shorter CPB duration is preferred, the OIG could not validate the facility data collection methodology used by the chief of surgery and could not draw conclusions regarding current versus historical CPB times.

The OIG noted that the heart transplant program was operating below target volumes, in part due to long periods of inactive status in 2019–2020 and 2023–2024. Extended inactive periods and low transplant volumes would lessen opportunities for the many specialized professionals to maintain clinical experience and proficiency and could contribute to variations in outcomes. The OIG expects VHA leaders to conduct rigorous surveillance of quality measures if the heart transplant program is reactivated and ensure attainable program target volumes would meet clinical experience requirements.

The OIG substantiated that the section chief engaged in unprofessional behavior toward staff. The section chief participated in leadership counseling and the chief of surgery informally addressed concerns through verbal counseling, yet this unprofessional conduct persisted. The chief of surgery should have considered the section chief's behavior as either repeated unprofessional or unacceptable employee behaviors and utilized options described in facility policies such as a focused professional practice evaluation for cause or progressive disciplinary action.

Facility and surgical leaders failed to incorporate the HRO pillar of creating a culture of safety to ensure staff felt comfortable reporting concerns. Staff members reported that facility leaders' efforts to provide the cardiothoracic team with information regarding psychological safety and conflict management were not successful in creating a culture of safety where staff felt comfortable reporting concerns without fear of retribution.

The VISN CMO reported consulting with facility leaders following an increase in patient safety event reports in summer 2023 regarding cardiac surgery; this consultation led to a decision to temporarily inactivate the heart transplant program on August 15, 2023. The OIG found that VISN leaders were aware of facility staff's cardiothoracic surgery concerns but did not provide timely follow-up to the Facility Director's February 2022 request for assistance with clinical reviews. The OIG expects that VISN leaders will support facility leaders as they address the potential impacts on patient safety and implement corrective actions outlined in the VISN action plan in a timely manner before reactivation of the transplant program.

Recommendations 1–6

1. The Richmond VA Medical Center Director ensures completion of a clinical review of patient 2's cardiothoracic surgical episode of care and takes action as appropriate.

2. The Under Secretary for Health ensures that consideration to reactivate the heart transplant program at the Richmond VA Medical Center includes a comprehensive analysis of transplant referral volume, leadership competency, and transplant team proficiency.

3. The Under Secretary for Health ensures that VA Mid-Atlantic Health Care Network and Richmond VA Medical Center leaders conduct a rigorous surveillance of quality measures if the heart transplant program is reactivated and emphasize safely meeting program target volumes to maintain clinical experience.

4. The Richmond VA Medical Center Director ensures the chief of surgery conducts a review of the cardiothoracic section chief's unprofessional behaviors and develops a plan to address complaints.

5. The Richmond VA Medical Center Director ensures surgical leaders review cardiothoracic staff's concerns and take action to create a culture of safety, and considers the use of resources such as the National Center for Organization Development.

6. The VA Mid-Atlantic Health Care Network Director develops a process for ensuring VA Mid-Atlantic Health Care Network staff provide timely and complete responses to facility leaders' requests for clinical care reviews.

Appendix A: Other Allegations—OIG Analysis and Findings

1. Allegation: Staff were indirectly told that peer reviews or chart reviews of cardiac surgery cases could no longer be sent outside of the facility for review.	**Finding:** The OIG did not substantiate that cardiac surgery peer reviews, and specifically the section chief's peer review cases, were not sent for external review.
VHA defines peer review as a confidential, non-punitive process for evaluating health care delivered by an individual provider.[82] The OIG learned through interviews and document review that the facility sent peer reviews to an external contracted company. The section chief's cases were reviewed through this process, and per VHA policy.	

2. Allegation: The OPTN was not notified that that the facility was "a one transplant surgeon program."	**Finding:** The OIG did not substantiate that the facility program had only one heart transplant surgeon, and therefore, there was no requirement to notify the OPTN.
The OPTN requires that heart transplant programs have heart transplant surgeons available 24 hours a day, 7 days a week, and 365 days a year.[83] The OPTN further states that "additional heart transplant surgeons must be credentialed" by the facility to provide heart transplant services.[84] VHA defines credentialing as the process of "obtaining, verifying, and assessing the qualifications of a health care provider to provide care or services in or for the VA health care system."[85] Only after a provider is credentialed can they be privileged or permitted to provide patient care independently, within the scope of the individual's license, based on clinical competence, experience, education, and training.[86] The OIG learned that the section chief and a heart transplant surgeon began employment at the facility during the same month in 2020. The heart transplant surgeon told the OIG of exiting employment in the middle of 2022. During interviews with the OIG, the chief of surgery and section chief reported that the program provided required coverage with two additional heart transplant surgeons.[87] A document review showed that the section chief and the two heart transplant surgeons were credentialed and privileged by the facility to perform heart transplants. The OIG also learned	

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

[83] OPTN, *Bylaws*, December 5, 2022; OPTN, *Bylaws*, December 5, 2023.

[84] OPTN, *Bylaws*, December 5, 2022; OPTN, *Bylaws*, December 5, 2023.

[85] VHA Directive 1100.20, *Credentialing of Health Care Providers*, September 15, 2021. "Credentials are documented evidence of licensure, education, training, experience, or other qualifications."

[86] VHA Handbook 1100.19; VHA Directive 1100.21(1).

[87] Both additional heart transplant surgeons were part-time employees.

that a second heart transplant surgeon was hired by the facility in late 2023 and was credentialed by the facility and privileged to perform heart transplants.

3. Allegation: The section chief was noncompliant with OPTN requirements for primary heart transplant surgeons and "the Department of Surgery as well as the Heart Transplant program" did not "monitor and provide audits every 6 months to track [the section chief's]" continuing education	**Finding:** The section chief complied with OPTN requirements for surgeons who are not certified by the American Board of Thoracic Surgery. The OIG found that while the facility clinical program manager notified the OPTN that six-month audits would be conducted, the OPTN did not require facility leaders to provide six-month audits to verify compliance with continuing education requirements.

The American Board of Thoracic Surgery offers board certification in thoracic surgery to physicians who meet eligibility and training requirements.[88] The OPTN allows surgeons who are ineligible for certification by the American Board of Thoracic Surgery to serve as primary heart transplant surgeons.[89] To qualify for this exception, the surgeon must submit a plan to complete a minimum 60 hours of education every three years, and provide two letters of recommendation from transplant program directors who do not work for the applying hospital.[90] Further, the surgeon must complete continuing education courses with a self-assessment component and obtain a 75 percent or better score for each course. The transplant facility must also ensure satisfaction of continuing education requirements.[91]

The section chief told the OIG of ineligibility for board certification and indicated following a plan to serve as the primary heart transplant surgeon, and the facility clinical program manager submitted documentation to the OPTN regarding the section chief's ineligibility for American Board of Thoracic Surgery certification through the traditional pathway.[92] The section chief told the OIG that the OPTN approved the application to serve as the primary heart transplant surgeon; this was supported by an OIG document review indicating that approval was granted in September 2020.

The heart transplant coordinator supplied the OIG with documentation of compliance. The OIG reviewed the training documentation and found that the section chief met the minimum

[88] "Pathways to Certification," American Board of Thoracic Surgery, accessed February 19, 2024, https://www.abts.org/ABTS/CertificationWebPages/Pathways%20to%20Certification.aspx.

[89] The primary heart transplant surgeon is responsible for "ensuring the operation and compliance of the program" according to OPTN requirements. OPTN, *Bylaws*, December 5, 2022. Replaced by OPTN, *Bylaws*, December 5, 2023.

[90] OPTN, *Bylaws*, December 5, 2022; OPTN, *Bylaws*, December 5, 2023.

[91] OPTN, *Bylaws*, December 5, 2022; OPTN, *Bylaws*, December 5, 2023.

[92] "Pathways to Certification," American Board of Thoracic Surgery. The inspection team used the term "traditional pathway" to describe pathway one of Pathways to Certification from the American Board of Thoracic Surgery.

60 hours of education to receive credit for course completion and exceeded the required pass rate of 75 percent.

The OIG found that the OPTN did not require program members to conduct recurring audits, only to provide documentation or proof of completion of the three-year continuing education requirement if requested by OPTN.

4. Allegation: Decisions related to the heart transplant waitlist were made only by the section chief.	**Finding:** The OIG did not substantiate that decisions related to the heart transplant waitlist were made independently by the section chief.

Per VHA, the interdisciplinary transplant team decides if patients meet criteria for placement on the waitlist to receive an organ.[93] The OIG interviewed members of the heart transplant interdisciplinary team, who reported that decisions regarding a patient's placement on or removal from the waitlist was made by an interdisciplinary team that met weekly. When interviewed, the heart transplant coordinator reported having responsibility for maintaining the patient list with OPTN.

5. Allegation: The section chief has poor surgical technique.	**Finding:** The OIG did not substantiate that the section chief had poor surgical technique.

The OIG interviewed a former NSO Surgical Advisory Board member specializing in cardiothoracic surgery, who advised that assessing technical skills is difficult as each surgeon has specific inclinations and idiosyncrasies. The former NSO Surgical Advisory Board member further explained that successful completion of a training program is generally accepted as evidence of technical skill.

The OIG's document review showed that the facility had completed the credentialing process to verify the training and education of the section chief. Additionally, when the OIG interviewed the section chief's surgical peers, none reported concerns with the section chief's technical skills.

[93] VHA Directive 2012-018(1); "VA National Transplant Program," VHA, accessed January 4, 2024, https://www.va.gov/health/services/transplant/.

6. Allegation: The section chief had not implanted a left ventricular assist device in more than 18 months.[94]	**Finding:** The OIG did not substantiate that the cardiothoracic surgeon had not performed a ventricular assist device insertion procedure in more than 18 months. Further, the OIG found the section chief was privileged to perform ventricular assist device procedures with no requirement for the number of procedures to be performed to maintain privileges.

VHA requires that providers be privileged to provide patient care independently, within the scope of the individual's license, based on clinical competence experience, education, and training.[95]

While the allegation specified a left ventricular assist device, the most common type of ventricular assist device, the OIG interpreted the concern to include lack of placement of all ventricular assist devices, as they share mechanical and procedural characteristics.[96]

The OIG reviewed the section chief's cases from October 1, 2021, through September 30, 2023, and found the section chief performed six ventricular assist device insertion procedures with no 18-month gap since beginning employment. The OIG further reviewed the section chief's privileging documentation and found the provider was privileged to perform ventricular assist device procedures. The OIG learned during an interview with the chief of surgery that there is no minimum number of ventricular assist devices that must be completed to maintain privileges.

[94] Ventricular assist devices (VADs) are "tiny implantable pumps [that] help circulate blood." Types of VADs vary and include left ventricular assist devices (LVADs), right ventricular assist devices (RVADs), and biventricular assist devices (BiVADs). "Ventricular Assist Devices," Cleveland Clinic, accessed on January 29, 2024, https://my.clevelandclinic.org/health/treatments/22600-ventricular-assist-devices.

[95] VHA Handbook 1100.19; VHA Directive 1100.21(1).

[96] "Fact Sheets, Ventricular Assist Device (VAD)," Yale Medicine, accessed March 1, 2024, https://www.yalemedicine.org/conditions/ventricular-assist-device-vad.

7. Allegation: The section chief explanted the native heart prior to the donor heart being available on two separate occasions.	**Finding:** The OIG substantiated that the cardiothoracic surgeon explanted the native heart prior to the arrival of the donor hearts on two separate occasions. However, the OIG learned that explantation of a recipient's heart prior to arrival of a donor's heart is an accepted clinical practice, the timing of which is based on the judgment of the attending surgeon after weighing many competing considerations and data specific to an individual patient and circumstance. For this reason, the OIG did not find that the timing of explantation of the recipients' hearts in the two reviewed cases was inappropriate.

The OIG interviewed peers of the section chief during the course of the inspection and learned that on occasions when challenges with removal of the native heart are expected to contribute to a longer explant time, the native heart may be explanted prior to the arrival of the donor heart.

During interviews, the OIG learned of two cases in which the native heart was reported to have been explanted prior to the arrival of the donor heart. The OIG reviewed the EHRs and determined that in both cases the native heart was explanted prior to the arrival of the donor heart. The OIG found both cases underwent quality reviews.[97] The VISN CMO reported being concerned with this practice, but stated that the NSO reviewed and did not have concerns with these two surgeries.

When interviewed by the OIG, the section chief reported that there are circumstances in which the native heart needs to be removed prior to the arrival of the donor heart due to the time frames involved and the difficulty expected with removal of the native heart. The section chief stated that in those cases, had either the donor heart not arrived or had it arrived in a nonfunctioning state, the plan would have been to implant a biventricular assist device or use extracorporeal membrane oxygenation.[98] The patient would then be relisted for another donor heart.

[97] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011; VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023; VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018; VHA Directive 1320, *Quality Management and Patient Safety Activities That Can Generate Confidential Records and Documents*, July 10, 2020. One case was evaluated through the patient safety reporting process and the other case underwent peer review. The OIG found these were in accordance with VHA policy.

[98] Extracorporeal membrane oxygenation is treatment that provides respiratory and circulatory support for a patient using an external device. *Merriam -Webster.com Dictionary*, "extracorporeal membrane oxygenation," accessed January 29, 2024, https://www.merriam-webster.com/medical/extracorporeal%20membrane%20oxygenation. "Ventricular Assist Devices," Cleveland Clinic.

8. Allegation: The section chief was difficult to locate during established work hours, and patients who had clinic appointments left without being seen when staff were not able to reach the section chief.	**Finding:** The OIG did not substantiate that the section chief was difficult to locate when patients arrived for clinic appointments.

VHA defines "cancelled by clinic as an action signifying that the VA medical facility (not the Veteran) has requested that a scheduled appointment be cancelled."[99] VHA further states that service leaders are responsible to ensure contingency plans are in place to minimize clinic cancellations.[100]

Through interviews, the OIG learned that the section chief had outpatient clinic on Tuesday afternoons. A scheduler stated that clinic cancellations occur due to urgent surgical cases and patients are typically offered consultations on the following Tuesday; with the second surgeon on board, the contingency plan would include seeing if the newer provider could see the patient. A scheduler stated that the section chief was responsive to alternative methods of contact.

During an interview, the primary heart transplant physician did not recall any issues with the section chief evaluating a heart transplant patient as scheduled. The physician elaborated that the team's process was to review all patients who completed a heart transplant evaluation during the previous week at the following week's interdisciplinary team meeting. The physician could not remember a time when a patient had been evaluated the previous week and was not discussed the following week without all elements of the evaluation completed.

[99] VHA Directive 1230(5), *Outpatient Scheduling Processes and Procedures*, July 15, 2016, amended September 24, 2021. Replaced by VHA Directive 1230, *Outpatient Scheduling Management*, June 1, 2022. The two policies contain similar language defining cancelled by clinic.

[100] VHA Directive 1230(5); VHA Directive 1230. The two policies contain similar language related to contingency plans.

9. Allegation: The section chief does not round on postoperative patients on the weekends.	**Finding:** The OIG was unable to determine with what frequency the section chief rounded on the weekends. However, given the 24/7 presence of surgical intensive care unit staff and the on-call schedule for cardiothoracic surgery staff, the OIG found that the chief of surgery did not expect the section chief to complete rounds for cardiothoracic post-surgical patients on the weekends.

The facility's bylaws require that progress notes for acutely ill patients be written once daily at a minimum by a provider.[101]

The chief of surgery informed the OIG that patients in the surgical intensive care unit were assigned to the cardiothoracic surgery service, but the care was comanaged between the surgical intensive care unit staff, who rounded on patients every day and provided coverage 24 hours a day, seven days a week, and the cardiothoracic surgery staff, who consisted of the section chief and a team of advanced practice providers. The chief of surgery further explained that the on-call schedule was the resource to be utilized if issues arose when no cardiothoracic surgery staff were available. The OIG also found that cardiothoracic surgery staff reported the section chief communicated via text or phone with on-site team members regarding patients during the weekends.

[101] Central Virginia Health Care System, *Bylaws and Rules of the Medical Staff*, May 21, 2021. Replaced by Central Virginia Health Care System, *Bylaws and Rules of the Medical Staff*, March 17, 2023. Unless otherwise specified, the 2023 bylaws contain the same or similar language regarding progress notes for acutely ill patients as the 2021 Bylaws.

10. Allegation: The section chief enters no notes on patients, even those with catastrophic adverse events. Two patient identifiers (patient 3 and patient 4) were provided.	**Finding:** The OIG did not substantiate that the section chief entered no notes for patient 3. The OIG found that patient 4 was assigned to the cardiology service and that daily notes were entered as required by that service. Further, the OIG determined that the section chief was involved in patient 4's care as a surgical consultant.

The facility's bylaws require that progress notes for acutely ill patients be written once daily at a minimum by a provider.[102]

The OIG reviewed the EHRs of the two patients provided by the complainant and found while patient 3 was admitted to the cardiothoracic surgery section, the section chief entered 4 notes, and 21 notes completed by an advanced practice provider indicated the section chief's involvement with the patient's care. Patient 4 was admitted to the cardiology service and not the cardiothoracic surgery service with daily notes completed by the cardiology service. Patient 4 was seen by the section chief and an advanced practice provider for surgical consultation with the advanced practice provider who entered the note; the section chief acknowledged receipt through electronic signature.

[102] Central Virginia Health Care System, *Bylaws and Rules of the Medical Staff*, May 21, 2021; Central Virginia Health Care System, *Bylaws and Rules of the Medical Staff*, March 17, 2023.

Appendix B: Responses to the Facility Director's Request for Further Clinical Review

Table B.1. Timeline of Responses

Date	Actions Taken
Late 2021	The Facility Director received an anonymous complaint regarding clinical concerns in the cardiothoracic department. The Facility Director requested risk managers complete a "focused review" based on surgical outcomes.
February 7, 2022	The Facility Director reported talking to the VISN Chief Nursing Officer about the clinical concerns in the cardiothoracic department and asked for advice on next steps. The VISN Chief Nursing Officer advised the Facility Director to consult another VISN 6 surgeon.
February 9, 2022	The VISN Chief Nursing Officer alerted the acting VISN CMO and Deputy CMO to the concerns raised by the Facility Director and concerns noted by the VISN VASQIP Lead.
February 11, 2022	Facility risk managers completed the preliminary review of cardiac and heart transplant surgeries (January 1–December 22, 2021) and provided the results to the Director. Risk managers highlighted 22 surgeries that included complications, returns to the operating room, and instances where the patient's sternotomy incision was left open.[103]
February 15, 2022	The Facility Director sent the risk managers' review of cardiac and heart transplant surgeries, including a patient list with highlighted concerns about quality of care, to VISN leaders.
March 11, 2022 (first request)	The Deputy CMO requested assistance from the VISN 9 CMO with reviewing cardiac and heart transplant surgeries. The VISN 9 CMO replied, noting a need to confer with the Chief of Staff at a VISN 9 facility where heart transplants are also offered.
March 11, 2022	The acting VISN chief surgical consultant reviewed the VASQIP report and files on cardiac issues, recommended review by an outside party, recognized opportunities for improvement, and did not recommend elevation to the NSO. The VISN quality management officer concurred with the acting VISN chief surgical consultant's recommendation.
March 23, 2022 (second request)	The Deputy CMO asked the chief of surgery at a VISN 19 facility with active heart transplant programs to review 21 cardiac and heart transplant surgeries performed in 2021.
April 5, 2022	The Deputy CMO asked the VISN 19 facility's chief of surgery for an update on the request to review the 21 cardiac and heart transplant surgeries.
April 7, 2022	The VISN 19 facility chief of surgery responded and inquired whether the review could wait "until after June" 2022 due to the surgeon's prior commitment.

[103] The risk managers are registered nurses. The OIG determined this calculation to be 21 cases with complications as noted by the risk managers.

Date	Actions Taken
April 12–13, 2022	The Facility Director asked the VISN quality management officer for an update on the review. The quality management officer responded that the VISN 9 facility was unable to complete the review, and that the VISN 19 facility was reviewing the cases.
May 4, 2022	The Deputy CMO contacted the VISN 19 facility chief of surgery to request a status update on the review. The chief of surgery replied, "I never heard anything back regarding my email question below. So, we have not done anything. If the timing is ok we need to get the list of patients and access to the charts. Again, we cannot really get this done until late June." The OIG observed that the Deputy CMO's follow-up came 27 days after the VISN 19 facility Chief of Staff's initial response.
May 6, 2022	The Deputy CMO advised the VISN quality management officer that the VISN 19 facility's review was delayed, and contact was initiated with a VISN 21 facility that had active heart transplant programs.[104]
July 12, 2022 (Third request)	The Deputy CMO again asked the VISN 9 CMO for assistance reviewing transplant surgeries (four from 2021). A VISN 9 facility heart transplant cardiologist responded two days later and agreed to complete the review and acknowledged a potential conflict of interest.
September 14, 2022	The Deputy CMO sent the VISN 9 CMO and VISN 9 facility heart transplant cardiologist a request to review five heart transplant surgeries (four from 2021 and one from 2020).
September 22, 2022	The VISN 9 facility heart transplant cardiologist replied to the Deputy CMO asking for additional patient information.
October 6, 2022	The Deputy CMO sent the VISN 9 facility heart transplant cardiologist the patient information for four heart transplant surgeries in 2021 but did not provide patient information for one heart transplant surgery performed in 2020. This occurred 14 days after the VISN 9 facility heart transplant cardiologist requested patient information.
November 22, 2022	The Deputy CMO sent the results of the VISN 9 facility heart transplant cardiologist's review of four heart transplant surgeries to the Facility Director. The Deputy CMO did not provide the fifth patient identifier to the surgeon for review.[105]

Source: OIG analysis of documentation provided by VISN and facility leaders and staff.

[104] The OIG did not receive documentation confirming the Deputy CMO's request for reviewing cardiac surgeries to the VISN 21 facility.

[105] These four heart transplant surgeries were included in the original February 2022 request by the Facility Director.

Appendix C: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: September 17, 2024

From: Under Secretary for Health (10)

Subj: Office of Inspector General (OIG) Draft Report, Heart Transplant Program Review: Facility Leaders Failed to Ensure a Culture of Safety and the Section Chief Engaged in Unprofessional Conduct at the Richmond VA Medical Center in Virginia (VIEWS 12015355)

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on OIG's draft report on Heart Transplant Program Review: Facility Leaders Failed to Ensure a Culture of Safety and the Section Chief Engaged in Unprofessional Conduct at the Richmond VA Medical Center in Virginia. The Veterans Health Administration (VHA) concurs with recommendations 1-6 and provides an action plan in the attachment.

2. VHA appreciates OIG's assistance in identifying an opportunity to strengthen our processes by including regional and national oversight of analyses of referral volume, program and facility leadership, and transplant team proficiency.

3. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at vacovha10oicoig@va.gov.

(Original signed by:)

Shereef Elnahal, M.D., MBA

[OIG comment: The OIG received the above memorandum from VHA on September 17, 2024.]

Office of the Under Secretary for Health Response

VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan
OIG Draft Report, Heart Transplant Program Review: Facility Leaders Failed to Ensure a Culture of Safety and the Section Chief Engaged in Unprofessional Conduct at the Richmond VA Medical Center in Virginia (OIG Project Number 2023-03526-HI-1391)

Recommendation 1: The Richmond VA Medical Center Director ensures completion of a clinical review of patient 2's cardiothoracic surgical episode of care and takes action as appropriate.

VHA Comments: Concur

Patient 2's record was reviewed independently by the Chief of Surgery and Medical Director for Heart Failure & Cardiac Transplantation who is an experienced cardiologist specializing in congestive heart failure. Both clinicians reached the same conclusion that the patient outcome was not causally related to prolonged CPB time. The VISN and Medical Center will collaborate with VHA's National Surgery Office and determine whether an additional independent evaluation of this case is warranted.

Completion Date: October 2024

Recommendation 2: The Under Secretary for Health ensures that consideration to reactivate the heart transplant program at the Richmond VA Medical Center includes a comprehensive analysis of transplant referral volume, leadership competency, and transplant team proficiency.

VHA Comments: Concur

The National Surgery Office will ensure that consideration to reactivate the heart transplant program at the Richmond VA Medical Center includes regional and national oversight of analyses of referral volume, program and facility leadership, and transplant team proficiency.

Target Completion Date: December 2024

Recommendation 3: The Under Secretary for Health ensures that VA Mid-Atlantic Health Care Network and facility leaders conduct a rigorous surveillance of quality measures if the heart transplant program is reactivated and emphasize safely meeting program target volumes to meet clinical experience requirements.

VHA Comments: Concur

The National Surgery Office will ensure continued oversight, monitoring, reviews, and analysis of Richmond VA Medical Center's cardiac transplant quality metrics, referral volumes, Organ Procurement and Transplantation Network membership requirements, and transplant outcomes through established VHA and external (Scientific Registry of Transplant Recipients) reporting and quality assurance programs to meet clinical experience goals.

Target Completion Date: December 2024

Recommendation 4: The Richmond VA Medical Center Director ensures the chief of surgery conducts a review of the cardiothoracic section chief's unprofessional behaviors and develops a plan to address complaints.

VHA Comments: Concur

The Medical Center Director and the Chief of Surgery conducted a review of the CT Section Chief's behaviors and, with the support of VA's National Center for Organization Development (NCOD), VISN 6, and facility organizational psychologists, created a leadership development and improvement plan. The Medical Center Director is tracking the plan. Additionally, the Section Chief was provided a coach from VA's National Center for Organization Development (NCOD) to enhance leadership skills. Progress with completion of this action plan will be closely monitored and, should further events occur, additional reviews and actions will be taken as warranted.

Completion Date: December 2024

Recommendation 5: The Richmond VA Medical Center Director ensures surgical leaders review cardiothoracic staff's concerns and take action to create a culture of safety and considers the use of resources such as the National Center for Organization Development.

VHA Comments: Concur

The Medical Center Director met with the cardiothoracic (CT) team on several occasions to discuss their concerns. The Medical Center Director consulted with NCOD, VISN 6, and facility organizational psychologists to create a development and strategic improvement plan with multiple requirements and timelines. For example, VISN 6 staff conducted Teams Training for the CT surgery team, which is part of VHA's High Reliability Organization (HRO) model. Following the training, the staff completed a unit-based safety initiative to enhance communication during patient transfer from the Operating Room to the Intensive Care Unit (ICU). The plan also included leader

coaching, All Employee Survey (AES) actions, mentoring, DiSC team assessment, whole health support, Inclusion, Diversity, Equity, and Access training, and bystander intervention training. The plan was initiated in January 2024.

The Medical Center Director provided information to all employees regarding Joint Patient Safety Reports (JPSR), good catch reporting, disruptive behavior reporting, workplace violence, fraud, waste and abuse, and whistleblower rights. The Medical Center Director also implemented a monthly Safety Forum, led by executive leadership and available to all employees, to highlight monthly HRO themes, to celebrate good catches, to promote systemwide improvements resulting from JPSRs, and to provide a forum for staff to speak up. As released on July 29, 2024, 9 of 11 FY 2024 AES Patient Safety questions, an HRO indicator, improved for the overall health care system. Improvements included overall perceptions of patient safety; education, training, and resources; freely speaking up; support each other; feedback from reports; discuss error prevention; error transparency and risk mitigation; risk identification and just culture; and teamwork, cohesion, and engagement. Also, CT work group scores increased for 6 out of 7 questions to include workgroup cooperation; no fear of reprisal; inclusivity; patient safety – freely speak up; workgroup psychological safety; and civility. All actions are intended to sustain and improve workgroup psychological safety and a culture of safety. The facility requests closure of this recommendation.

Completion Date: August 2024

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

Recommendation 6: The VA Mid-Atlantic Health Care Network Director develops a process for ensuring VA Mid-Atlantic Health Care Network staff provide timely and complete responses to facility leaders' requests for clinical care reviews.

VHA Comments: Concur

The VISN 6 Network Director established a VISN level tracking tool to ensure all requested clinical care reviews are completed and returned in a timely manner. A review of the tracking tool was added as a standing agenda item for the VISN 6 Quality Patient Safety Committee, with status updates provided monthly (or as applicable). Requested reviews will be tracked until they are returned to the facility.

Target Completion Date: September 30, 2024

Appendix D: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: September 13, 2024

From: Director, VA Mid-Atlantic Health Care Network (15N6)

Subj: Healthcare Inspection—Heart Transplant Program Review: Facility Leaders Failed to Ensure a Culture of Safety and the Section Chief Engaged in Unprofessional Conduct at the Richmond VA Medical Center in Virginia

To: Under Secretary for Health (10)
Director, Alison Loughran, Office of Healthcare Inspections (54HL07)
Executive Director, Office of Integrity and Compliance (10OIC)

1. We are committed to ensuring Veterans receive quality care that utilizes the high reliability pillars, principles, and values, including leadership commitment, sensitivity to operations, and deference to expertise. We appreciate the opportunity to review and comment on the Office of Inspector General (OIG) report, Heart Transplant Program Review: Facility Leaders Failed to Ensure a Culture of Safety and the Section Chief Engaged in Unprofessional Conduct at the Richmond VA Medical Center in Virginia.

2. I have reviewed and concur with the OIG recommendations and the action plans submitted by the Richmond VA Medical Center. As we remain committed to ensuring our Veterans receive exceptional care, Veterans Integrated Services Network (VISN) 6 Leadership will ensure the actions to correct the findings are completed and sustained as described in their responses.

3. I would like to thank the Office of Inspector General for their thorough review, and if there are any questions regarding responses or additional information required, please contact the VISN 6 Quality Management Officer.

(*Original signed by:*)

Paul S. Crews, MPH, FACHE

[OIG comment: The OIG received the above memorandum from VHA on September 17, 2024.]

Appendix E: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: September 13, 2024

From: Director, Richmond Department of Veterans Affairs (VA) Medical Center (652)

Subj: Healthcare Inspection— Heart Transplant Program Review: Facility Leaders Failed to Ensure a Culture of Safety and the Section Chief Engaged in Unprofessional Conduct at the Richmond VA Medical Center in Virginia

To: Director, VA Mid-Atlantic Health Care Network (15N6)

1. I deeply regret any circumstances identified in the Office of Inspector General (OIG) report that may have impacted the care of Veterans and thank the OIG for their comprehensive assessment. I appreciate the opportunity to review and comment on the report, Heart Transplant Program Review: Facility Leaders Failed to Ensure a Culture of Safety and the Section Chief Engaged in Unprofessional Conduct at the Richmond VA Medical Center in Virginia.

2. Our team appreciates the opportunity to work with the Office of Inspector General's Office of Healthcare Inspections as we continuously strive to improve the quality and safety of health care for Veterans. Central Virginia VA Health Care System leadership takes the safety of our patients very seriously and is committed to further strengthening our Culture of Safety as part of our High Reliability journey.

3. I concur with the recommendations and value them to support our continuous process improvement efforts. Responses to Recommendations 1, 4, and 5 are provided on the attached document.

(*Original signed by*:)

J. Ronald Johnson, MHA, FACHE

[OIG comment: The OIG received the above memorandum from VHA on September 17, 2024.]

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