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Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficiencies in Invasive Procedure Complexity Infrastructure, Surgical Resident Supervision, Information Security, and Leaders' Response at the Lieutenant Colonel Charles S. Kettles VA Medical Center in Ann Arbor, Michigan

Healthcare Inspection	24-00234-53	February 4, 2025

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations regarding deficiencies in meeting invasive procedure complexity infrastructure requirements, supervision of postgraduate year one (PGY-1) surgical residents, completion of operative documentation, protection of patient privacy and information security, and facility leaders' response to reported patient safety concerns at the Lieutenant Colonel Charles S. Kettles VA Medical Center (facility) in Ann Arbor, Michigan.[1] The OIG identified additional concerns related to reliance on patient transfers to external hospitals, engagement and communication between Surgery Service and the blood bank, disclosure of patient harm, interpretation of the Veterans Health Administration (VHA) resident supervision directive, methodology for monitoring operative documentation compliance, and facility leaders' implementation of action plans.

Deficiencies in Invasive Procedure Complexity Infrastructure

The VHA invasive procedure complexity model ensures that facilities have the infrastructure to safely support the level of the invasive procedures performed. VHA assigns an invasive procedure designation to a facility, and scheduled procedures cannot exceed the infrastructure capabilities of the facility. When a facility lacks required infrastructure for the invasive procedure designation and facility leaders do not want to reduce the complexity level, a waiver must be requested for specific infrastructure deficiencies.[2] Waiver requests are routed through the Veterans Integrated Service Network (VISN) to VHA Clinical Services (Clinical Services) for review and final determination by the Invasive Procedure Complexity Waiver Clinical Council.[3]

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[1] VHA Directive 1220(1), *Facility Procedure Complexity Designation Requirements to Perform Invasive Procedures in Any Clinical Setting*, May 13, 2019, amended February 11, 2020. "[I]nvasive procedures are those procedures that require signature informed consent and involve a skin incision or puncture, or endoscopy." VHA Directive 1400.01, *Supervision of Physician, Dental, Optometry, Chiropractic, and Podiatry Residents*, November 7, 2019. A PGY-1 resident, also known as an "intern," is a health professional trainee in a graduate training program and in the first year of postgraduate clinical training. For purposes of this report, PGY-1 surgery residents refer to residents in general surgery and surgical specialty residency programs.

[2] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "For Action: Annual Certification of Infrastructure Requirements for Sites Performing Invasive Procedures," memorandum to Veterans Integrated Service Network (VISN) Directors (10N1-23), February 8, 2024.

[3] The Invasive Procedure Complexity Waiver Clinical Council includes members from Specialty Care Services, the National Diagnostics Office, and the National Surgery Office. VHA policy states that waivers may be granted when interventional cardiology, interventional neuroradiology, and non-vascular or vascular interventional radiology services are provided off-site, or when any infrastructure deficiency has undergone a risk assessment. The OIG learned that the committee may approve permanent or temporary waivers for specific infrastructure requirements.

The OIG substantiated that the facility lacked services required to support the assigned inpatient invasive procedure designation of *inpatient complex*. Specifically, the facility did not provide on-site interventional neuroradiology services or after hours on-call vascular and non-vascular interventional radiology and cardiac catheterization services. The OIG found delays with waiver requests for these requirements. Additionally, the OIG identified a concern with the failure to monitor and track timeliness of patient transfers.

The OIG did not substantiate the facility failed to meet blood bank or surgical coverage infrastructure requirements, but identified concerns with Surgery Service engagement in the blood utilization review committee (BURC) and facility leaders' failure to consider an institutional disclosure for an adverse event.

Delays in Infrastructure Waiver Requests

The OIG found delays in waiver requests and approvals resulted from facility leaders' lack of awareness of available surgical infrastructure, administrative delays at the VISN level, and conflicting guidance on waiver submission requirements provided by VISN leaders and Clinical Services staff (see appendix A for the timeline of waiver requests).[4]

In a November 2022 annual review of infrastructure, the chief of surgery endorsed deficiencies in interventional neuroradiology services, but not vascular and non-vascular interventional radiology services and cardiac catheterization services.[5] The OIG confirmed with facility leaders that the facility last had after hours on-call vascular and non-vascular interventional radiology coverage in December 2020, and that there had never been after hours cardiac catheterization services available at the facility. The chief of surgery told the OIG the previous chief of surgery did not clearly communicate infrastructure requirements or the need for waivers.

In a December 2023 response to the OIG's initial inquiry related to the complainant's allegations, the Facility Director acknowledged a lack of on-site interventional neuroradiology services and stated that a waiver request was planned "pending completion of a formal [transfer agreement] with the [non-VA hospitals]." Following the announcement of the OIG inspection in February 2024, the OIG learned that the facility was also planning to request waivers for vascular and non-vascular interventional radiology and cardiac catheterization due to lack of after hours on-call availability for these services. A facility deputy chief of staff (deputy chief of staff 1) told the OIG of learning from the VISN Chief Surgical Consultant in February 2024 that

[4] 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.

[5] Facility service chiefs are responsible for conducting an annual review of the available infrastructure, which must be certified by the facility director and VISN leaders, including the VISN Chief Surgical Consultant and the VISN Director.

the existing community care contract fulfilled the requirement for a transfer agreement, and that additional transfer agreements were not necessary.[6]

On April 29, Clinical Services approved a permanent waiver for cardiac catheterization laboratory services and a temporary (12 month) waiver for vascular and non-vascular interventional radiology, but the approval memorandum did not indicate review of a waiver for interventional neuroradiology services.

The OIG reviewed an April 2024 VISN waiver tracking spreadsheet that erroneously noted that the interventional neuroradiology waiver request had already been submitted to Clinical Services for approval. A VISN staff member stated that there was "some miscommunication," and the waiver request for interventional neuroradiology was "inadvertently overlooked" and not submitted to Clinical Services until May 2024. The VISN staff member later told the OIG that a Clinical Services staff member had requested additional support for the waiver request. While the Assistant Under Secretary for Health for Clinical Services approved the waiver in October 2024, the OIG is concerned that the direction from Clinical Services conflicted with VHA policy addressing waiver request submissions and information provided by the VISN Chief Surgical Consultant.[7]

The OIG found that a lack of awareness of available services, unclear direction about waiver requirements, deficient tracking and communication of the waiver request status, and lack of VISN oversight led to delays in submission and approval of the waiver requests. Delays in waiver requests may lead to facilities operating at a complexity level without the required infrastructure, and without required review from relevant program offices.

Additional Concerns Related to Invasive Procedure Infrastructure Requirements

The OIG identified an additional concern with the failure to monitor and track timeliness of patient transfers. The facility waiver requests indicated that after hours vascular and non-vascular interventional radiology and cardiac catheterization services would be provided through transfer to non-VA hospitals.

The waiver requests submitted by the facility noted potential risks to patients including lack of bed availability at non-VA hospitals and delays in treatment due to ambulance service availability. As a condition of granting the temporary waiver, Clinical Services also required "the

[6] A transfer agreement was completed with one non-VA hospital in March 2024, and included with the waiver request for vascular and non-vascular interventional radiology and cardiac catheterization. Deputy chief of staff 1 told the OIG that the other transfer agreement was still in progress at the time of the site visit.

[7] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "Directive 1220 Waiver Request for Interventional Neuroradiology Services, Lt. Col. Charles S. Kettles Veterans Affairs Medical Center, (Station 506), Ann Arbor, Michigan (VIEWS 11966269)," memorandum to Director, Veterans Integrated Service Network 10 et al., October 15, 2024.

facility . . . to monitor and track any adverse outcomes that arise from outsourcing IR [interventional radiology] services and report the findings to the facility quality/safety manager, chief of staff, and medical center director."[8]

In the waiver requests, facility leaders stated that transfers from Surgery Service to non-VA hospitals for waived services would be tracked and reviewed through the facility bed utilization committee quarterly. While deputy chief of staff 1 told the OIG in early April 2024 that monitoring transfer times through the committee would begin within the next few weeks, the OIG reviewed committee minutes from May 2024, and did not find evidence of reviews that included the elements specified in the waiver requests. The OIG would expect that facility leaders would have monitored transfer delays immediately upon submitting the waiver requests to identify any transfer delays and ensure safe and timely patient care.

The OIG did not substantiate that the facility failed to meet blood bank infrastructure requirements for the invasive procedure complexity designation; blood bank services and blood products were available as required. However, the OIG identified an additional concern with a lack of engagement and communication between Surgery Service and blood bank staff and leaders.

The OIG reviewed BURC meeting minutes and found no evidence that the chief of surgery, or a Surgery Service representative, attended from April 2022 through March 2024 as required per the facility BURC charter. Facility leaders and staff informed the OIG about concerns with communication between blood bank staff and Surgery Service staff and leaders regarding blood bank operations and capabilities. Consistent Surgery Service representation on the BURC may improve communication of changes to blood product needs and minimize miscommunication about blood product availability.

The OIG did not substantiate that the facility lacked Surgery Service provider coverage, as required for the invasive procedure complexity designation. However, the OIG found that facility leaders failed to consider conducting an institutional disclosure after an adverse event involving a patient (patient B) identified by the complainant.[9] The OIG determined that given patient B's death, and facility leaders' acknowledgment of deficiencies in care, the event met the criteria for an institutional disclosure.

[8] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "Directive 1220 Invasive Procedure Complexity Waiver Request for Vascular and Non-vascular Interventional Radiology (IR) Services and Interventional Cardiac Catheterization Laboratory (Cardiac Cath) services at the Lieutenant Colonel Charles S. Kettles Department of Veterans Affairs Medical Center (LtCol Charles S. Kettles VAMC), Station 506, (VIEWS 11682654)," memorandum to Director, Veterans Integrated Service Network 10 et al., April 29, 2024.

[9] The OIG determined the adverse event was specific to one on-call attending surgeon who was not available within 60 minutes on-site, as required by VHA policy. Facility leaders reviewed patient B's care and addressed the on-call surgeon's management of patient B's clinical care separately.

In a response to the OIG, the Facility Director indicated that patient B's death was likely related to a delay in surgical treatment, and that the attending surgeon's clinical privileges at the facility had been revoked as a result.[10] However, the OIG found no electronic health record (EHR) documentation indicating that the delay in surgical intervention and suboptimal care by the attending surgeon was disclosed to patient B's family. The Chief of Staff and the risk manager were aware of the adverse event but told the OIG that the focus was on the attending surgeon's actions to ensure the surgeon was held accountable but that it would be reasonable to conduct an institutional disclosure.[11] Failure to disclose adverse events may negatively affect patients' trust in VA health care.

PGY-1 Surgery Resident Supervision

The OIG was unable to determine if facility leaders failed to ensure that on-site supervision was provided to PGY-1 surgery residents as required by VHA. The OIG found inconsistencies with interpretation of VHA policy related to the supervision of PGY-1 surgery residents among facility providers and VISN and program office leaders. Additionally, the OIG is concerned that Office of Academic Affiliations (OAA) guidance given to VISN 10 leaders regarding current PGY-1 surgery resident supervision does not meet the intent of VHA policy.

VHA policy requires that PGY-1 residents "have on-site supervision at all times by either a supervising practitioner or a more advanced resident."[12] VHA also notes that supervising practitioners can only provide supervision for activities in which they hold clinical privileges, and that a hospitalist may directly supervise a PGY-1 surgery resident "for non-surgical patient management" when documented relationships are in place and approved by the residency program.[13]

The OIG learned facility leaders implemented a facility standard operating procedure (SOP) describing a process for off-tour supervision of PGY-1 surgery residents by hospitalists and that the SOP was reviewed and supported by OAA and by the affiliate surgery residency program director.[14] The OIG found (1) while the SOP provided a plan for on-site supervision, the SOP did not provide means for on-site supervision for surgical patient management, for which hospitalists

[10] The OIG reviewed patient B's case and determined that the delay in surgical treatment may have contributed to the patient's outcome.

[11] As of October 2024, the OIG found no documentation of an institutional disclosure in patient B's EHR.

[12] VHA Directive 1400.01. A more advanced resident is a resident who has completed the first year of a residency program.

[13] VHA Directive 1400.01. A hospitalist is a physician, usually trained in general internal medicine, who specializes in managing the care of hospitalized patients. "Hospital Medicine," American College of Physicians, accessed June 4, 2024, https://www.acponline.org/about-acp/about-internal-medicine/general-internal-medicine/hospital-medicine.

[14] For purposes of this report, off-tour refers to weekends, nights, and holidays. The facility has a medical education affiliation with the University of Michigan Health System in Ann Arbor.

are not privileged to provide, and (2) the relationship established in the SOP between the hospitalists and the PGY-1 surgery residents may not meet VHA's definition of supervision.

The OIG found that the SOP established a "process for supervision overnight," but characterized the relationship between hospitalists and PGY-1 surgery residents as consultative rather than supervisory. While confirming support of the facility SOP and that hospitalists can serve as supervisors of PGY-1 surgery residents, an OAA leader shared a similar characterization with the OIG. Additionally, through multiple interviews and correspondence with key stakeholders of the supervision process outlined in the SOP, the OIG was informed of minimal interaction between the hospitalists and the PGY-1 surgery residents and opines that this minimal engagement may not meet VHA's definition of supervision.

Similar issues were raised in a recent OIG report that included a recommendation that VISN 10 facilities comply with VHA requirements regarding resident supervision, specifically related to PGY-1 on-site direct supervision.[15] The OIG is concerned that varying interpretations between policy and OAA guidance is likely to result in non-standardized supervision for residents across VHA who may not have the experience required to provide independent patient care.

Inconsistent Completion of Operative Documentation

The OIG did not substantiate that facility surgeons failed to abide by facility bylaws and The Joint Commission standards for postoperative documentation as alleged by the complainant. The OIG found facility leaders were aware that surgeons were not consistently completing a required operative note before patients were transferred to the next level of care and took action to monitor and improve compliance. However, the OIG is concerned that the current monitoring methodology may result in inaccurate compliance data.

The OIG found that in February 2023, Surgical Work Action Group (SWAG) committee members acknowledged concerns with operative note documentation and began reporting compliance through the committee in April 2023.[16] Surgery Service and facility leaders implemented corrective actions including education, sharing compliance rates with surgeons, and having post anesthesia care unit (PACU) nurses check for operative note completion prior to discharging patients from the PACU.[17]

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[15] The VA OIG published *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 on July 18, 2023.

[16] *Facility Surgical Workgroup (SWAG) Committee Charter*, July 13, 2023. The responsibilities of SWAG include facilitation of "transparent discussion[s] of surgical quality improvement data, practice and quality improvement, patient safety, outcomes data, and best practices." SWAG "serves as a formal reporting mechanism and provides operational oversight." The SWAG committee is co-chaired by the chief of surgery and associate nurse for surgery and perioperative services.

[17] Compliance improved from 62 percent in March 2023 to 93 percent by the second half of December 2023.

The associate chief nurse provided the OIG with documentation indicating that from March through December 2023, the chief surgical nurse monitored compliance through random sampling of operative cases. In January 2024, the PACU nurses assumed responsibility for monitoring operative documentation compliance and the methodology changed to tracking the number of cases without an operative note, as documented by PACU nurses. The OIG is concerned that variables including nursing staff turnover and workload demands could affect how consistently PACU nurses identify missing documentation, potentially resulting in inaccurate compliance data.

The OIG questions the reliability of the methodology used to measure compliance, without a retrospective audit to ensure that missing documentation is consistently captured. Additionally, the OIG would expect oversight of operative documentation compliance by Surgery Service leaders rather than PACU nurses to ensure that important clinical information is available to clinicians after an operative procedure.

Deficiencies in Information Security Practices and Protection of Patient Privacy

The OIG substantiated that facility leaders failed to ensure adherence to information security practices. Specifically, anesthesiology attending physicians provided unauthorized VA computer access to anesthesiology residents practicing in operating rooms. The OIG found a deputy chief of staff (deputy chief of staff 2) was aware unauthorized access was occurring, but the OIG was unable to determine if attending physicians provided unauthorized access at the direction of deputy chief of staff 2, as alleged by the complainant. After observing the surgical waiting area, interviewing facility surgeons, and learning of no related privacy complaints, the OIG did not substantiate that routine privacy violations occurred in the surgical waiting area.

Attending physicians told the OIG of providing unauthorized and unmonitored computer access to residents who lacked computer access at the start of a VA rotation to facilitate documentation of anesthesia care. Attending physicians reported that while no direction was received from facility leaders to provide unauthorized access, facility leaders were aware unauthorized access occurred. Deputy chief of staff 2 reported a recent awareness that attending physicians provided residents with unauthorized computer access and denied directing attending physicians to do so.[18] Through interviews with the facility associate chief of staff for education and VISN and OAA leaders, the OIG learned that barriers to resident computer access on the first day of a VHA rotation were a concern at the VISN and national levels.

[18] An OIG review of electronic communication did not find evidence contradicting the report of deputy chief of staff 2.

Facility Leaders Failed to Resolve Reported Patient Safety Concerns

The OIG did not substantiate that facility leaders were unresponsive to patient safety concerns raised by the surgical intensive care unit (SICU) providers. When facility leaders learned of patient safety concerns, prompt action was taken to review the concerns and develop action plans. However, the OIG found concerns with implementation, monitoring of outcomes, and communication related to the action plans.

The OIG reviewed email communication between SICU providers and facility leaders regarding patient safety concerns and a subsequent meeting held in March 2023 to discuss the concerns. The Chief of Staff established a committee to "evaluate, triage, and work through" the concerns. The OIG reviewed the spreadsheet used by the committee to track the concerns and related proposed solutions, and found action plans to address reported patient safety concerns were developed within two months. The OIG reviewed the spreadsheet to determine if the action plans addressed the concerns raised by the SICU providers; the OIG identified the failure of facility leaders to ensure assigned corrective actions were carried out, develop and implement outcome measures to determine if corrective actions were effective, establish short-term mitigation plans when a long-term corrective action was incomplete, and communicate the status of the action plans to the staff who raised the concerns.

The OIG made three recommendations to the Under Secretary for Health related to ensuring guidance provided to VISNs and facilities regarding invasive procedure complexity infrastructure and supervision of PGY-1 surgery residents is in alignment with policy, and evaluating the process for health profession trainee computer access.

The OIG made three recommendations to the VISN Director related to communicating invasive procedure complexity infrastructure waiver request requirements to facility leaders and tracking the status of waiver requests, and ensuring the corrective actions developed by facility leaders to address SICU patient safety concerns are completed and evaluated for effectiveness.

The OIG made six recommendations to the Facility Director related to accurately reporting facility surgical infrastructure, tracking and evaluating emergent interfacility transfer times, ensuring required participation on the blood utilization committee, evaluating patient care for an institutional disclosure, reviewing operative documentation to ensure compliance, and reviewing compliance with rules of behavior as it applies to computer access.

VA Comments and OIG Response

The Under Secretary for Health and the VISN and Facility Directors concurred with the recommendations and provided acceptable action plans (see appendixes B, C, and D). Based on information provided, the OIG considers recommendations 2 and 7 closed. For the remaining open recommendations, the OIG will follow up on the planned actions until they are completed.

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Contents

Abbreviations

ACGME	Accreditation Council for Graduate Medical Education
BURC	blood utilization review committee
EHR	electronic health record
HFMEA	Healthcare Failure Mode Effect Analysis
JPSR	Joint Patient Safety Report
OAA	Office of Academic Affiliations
OIG	Office of Inspector General
PACU	post anesthesia care unit
PGY-1	postgraduate year one
SICU	surgical intensive care unit
SOP	standard operating procedure
SWAG	Surgical Work Action Group
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations regarding deficiencies in meeting invasive procedure complexity infrastructure requirements, supervision of postgraduate year one (PGY-1) surgical residents, completion of operative documentation, protection of patient privacy and information security, and facility leaders' response to reported patient safety concerns at the Lieutenant Colonel Charles S. Kettles VA Medical Center (facility) in Ann Arbor, Michigan.[1]

Background

The facility is part of Veterans Integrated Service Network (VISN) 10 and includes the Lieutenant Colonel Charles S. Kettles VA Medical Center in Ann Arbor and eight outpatient clinics throughout Michigan and northwestern Ohio. Classified by the Veterans Health Administration (VHA) as high complexity level 1b, the facility includes 106 acute care hospital beds, and offers surgical specialties including neurosurgery, orthopedic, vascular, and cardiac surgery.[2] The facility invasive procedure complexity designation level (invasive procedure designation) is *inpatient complex* with 4,260 invasive procedures completed from October 1, 2022, through September 30, 2023.[3] The facility has major medical education affiliations with three institutions, including the University of Michigan Health System (affiliate) in Ann Arbor, and provided trainee education to 692 physician residents (residents) in academic year 2022–2023.[4]

[1] VHA Directive 1400.01, *Supervision of Physician, Dental, Optometry, Chiropractic, and Podiatry Residents*, November 7, 2019. A PGY-1 resident, also known as an "intern," is a health professional trainee in a graduate training program and in the first year of postgraduate clinical training. For purposes of this report, PGY-1 surgery residents refer to residents in general surgery and surgical specialty residency programs.

[2] VHA Office of Productivity, Efficiency and Staffing (OPES), "Facility Complexity Level Model Data Definitions," October 1, 2023. 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, or 3. Level 1a facilities are considered the most complex and level 3 facilities are the least complex.

[3] VHA Directive 1220(1), *Facility Procedure Complexity Designation Requirements to Perform Invasive Procedures in Any Clinical Setting*, May 13, 2019, amended February 11, 2020. "[I]nvasive procedures are those procedures that require signature informed consent and involve a skin incision or puncture, or endoscopy." Facilities that perform invasive procedures in any clinical setting are assigned a facility invasive procedure complexity designation that includes corresponding infrastructure requirements.

[4] VHA Directive 1400.01. A resident physician participates in a medical training program and is supervised by an approved practitioner (also called an attending) when providing patient care.

VHA Resident Physician Training

Under federal law, VHA "shall develop and carry out a program of education and training of health personnel."[5] As part of one of four statutory missions, VHA conducts an education and training program for resident physicians to enhance the quality and timeliness of health care.[6] In accordance with this mission, the VA Office of Academic Affiliations (OAA) oversees affiliation agreements, outlining partnerships between VA medical centers and academic institutions with residency programs, and ensures compliance with Accreditation Council for Graduate Medical Education (ACGME) requirements.[7]

Key leaders involved in an affiliate partnership include the residency program director and the facility associate chief of staff for education. The residency program director "may be based at the VA or the affiliate institution" and "is the person designated with authority and accountability" for residency program operations.[8] The associate chief of staff for education is responsible for ensuring "a process for identifying and remediating areas with insufficient resident supervision," and assists in "assessing the quality of residency training programs and the quality of care provided by supervising practitioners and residents."[9]

Prior OIG Reports

In July 2023, the OIG published a report, *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*. The OIG found PGY-1 general surgery residents were not supervised per VHA requirements. The OIG made nine recommendations including that the VISN Director evaluate and ensure that all VISN 10 facilities comply with VHA requirements

[5] 38 U.S.C. § 7302.

[6] "Office of Academic Affiliations," VA Office of Academic Affiliations, accessed May 22, 2024, https://www.va.gov/oaa/.

[7] VHA Directive 1400, *Office of Academic Affiliations,* November 9, 2018; VHA Directive 1400.01; Upon graduation from medical school, a physician interested in pursuing specialization enters a residency program for that specialty. "Physician Education," Accreditation Council for Graduate Medical Education, accessed May 23, 2024, https://www.acgme.org/about/physician-education/. The ACGME is a national organization that monitors professional education standards for physicians and oversees the accreditation of residency programs across the United States. "About the ACGME," Accreditation Council for Graduate Medical Education, accessed May 23, 2024, https://www.acgme.org/about/overview/.

[8] VHA Directive 1400.01. The affiliate surgical residency program director told the OIG of working at the affiliate institution and confirmed not holding a dual appointment at the facility.

[9] VHA Directive 1400.01.

regarding PGY-1 resident supervision.[10] As of December 17, 2024, this recommendation remained open.[11]

Allegations and Related Concerns

On August 1, 2023, the OIG received a complaint with accompanying patient examples from a former facility provider alleging that facility leaders failed to

- meet select invasive procedure complexity designation requirements,
- provide required on-site supervision of PGY-1 surgery residents,
- adhere to The Joint Commission requirements for documentation of complex surgical procedures,
- ensure adherence to information security and privacy practices, and
- respond to patient safety concerns raised by the surgical intensive care unit (SICU) staff.[12]

On August 31, 2023, the OIG reviewed the allegations, determined further information was necessary, and contacted facility leaders who responded on December 19. The OIG determined the response was inadequate, and opened an inspection on January 16, 2024, to review allegations submitted by the complainant.

[10] 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. Of note, the facility is part of VISN 10.

[11] The OIG will consider the resolution of this open recommendation in the context of the current inspection, as the two facilities are in the same VISN, and the concerns identified in the prior report are relevant to the facility as well.

[12] The select invasive procedure complexity designation requirements included in the allegation were related to the availability of interventional neuroradiology, interventional radiology, and cardiac catheterization services, as well as blood product availability, and inpatient surgical coverage. Interventional radiology is the diagnosis and treatment of disease through the insertion of catheters or wires from outside the body guided by imaging. "Interventional Radiology," Johns Hopkins Medicine, accessed January 29, 2024, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/interventional-radiology; Interventional neuroradiology also uses catheters and imaging to treat neurological conditions and diseases. "Endovascular Neurosurgery and Interventional Neuroradiology," Johns Hopkins Medicine, accessed February 15, 2024, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/endovascular-neurosurgery-and-interventional-neuroradiology; Cardiac catheterization is the use of a thin, hollow tube, guided to the heart through a blood vessel, to test for problems or provide treatments. "Cardiac Catheterization," Mayo Clinic, accessed February 26, 2024, https://www.mayoclinic.org/tests-procedures/cardiac-catheterization/about/pac-20384695; The Joint Commission accredits and certifies health care organizations and programs and sets standards for hospitals and other health care delivery centers. The Joint Commission, Joint Commission FAQs, accessed June 26, 2024, https://www.jointcommission.org/who-we-are/facts-about-the-joint-commission/joint-commission-faqs/.

During the inspection, the OIG identified additional concerns related to

- reliance on patient transfers to external hospitals;
- engagement and communication between Surgery Service and the blood bank;
- disclosure of patient harm;
- interpretation of the VHA resident supervision directive;
- methodology for monitoring operative documentation compliance; and
- implementation, monitoring of outcomes, and communication of action plans.

On January 24, 2024, the Office of Special Counsel sent a referral to the VA Secretary and OIG with allegations from the complainant that were similar to the allegations accepted by the OIG for inspection. The OIG accepted the referral from the Office of Special Counsel.[13]

Scope and Methodology

The OIG conducted a site visit from April 2 through 4, 2024, and virtual interviews through May 23, 2024.

The OIG interviewed leaders from VHA national program offices, VISN surgical and education leaders, facility leaders and staff, and the affiliate surgical residency program director.[14] The OIG reviewed relevant VHA and facility policies and procedures, Joint Patient Safety Report (JPSR) data, organizational charts, committee meeting minutes, electronic communications, quality reviews, on-call schedules, and patient electronic health records (EHRs).[15] The OIG also reviewed relevant ACGME program requirements and The Joint Commission standards.

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

[13] "The Office of Special Counsel (OSC) handles disclosures of wrongdoing within the executive branch of the federal government from current federal employees, former federal employees, and applicants for federal employment." "Disclosure of Wrongdoing Overview," US Office of Special Counsel, accessed May 16, 2024, https://osc.gov/Services/Pages/DU.aspx.

[14] The VHA Program Offices included the Office of Academic Affiliations (OAA), Office of Specialty Care, Diagnostic Services, National Radiology Program, and National Pathology and Laboratory Medicine.

[15] The OIG reviewed patient examples provided by the complainant and through JPSRs and included patient examples in this report only when relevant to a substantiated allegation or OIG concern.

place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

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

The VHA invasive procedure complexity model ensures that facilities have the infrastructure to safely support the level of the invasive procedures performed.[16] VHA assigns an invasive procedure designation to a facility, and scheduled procedures cannot exceed the infrastructure capabilities of the facility. When a facility lacks required infrastructure for the invasive procedure designation and facility leaders do not want to reduce the complexity level, a waiver must be requested for specific infrastructure deficiencies.[17] The OIG learned that complexity waivers are generated at the facility level and routed through the VISN to VHA Clinical Services (Clinical Services) for review and final determination by a committee, which includes members from Specialty Care Services, the National Diagnostics Office, and the National Surgery Office.[18]

Delays in Infrastructure Waiver Requests

The OIG substantiated that the facility lacked the required infrastructure supporting the assigned inpatient invasive procedure designation of *inpatient complex*. Specifically, the facility did not provide on-site interventional neuroradiology services or after hours on-call vascular and non-vascular interventional radiology and cardiac catheterization services.

[16] VHA Directive 1220(1). Invasive procedures are "procedures that require signature informed consent and involve a skin incision or puncture, or endoscopy."

[17] VHA Directive 1220(1); Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "For Action: Annual Certification of Infrastructure Requirements for Sites Performing Invasive Procedures," memorandum to Veterans Integrated Service Network (VISN) Directors (10N1-23), February 8, 2024.

[18] Through review of email communication, the OIG learned the committee is called the Invasive Procedure Complexity Waiver Clinical Council. In interviews, the OIG learned that the committee may approve permanent or temporary waivers for specific infrastructure requirements and that the duration of temporary waivers varies.

VHA requires that facilities with the *inpatient complex* designation have vascular and non-vascular interventional radiology, cardiac catheterization laboratory, and interventional neuroradiology services "available on-site during dayshift; at all other times, these services must be available on-call within 60 minutes."[19]

The OIG found that although facility leaders pursued waivers for the lacking required infrastructure, the leaders did not submit the requests for approval until after the OIG announced the inspection despite long-standing infrastructure gaps. (See appendix A for a detailed timeline of waiver requests.)[20] The OIG found delays in waiver requests and approvals resulted from

- facility leaders' lack of awareness of available surgical infrastructure,
- administrative delays at the VISN level, and
- conflicting guidance on waiver submission requirements provided by VISN leaders and Clinical Services staff.

In the December 2023 response to the OIG's initial inquiry related to the complainant's allegations, the Facility Director acknowledged a lack of on-site interventional neuroradiology services and stated that a waiver request was planned for submission to the VISN Director "pending completion of a formal [transfer agreement] with the [non-VA hospitals]." Following the announcement of the OIG inspection in February 2024, and in response to an OIG document request, the OIG learned that the facility was planning to request waivers for vascular and non-vascular interventional radiology and cardiac catheterization due to lack of after hours on-call availability for these services. The chief of surgery submitted draft infrastructure waiver requests on March 4, 2024, five days after the OIG notified facility leaders of the inspection. The OIG learned through review of documentation provided by Clinical Services, the waiver requests were signed by the VISN Chief Surgical Consultant and VISN Director on March 12. On April 29, Clinical Services approved a permanent waiver for cardiac catheterization laboratory services and a temporary (12 month) waiver for vascular and non-vascular interventional radiology. However, the approval memorandum did not indicate review of a waiver for interventional neuroradiology services.

Delay in Identification of Need for Infrastructure Waivers

The OIG learned that while there had been long-standing deficiencies in required infrastructure, the chief of surgery was not aware of the lack of after hours on-call coverage for some services

[19] VHA Directive 1220(1). The requirement for interventional neuroradiology applies only to facilities with an approved VHA neurosurgery program. The facility has an approved neurosurgery program.

[20] 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.

supporting the designation of *inpatient complex* despite completing the required annual review of infrastructure in November 2022.

Facility service chiefs are responsible for conducting an annual review of the available infrastructure, which must be certified by the facility director and VISN leaders, including the VISN Chief Surgical Consultant and the VISN Director.[21]

The OIG reviewed the required annual reviews of infrastructure, which were completed by the chief of surgery in November 2022 and March 2024. In the annual review completed in November 2022, the chief of surgery endorsed deficiencies in interventional neuroradiology services, while indicating that the requirement was "fully met" for vascular and non-vascular interventional radiology and cardiac catheterization services. In the annual review completed in March 2024, the chief of surgery noted deficiencies with vascular and non-vascular interventional radiology services and cardiac catheterization services, as well as interventional neuroradiology services.

In an OIG interview, the Chief of Staff reported that the chief of surgery was responsible for completing the annual review of required invasive procedure infrastructure. The chief of surgery told the OIG of first recognizing the need for a waiver for interventional neuroradiology in December 2022, while in the role of acting chief of surgery.[22] However, the chief of surgery told the OIG of not identifying the lapses in interventional radiology and cardiac catheterization until completing an online checklist of infrastructure requirements in March 2024. The OIG confirmed with facility leaders that the facility last had after hours on-call vascular and non-vascular interventional radiology coverage in December 2020, and there had never been after hours cardiac catheterization services available at the facility.

The chief of surgery told the OIG the previous chief of surgery did not clearly communicate infrastructure requirements or the need for waivers, stating "[the previous chief of surgery] hadn't done any of the waivers . . . I'm not sure [the previous chief of surgery] was aware . . . it wasn't something that was conveyed to me as being as critical."

Conflicting Guidance on Waiver Requirements and Administrative Delays

The OIG also found that the waiver request process was hindered by lack of clarity regarding the waiver process and requirements, and poor communication of the waiver request status between facility and VISN leaders.

[21] VHA Directive 1220(1); Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "For Action: Annual Certification of Infrastructure Requirements for Sites Performing Invasive Procedures," memorandum. The annual review is accomplished through completion of the Invasive Procedure Infrastructure Inventory Tool (IPIIT).

[22] The chief of surgery told the OIG of serving in an acting role from August 2022 to February 2023 before becoming the permanent chief of surgery.

VHA policy states that waivers may be granted when interventional cardiology, interventional neuroradiology, and non-vascular or vascular interventional radiology services are provided off-site, or when any infrastructure deficiency has undergone a risk assessment using the Healthcare Failure Mode Effect Analysis (HFMEA) process.[23] The VISN Director is responsible for submitting endorsed waiver requests to the Office of Specialty Care Services and the National Surgery Office.[24]

VHA policy also requires that infrastructure requirement waiver requests include

- the travel distance between the VA medical facility and the facility providing the service,
- a document establishing a transfer agreement, and
- a plan for monitoring and reviewing the quality of care being provided.[25]

In an interview with the OIG, a facility deputy chief of staff (deputy chief of staff 1) reported that the waivers were not submitted to VISN leaders until March 2024 due to facility leaders' belief that the waiver submission required a formal patient transfer agreement with non-VA hospitals. Deputy chief of staff 1 reported that facility leaders were waiting to submit the waiver requests until the transfer agreements had been completed. In an interview, deputy chief of staff 1 told the OIG of learning from the VISN specialty care integrated clinical community lead that the existing community care contract fulfilled the requirement for a transfer agreement in February 2024, and that additional transfer agreements were not necessary, and stated "it just felt . . . a little bit like a wasted effort."[26] The VISN Chief Surgical Consultant also told the OIG of advising the facility that an additional transfer agreement would not be necessary if the non-VA hospital was part of the community care network.[27]

The OIG found that the waiver approval memorandum provided by Clinical Services did not show review or approval of the waiver request for interventional neuroradiology. A VISN staff member informed the OIG that facility leaders submitted a waiver request for interventional

[23] VHA Directive 1220(1); An HFMEA is a healthcare focused prospective tool for proactive risk assessment meant to identify possible risks in a process before they occur. VHA National Center for Patient Safety, "Introduction and General Overview," *Guide to Completing Healthcare Failure Modes and Effects Analysis*, Version 3, February 2023.

[24] VHA Directive 1220(1).

[25] VHA Directive 1220(1). In addition to the listed requirements, the waiver request must also contain the infrastructure component for which the waiver is requested and the name of the facility performing the procedure. A transfer agreement can be documented in a memorandum of understanding or contract.

[26] A transfer agreement was completed with one non-VA hospital in March 2024, which the facility included with the waiver request for vascular and non-vascular interventional radiology and cardiac catheterization. Deputy chief of staff 1 told the OIG that the other transfer agreement was still in progress at the time of the site visit.

[27] A community care network is a network of non-VA providers who, with approved agreements, provide care to veterans who cannot receive the service at a VA facility. VA, "Community Care Network (CCN) – Regions 1–5 For Community Providers" (fact sheet), January 27, 2022.

neuroradiology to the VISN in January 2024 without a required checklist. Although facility leaders submitted the checklist in March 2024, the VISN staff member stated that there was "some miscommunication," and the waiver request for interventional neuroradiology was "inadvertently overlooked" until submitted to Clinical Services in May 2024.[28]

In an interview, the VISN Chief Surgical Consultant told the OIG of implementing a tracking mechanism for monitoring the status of waiver requests. The OIG reviewed VISN surgical workgroup meeting minutes in which the workgroup identified the need for a waiver request tracking system in November 2023.[29] A VISN staff member provided a copy of the tracking spreadsheet in April 2024. Upon review, the OIG found that the tracking spreadsheet erroneously indicated that the interventional neuroradiology waiver request had already been submitted to Clinical Services for approval.

In follow-up communication about the status of the interventional neuroradiology waiver request, a VISN staff member told the OIG that a Clinical Services staff member had requested additional support for the waiver request, including documentation of a transfer agreement and evidence of an HFMEA. In August 2024, the VISN staff member told the OIG through email correspondence that the HFMEA had been completed and submitted to Clinical Services. The Assistant Under Secretary for Health for Clinical Services approved the waiver on October 15, 2024, following review by the Invasive Procedure Complexity Waiver Clinical Council.[30]

The OIG is concerned that the direction given from Clinical Services is not congruent with (1) information the OIG received from the VISN Chief Surgical Consultant and (2) the VHA policy that addresses waiver request submissions. Specifically, it was not clear that an HFMEA was required for interventional neuroradiology waivers and there was conflicting guidance on whether the community care contract fulfilled the requirement for a transfer agreement. These inconsistencies further delayed the waiver request process, which was already prolonged by facility leaders' lack of awareness of available infrastructure and administrative delays at the VISN level.

The OIG determined that the facility lacked required infrastructure for vascular and non-vascular interventional radiology, cardiac catheterization, and interventional neuroradiology, but that the

[28] The OIG learned, through review of email communication provided by the VISN staff member, that the chief of surgery submitted waiver request memos for interventional neuroradiology to the VISN in February 2023 and again in January 2024. The VISN staff member explained that the requests submitted by the facility in February 2023 and January 2024 lacked required information.

[29] Duties of the VISN surgical workgroup include ensuring facility compliance with infrastructure requirements. VHA Directive 1102.01(2), *National Surgery Office*, April 24, 2019, amended April 19, 2022.

[30] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "Directive 1220 Waiver Request for Interventional Neuroradiology Services, Lt. Col. Charles S. Kettles Veterans Affairs Medical Center, (Station 506), Ann Arbor, Michigan (VIEWS 11966269)," memorandum to Director, Veterans Integrated Service Network 10 et al., October 15, 2024.

chief of surgery initiated waivers for these requirements after becoming aware of the deficiencies. The OIG found that a lack of awareness of available services, unclear direction about waiver requirements, deficient tracking and communication of the waiver request status, and lack of VISN oversight led to delays in submission and approval of the waiver requests. Delays in waiver requests may lead to facilities operating at a complexity level without the required infrastructure, and without required review from relevant program offices.

Concern with Reliance on Patient Transfers to External Hospitals Despite Delays

While facility leaders submitted waivers for the lacking required infrastructure, the OIG identified an additional concern with the failure to monitor and track timeliness of patient transfers.

Infrastructure requirement waivers must include the travel distance and transfer protocol between the VA facility and the facility performing the procedure, as well as "a plan for monitoring and reviewing the quality of care being provided."[31] VHA also requires that medical facilities have a written plan "that identifies the safe and timely transfer of the patient who requires treatment or therapy which the VA medical facility is unable to provide."[32]

VHA leaders from the Office of Specialty Care shared that during the waiver evaluation process, reviewers do not assess the effectiveness of a transfer plan beyond reviewing the distance from the VA facility to the transfer location, and the facility is expected to monitor the care provided, including timeliness of transfer.

The OIG reviewed the waiver requests submitted by the facility, which noted lack of bed availability at non-VA hospitals and delays in treatment due to ambulance service availability as potential risks to patients. The requests listed mitigating actions including (1) drafting a transfer agreement that "captures our current transfer process," (2) transferring to emergency departments at non-VA hospitals, and (3) implementing a facility operated ambulance service. As a condition of granting the temporary waiver, Clinical Services also required "the facility . . . to monitor and track any adverse outcomes that arise from outsourcing IR [interventional radiology] services and report the findings to the facility quality/safety manager, chief of staff, and medical center director."[33]

[31] VHA Directive 1220(1).

[32] VHA Directive 1220(1).

[33] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "Directive 1220 Invasive Procedure Complexity Waiver Request for Vascular and Non-vascular Interventional Radiology (IR) Services and Interventional Cardiac Catheterization Laboratory (Cardiac Cath) services at the Lieutenant Colonel Charles S. Kettles Department of Veterans Affairs Medical Center (LtCol Charles S. Kettles VAMC), Station 506, (VIEWS 11682654)," memorandum.

The OIG also reviewed an episode of care identified by the complainant that demonstrated a significant delay in the transfer of a patient (patient A) to the affiliate for interventional neuroradiology in spring 2023.[34] The OIG found that it took over four hours to transfer patient A for interventional neuroradiology services. A former facility physician, who provided care for the patient while awaiting transfer, told the OIG that "many levels of administrative failure" led to transfer delays for the patient. The OIG learned through the Facility Director's response to the OIG's initial inquiry that facility leaders had conducted a root cause analysis to review the patient event and implemented corrective actions as warranted.[35]

In interviews, the OIG was told of concerns with the transfer process to non-VA hospitals from facility clinical staff and leaders, including delays in ambulance services, issues with regional bed availability, a tendency for providers to rely primarily on the affiliate for transfers, and lack of clarity about the transfer process. Facility leaders and a patient safety specialist shared plans to institute a facility operated ambulance service to reduce reliance on community ambulance services as a result of the concerns.[36] The chief of surgery explained that the ambulance service will initially only be available during business hours.[37]

When asked about the lack of bed availability at non-VA hospitals, as indicated in the waiver request, deputy chief of staff 1 told the OIG that issues with non-VA hospital bed availability may be a "perception . . . more than the true reality" and that because of the facility's close relationship with the affiliate, it was often the first choice for physicians when transferring patients, even when there was not an available bed. The Chief of Staff and a patient safety specialist also agreed that providers and residents tended to primarily rely on the affiliate for transfers. The Chief of Staff described reinforcing with residents to route transfers through the designated administrator to facilitate transfers to a hospital with an available bed.

In addition, the OIG learned of concerns about the administrative process for transfer requests. A former facility physician told the OIG of concerns with being able to efficiently transfer patients to non-VA hospitals for needed services and described challenges in the administrative management of transfers, including inadvertent cancellation of transfer orders. A facility patient safety specialist also shared short-term interventions to address the administrative portion of the transfer process, including creating a checklist for residents coordinating transfers and

[34] The affiliate is located approximately 1.2 miles from the facility.

[35] A root cause analysis is "a comprehensive team-based, systems-level investigation with a formal charter for review of health care adverse events and close calls." VHA Directive 1050.01(1), *VHA Quality and Patient Safety Programs*, March 24, 2023, amended March 5, 2024.

[36] The waiver request memorandums indicated that the facility planned to implement the facility operated ambulance service by the end of September 2024. In an email to the OIG, deputy chief of staff 2 shared that the facility was actively hiring paramedic staff and expected to have an ambulance service available in fall 2024.

[37] The OIG learned through email communication with the facility chief of radiology and review of the waiver requests that on-site services for interventional radiology and cardiac catheterization are available during business hours.

standardizing an updated transfer policy. A SICU physician told the OIG that the new transfer checklist had been helpful for both residents and attending physicians to facilitate the transfer process.

In the waiver requests, facility leaders stated that transfers from Surgery Service for acute or emergent vascular and non-vascular interventional radiology and cardiac catheterization would be tracked and reviewed through the facility bed utilization committee quarterly. The waiver requests specified that reviews would include "appropriateness of transfer, timeliness of transfer, systems issues in the transfer process, and clinical outcomes." In an interview in early April 2024, deputy chief of staff 1 shared that monitoring transfer times through the bed utilization committee had not yet started but would begin within the next few weeks. The OIG reviewed facility bed utilization committee minutes from May 2024, and did not find evidence of reviews that included the elements specified in the waiver requests.

The OIG learned of existing transfer challenges that could delay patient transfers for acute or emergent medical conditions. While facility leaders updated the facility transfer policy and procedures, and described efforts to address the reliance upon the affiliate for transfers, some efforts, including establishment of an in-house ambulance service, are still in progress. The OIG would expect that facility leaders would have monitored transfer delays immediately upon submitting the waiver requests to identify any transfer delays and contributing factors that could affect the ability to ensure safe and timely patient care.

Blood Bank

The OIG did not substantiate that the facility failed to meet blood bank infrastructure requirements for the invasive procedure complexity designation. The OIG found that blood bank services and blood products were available as required.[38] However, the OIG identified an additional concern with a lack of engagement and communication between Surgery Service and blood bank staff and leaders.

VHA requires that facilities with an *inpatient complex* invasive procedure designation have blood and blood components available within 60 minutes at all times but does not specify quantities or types of blood products that must be kept on-site.[39]

Facility blood bank procedures and guidance state that blood bank services are available at all times and the blood bank maintains an inventory of red blood cells, fresh frozen plasma, and

[38] As part of the allegations to the OIG, the complainant alleged both that the facility did not have blood bank services and blood products as required and that the facility lacked a massive transfusion protocol. The OIG found that a massive transfusion protocol was not an infrastructure requirement for the invasive procedure complexity designation. A massive transfusion protocol defines procedures for transfusing a large volume of blood within a specific period of time.

[39] VHA Directive 1220(1).

cryoprecipitate blood products.[40] While the blood bank does not maintain a stock of platelets, platelets can be ordered as needed. The OIG did not identify any patient safety events resulting from a lack of available blood products.

The Executive Director, National Pathology and Laboratory service told the OIG that it was not unusual for facilities to order platelets as needed and that this process would not make a facility noncompliant with procedural complexity infrastructure requirements because other blood components could be utilized until platelets were available.

While the OIG found that the facility blood bank did not maintain an inventory of platelets, the OIG determined that this was not a requirement to meet the procedural complexity infrastructure requirements and that blood bank services and blood products were available as required.

Concern with Engagement and Communication Between Surgery Service and Blood Bank

The OIG identified concerns with communication between Surgery Service and blood bank staff and leaders.

VHA requires that medical facilities that transfuse blood or blood products have a blood transfusion utilization review committee, which must review the "ability of services to meet patient needs."[41] The chief of surgery, or designee, is listed as a required committee member in the facility blood utilization review committee (BURC) policy.[42]

In interviews, facility leaders and staff told the OIG about concerns with communication between blood bank staff and Surgery Service staff and leaders regarding blood bank operations and capabilities. When discussing balancing the need to have blood products available and minimizing wasting of blood products, a patient safety specialist told the OIG, "we do hear concerns from the clinical side about what our blood bank is capable of . . ." and further stated, "the clinical side doesn't understand also the business side of the blood bank."[43] The blood bank supervisor reported a general lack of communication about changes to Surgery Service blood

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[40] VA Ann Arbor Healthcare System, "Blood Bank" (procedure guidance), n.d.; VA Ann Arbor Healthcare System, "Blood Bank Manual of Standard Operating Procedures," January 5, 2020, reviewed January 26, 2023; Cryoprecipitate is a portion of the liquid part of blood, which contains clotting factors that can slow or stop bleeding to reduce blood loss. "What is Cryoprecipitate? Why is it important?," American Red Cross, Red Cross Blood Services, accessed May 16, 2024, https://www.redcrossblood.org/donate-blood/dlp/cryoprecipitate.html.

[41] VHA Directive 1106, *Pathology and Laboratory Medicine Service*, January 24, 2024. Prior to publication of this directive, requirements for the blood utilization committee were addressed in a handbook, which requires that each VA medical facility must have a blood utilization review committee composed of multidisciplinary members; VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016, rescinded January 24, 2024.

[42] VA Ann Arbor Healthcare System. "Blood Utilization Review" (Committee Policy), March 24, 2020.

[43] The patient safety specialist described plans to initiate a steering committee to address concerns with the blood bank but reported that meetings had not started at the time of the site visit.

product needs. The blood bank supervisor told the OIG that better communication could allow for inventory adjustments as the quantity and complexity of surgical cases increased.

In an interview, when discussing the blood bank, the chief of surgery stated, "I think communication is the biggest barrier that we have to keep working on." The OIG reviewed BURC meeting minutes and found no evidence that the chief of surgery, or a Surgery Service representative, attended from April 2022 through March 2024.

The OIG identified a concern regarding communication between the blood bank and surgical leaders, as well as lack of engagement of the chief of surgery with the BURC. Consistent Surgery Service representation on the BURC may improve communication of changes to blood product needs and minimize miscommunication about blood product availability.

Inpatient Surgical Coverage

The OIG did not substantiate that the Surgery Service lacked coverage to ensure a provider was available on-call within 15 minutes by phone and within 60 minutes on-site, or that the facility lacked qualified inpatient coverage, as required for the invasive procedure complexity designation.

VHA policy requires a formal call schedule that includes 24/7 coverage by attending surgeons, fellows or residents in surgical training programs, or trained advanced practice providers available on-call within 15 minutes by phone and on-site within 60 minutes.[44] Additionally, "there must be qualified inpatient coverage in house for all inpatients."[45]

During the inspection, the OIG reviewed surgical on-call schedules and patient cases provided by the complainant as examples of a lack of required surgical coverage.[46] The OIG found the facility used a schedule for surgeons to know when they were expected to be on-call and a paging system through the affiliate for facility staff to contact the scheduled on-call surgeon.[47]

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[44] VHA Directive 1220(1). Advance practice providers are "qualified health care providers that work under the supervision of a licensed independent provider credentialed and privileged by the VA medical facility" and may include a certified registered nurse anesthetist, a nurse practitioner, or a physician assistant. The directive specifies the surgical specialty on-call requirement applies to Thoracic Surgery, Urology, Vascular Surgery, Cardiac Surgery, and Neurosurgery.

[45] VHA Directive 1220(1); "A 'physician or other qualified health care professional' is an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his or her scope of practice and independently reports that professional service." American Medical Association, "CPT Evaluation and Management (E/M) Code and Guideline Changes," January 1, 2023, https://www.ama-assn.org/system/files/2023-e-m-descriptors-guidelines.pdf.

[46] On-call schedules were provided for Thoracic Surgery, Urology, Vascular Surgery, Cardiac Surgery, Neurosurgery, Orthopedics, and General Surgery.

[47] The Chief of Staff reported to the OIG that the facility uses a "split model" with the affiliate whereby many surgeons work both for the facility and the affiliate.

The OIG determined one of the patient cases (patient B) provided by the complainant involved an on-call attending surgeon who was not available within 60 minutes on-site. In an OIG interview, the chief of surgery described a communication escalation process, implemented in spring 2023, that addressed concerns related to provider response times and ability of staff to escalate concerns beyond residents when needed.[48] A facility patient safety specialist told the OIG that effectiveness of the escalation process was monitored through review of patient safety reports. The OIG reviewed patient safety reports related to on-call surgical coverage and noted a decrease in the number of reports after implementation of the escalation process. Additionally, the reports entered after implementation did not reflect systemic difficulty reaching the covering surgeon. The OIG verified with the chief of hospital medicine that the facility is continuously staffed by hospitalists, which meets the requirement for qualified in-house coverage for all inpatients.

The OIG found the facility Surgery Service utilizes a formal call schedule for required surgical services, a mechanism to escalate challenges with reaching on-call surgical providers, and has qualified in-house coverage for all inpatients.

Concern with Failure to Disclose Patient Adverse Event

The OIG identified an additional concern related to a lack of disclosure, per VHA policy, to patient B's family that patient B experienced deficiencies in care that may have contributed to the patient's death. The OIG determined that facility leaders failed to consider conducting an institutional disclosure for an adverse event.

VHA requires disclosure of "harmful or potentially harmful adverse events to patients or their personal representatives."[49] Institutional disclosure is required for an adverse event that results in, or is reasonably expected to result in, death or serious injury. The facility risk manager is responsible for notifying facility leaders when made aware of any significant adverse event that may require institutional disclosure. The facility chief of staff must participate in discussions about institutional disclosure and also notify the facility director of significant adverse events. The facility director is responsible for ensuring that relevant staff are aware of the VHA requirements for disclosures and that disclosures of adverse events are performed "openly and promptly." VHA requirements for institutional disclosure include "an apology, including an

[48] The escalation process specified a communication hierarchy beginning with the resident on-call and ending with the Chief of Staff. The document supporting this process provided to the OIG by a facility representative was referred to as a facility policy; however, the document did not include a policy number or signature. The OIG spoke with facility leaders and staff who were aware of the document and its contents; therefore, the OIG is confident this document has been widely accepted as a facility policy.

[49] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. Types of adverse event disclosure recognized by VHA include clinical, institutional, and large scale disclosures. A clinical disclosure is typically conducted for "adverse events that cause only minor harm" or as the first step before conducting an institutional disclosure. A large scale disclosure is used when there is harm or potential harm to multiple patients.

explanation of the facts," "information about potential compensation," and documentation in the EHR using a templated note.[50]

The Facility Director indicated, in the response to the OIG's initial inquiry related to the complainant's allegations, that patient B's death was likely related to a delay in surgical treatment, and that the attending surgeon's VHA privileges had been revoked as a result.[51] However, the OIG reviewed patient B's EHR and found no documentation of an institutional disclosure.[52]

When asked if an institutional disclosure was discussed for patient B, the risk manager told the OIG that the focus was on the attending surgeon's actions and it was not clear that the delay in surgical intervention caused the patient's death. The risk manager also reported being new to the role at the time of the incident and, in hindsight, the case should have been brought forward to the Chief of Staff for consideration for institutional disclosure. The Chief of Staff could not remember a conversation about an institutional disclosure, but added that a disclosure for this patient event "would be reasonable."

The chief of surgery told the OIG of meeting with patient B's family to discuss "what I felt was a delay in treatment . . . related to . . . suboptimal care delivered by the [attending surgeon]." However, there was no EHR documentation indicating that the delay in surgical intervention and suboptimal care by the attending surgeon was disclosed to patient B's family. The Chief of Staff also told the OIG that the priority was to ensure that the attending surgeon was held accountable.

The OIG found that despite facility leaders' acknowledgment that a delay in surgical treatment may have contributed to patient B's death, facility leaders failed to consider an institutional disclosure. The OIG determined that given patient B's death, and facility leaders' acknowledgment of the deficiencies in care, the event met the criteria for an institutional disclosure. Failure to disclose adverse events may negatively affect patients' trust in VA health care.

2. PGY-1 Surgery Resident Supervision

The OIG was unable to determine if facility leaders failed to ensure that on-site supervision was provided to PGY-1 surgery residents as required by VHA. The OIG found facility leaders implemented a facility standard operating procedure (SOP) describing a process for off-tour supervision of PGY-1 surgery residents by hospitalists and that this SOP was reviewed and

[50] VHA Directive 1004.08.

[51] The OIG reviewed patient B's case and determined that the delay in surgical treatment may have contributed to the patient's outcome.

[52] As of October 2024, the OIG found no documentation of an institutional disclosure in patient B's EHR.

supported by OAA and by the affiliate surgery residency program director (residency program director).[53]

However, the OIG found inconsistencies with interpretation of VHA policy related to the supervision of PGY-1 surgery residents among facility providers and VISN and program office leaders. Specifically, the OIG found (1) while the SOP provided a plan for on-site supervision, the SOP did not provide means for on-site supervision for surgical patient management, for which hospitalists are not privileged to provide, and (2) the relationship established in the SOP between the hospitalists and the PGY-1 surgery residents may not meet VHA's definition of supervision. The OIG is concerned that OAA guidance given to VISN 10 leaders regarding current PGY-1 surgery resident supervision does not meet the intent of VHA policy.

As the largest provider of health professional education in the United States, VHA policy notes a mutually enhancing link between the successful educational experience of residents and the quality of patient care delivered to veterans.[54] VHA also identifies that a clear delineation of oversight responsibilities for supervisors of residents is imperative to ensure veterans receive high-quality patient care.[55]

While the ACGME requires that PGY-1 residents "must initially be supervised directly," the ACGME further elaborates that "the degree of supervision is expected to evolve progressively as a resident gains more experience. . . ."[56] VHA policy is more restrictive and requires that PGY-1 residents "have on-site supervision at all times by either a supervising practitioner or a more advanced resident."[57] VHA also notes that supervising practitioners can only provide supervision for activities in which they hold clinical privileges, and that a hospitalist may directly supervise a PGY-1 surgery resident "for non-surgical patient management" when documented relationships are in place and approved by the residency program.[58]

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[53] For purposes of this report, off-tour refers to weekends, nights, and holidays.

[54] VHA Directive 1400.01; "Office of Academic Affiliations," VA Office of Academic Affiliations, accessed May 22, 2024, https://www.va.gov/oaa/.

[55] VHA Directive 1400.01.

[56] Accreditation Council for Graduate Medical Education, *ACGME Program Requirements for Graduate Medical Education in General Surgery*, July 1, 2022. These requirements were revised on July 1, 2023. The focus of this report covers time periods in which both requirements were in place, and both contain the same language related to the program's role in defining when supervision of the resident requires the physical presence of the supervising practitioner. The residency program is responsible for defining tasks "for which PGY-1 residents must be supervised directly until they have demonstrated competence as defined by the program director."

[57] VHA Directive 1400.01. A more advanced resident is a resident who has completed the first year of a residency program.

[58] VHA Directive 1400.01; A hospitalist is a physician, usually trained in general internal medicine, who specializes in managing the care of hospitalized patients. "Hospital Medicine," American College of Physicians, accessed June 4, 2024, https://www.acponline.org/about-acp/about-internal-medicine/general-internal-medicine/hospital-medicine.

VHA defines supervision as

> an intervention provided by a supervising practitioner . . . that occurs as residents provide patient care. . . . The relationship of the supervising practitioner to the resident is evaluative, extends over time, and has the simultaneous purposes of enhancing the professional functioning of the resident while monitoring the quality of professional services delivered. Supervision is exercised through direct involvement with the patient and resident, observation of care provided by the resident, oversight of patient care, directing the learning of the resident, and role modeling communication and professional skills.[59]

The OIG found that in May 2022, facility leaders became aware of noncompliance with VHA requirements related to PGY-1 resident supervision.[60] As a result, the associate chief of staff for education facilitated implementation of an SOP in November 2022 that formalized a supervisory relationship between off-tour PGY-1 surgery residents and hospitalists to "provide supervision for acute non-surgical issues." The SOP instructs a PGY-1 surgery resident to first call an off-site senior surgical resident or attending surgeon for questions or any concerns about patient care management. In cases where the surgical team determines immediate supervision is needed, the PGY-1 surgery resident would page the hospitalist for assistance while the senior surgical resident or attending surgeon returns to the hospital. For immediate on-site supervision for non-surgical management, the PGY-1 surgery resident would be instructed by the surgical team to page the hospitalist.[61]

The OIG confirmed in interviews that OAA leaders felt the SOP complied with VHA requirements for PGY-1 resident supervision, and the residency program director was supportive of the supervisory relationship between hospitalists and PGY-1 surgery residents as outlined in the SOP. The residency program director characterized VA resident supervision as "excellent," and further clarified understanding that "all surgical issues are still staffed directly with the surgeon on-call."

[59] VHA Directive 1400.01.

[60] Noncompliance with VHA requirements was noted as result of email correspondence between facility leaders and a staff physician at another facility, who reached out for guidance on the topic. At that time, PGY-1 surgery residents at the facility did not have on-site supervision on off-tours.

[61] The document provided to the OIG by a facility representative was referred to as an SOP; however, the document did not include a title, date, or signature. The OIG spoke with facility, VISN, and program office leaders who were aware of the document and its contents; therefore, the OIG is confident this document has been widely accepted as an SOP.

Concerns with Interpretation of VHA Resident Supervision Directive

The OIG heard from the VISN 10 Chief Surgical Consultant of concerns regarding the facility SOP related to the lack of on-site supervision for surgical patient management on off-tours at the facility. The VISN 10 Chief Surgical Consultant told the OIG, "I think you need much more direct supervision . . . even if the OAA gave it the rubber stamp of approval, I personally don't think an intern [PGY-1 resident] can appropriately manage a complex cardiac [surgery] patient at night even if there is a medical person who is available."

Similar concerns were raised at the VISN 10 Healthcare Delivery Committee in November 2023.[62] The Acting VISN 10 Academic Officer reached out to OAA leaders for consultation and was told that the SOP was compliant with VHA requirements as long as the residency program director was supportive of the supervisory plan.[63]

Despite facility, affiliate, and OAA support of the SOP, the OIG found the SOP was not consistent with VHA requirements to provide on-site supervision for PGY-1 residents at all times.[64] While the SOP outlines a plan for on-site supervision, it does not provide means for on-site supervision for surgical patient management, for which hospitalists are not privileged to provide.

The OIG also learned of concerns related to the level of supervisory interaction between the hospitalists and PGY-1 residents on off-tours. The complainant told the OIG that the supervisory relationship between the hospitalists and PGY-1 surgery residents was a plan "essentially put on paper" and that the relationship occurring in practice between the hospitalists and the residents was consultative rather than supervisory.[65] The OIG found that although the SOP established a "process for supervision overnight," it characterized the relationship between hospitalists and PGY-1 surgery residents as consultative rather than supervisory stating, "In the event that a

[62] The VA OIG published *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 on July 18, 2023. This report included a recommendation that VISN 10 comply with VHA requirements regarding resident supervision, specifically related to postgraduate year one on-site direct supervision. Minutes from the November 2023 VISN 10 Healthcare Deliver Committee meeting were submitted to the OIG as part of a request for closure of the recommendation.

[63] The OAA is the responsible office for the content of the resident supervision directive. VHA Directive 1400.01.

[64] The OIG reviewed patient cases provided by the complainant and patient safety reports related to resident supervision and did not find any evidence of patient harm related to the supervision of PGY-1 surgery residents. The OIG defined patient harm as a significant negative impact on the patient's care, including delays in care.

[65] Consultation between medical providers is defined as a "type of service provided by a physician whose opinion or advice regarding evaluation and/or management of a specific problem is requested by another physician or appropriate sources." "Coding- Is That Really a Consultation?" Yale School of Medicine, accessed June 5, 2024, https://medicine.yale.edu/news-article/codingis-that-really-a-consultation/.

surgical intern requests immediate assistance on a *non-surgical* issue, the medicine hospitalists will provide assistance in a consultative fashion."

PGY-1 surgery residents, hospitalists, and the chief of hospital medicine told the OIG that the process outlined in the SOP was rarely used.[66] The chief of hospital medicine confirmed there was no formal process for the hospitalists and PGY-1 surgery residents to engage during off-tour hours unless the resident reached out to the hospitalist with a patient care issue. In addition, hospitalists confirmed with the OIG that they would only engage if the resident initiated contact.

When asked if their interactions with PGY-1 surgery residents were sufficient to be considered supervision for non-surgical management, a hospitalist told the OIG, "we function more as a consultant than a supervising provider. As one would expect a supervising provider to demonstrate a more wholistic approach." While confirming support of the facility SOP and that hospitalists can serve as supervisors of PGY-1 surgery residents, an OAA leader shared a similar characterization with the OIG, stating "although they're serving in a supervisory role . . . [t]hey're functioning kind of as a . . . consult for anything super acute where a patient may be harmed that is non-surgical."

Through multiple interviews and correspondence with key stakeholders of the supervision process outlined in the SOP, the OIG was informed of minimal interaction between the hospitalists and the PGY-1 surgery residents and opines that this minimal engagement may not meet VHA's definition of supervision.

During the course of the inspection, OAA leaders informed the OIG that the VHA resident supervision directive is under review and revision to align with ACGME requirements.[67] While the OIG notes that a revision to VHA policy may resolve the conflicts identified above, the OIG would expect OAA leaders to guide facilities per current policy until formal changes are approved and communicated to the field, thereby ensuring that PGY-1 supervision is standardized across all VHA facilities.[68]

Although facility leaders implemented an SOP for PGY-1 surgery residents that was supported by OAA leaders and the residency program director, the OIG found the SOP did not address on-site supervision for surgical patient management. In addition, the level of interaction between

[66] The OIG interviewed two PGY-1 surgery residents; neither had ever sought support from a hospitalist during off-tour hours. The OIG also engaged in email correspondence with six hospitalists who work at night; three reported having no interactions with PGY-1 surgery residents, one reported a single interaction in the past year, one reported only being contacted via the formal consult process, and one did not respond.

[67] OAA leaders could not confirm when the policy updates would be approved and released but anticipated it would occur before the end of 2024.

[68] The OIG is not aware of specific details regarding proposed revisions to the VHA resident supervision policy. Of note, in electronic correspondence, an ACGME representative told the OIG that it would be "highly unusual" for a hospitalist to act as a supervising practitioner for a PGY-1 surgery resident, but that factors such as faculty and specialty status would have to be considered before a final determination was made.

hospitalists and PGY-1 surgery residents may not meet VHA's definition of supervision. The OIG is concerned that varying interpretations between policy and OAA guidance is likely to result in non-standardized supervision for residents who may not have the experience required to provide independent patient care across VHA.

3. Inconsistent Completion of Operative Documentation

The OIG did not substantiate that facility surgeons failed to abide by facility bylaws and The Joint Commission standards for postoperative documentation. While surgeons were not consistently completing a required operative note before patients were transferred to the next level of care, the OIG found that facility leaders became aware of the issue prior to the inspection, and took action to monitor and improve compliance. However, the OIG is concerned that the current monitoring methodology may result in inaccurate compliance data.

VHA states that healthcare providers are responsible for "[c]ompleting and authenticating (i.e., signing or co-signing) health record documentation within time frames defined by [VHA] directive, VA medical facility SOPs, guidelines and medical staff bylaws. . . ."[69] The facility bylaws require that "operative reports are to be dictated or written in the medical record immediately after surgery and must contain a description of the findings, the technical procedures used, the specimens removed, blood loss, complications, the postoperative diagnosis, and the names of the primary surgeon and any assistant."[70] The Joint Commission standards for hospitals contain similar documentation content requirements related to operative reports and requires that an operative report is written or dictated "before the patient is transferred to the next level of care."[71]

The OIG reviewed facility Surgical Work Action Group (SWAG) committee minutes from April 2022–February 2024 and found that in February 2023, committee members acknowledged concerns with operative note documentation.[72] Facility Surgery Service leaders and a deputy chief of staff (deputy chief of staff 2) initiated reporting of operative note documentation compliance through the SWAG committee in April 2023. The OIG reviewed compliance data provided by the associate chief nurse for surgery and perioperative services (associate chief

[69] VHA Directive 1907.01(1), *VHA Health Information Management and Health Records*, April 5, 2021, amended December 11, 2023.

[70] Medical Staff Bylaws and Rules and Regulations of Veterans Health Administration (VHA), VA Ann Arbor Healthcare System, Ann Arbor, Michigan, July 24, 2023. The previous bylaws contained similar language regarding operative reports. Medical Staff Bylaws and Rules and Regulations of Veterans Health Administration (VHA), VA Ann Arbor Healthcare System, Ann Arbor, Michigan, September 2, 2021.

[71] The Joint Commission, *Standards Manual e-dition*, RC.02.01.03, January 2024.

[72] *Facility Surgical Workgroup (SWAG) Committee Charter*, July 13, 2023. The responsibilities of SWAG include facilitation of "transparent discussion[s] of surgical quality improvement data, practice and quality improvement, patient safety, outcomes data, and best practices." SWAG "serves as a formal reporting mechanism and provides operational oversight." The SWAG committee is co-chaired by the chief of surgery and associate nurse for surgery and perioperative services.

nurse) that showed in March 2023, 62 percent of operative notes were documented as required by facility policy.[73]

The OIG also learned of a complaint submitted to The Joint Commission regarding operative note documentation. The facility response to The Joint Commission in September 2023 indicated that staff received related training and facility leaders "established a protocol to identify and address documentation concerns." The Joint Commission reviewed the facility response and took no further action.

The chief of surgery told the OIG of actions taken to address completion of operative note documentation, including educating and sharing individual compliance data with providers. In December 2023, the SWAG committee minutes reflected an operative note compliance of 88 percent. To improve compliance, deputy chief of staff 2 facilitated implementation of a "hard stop" process, requiring completion of the operative note prior to patient discharge from the post anesthesia care unit (PACU). Compliance improved to 93 percent by the second half of December 2023 after this "hard stop" process was implemented.

While the OIG recognizes the improvements in operative note completion, the OIG identified a concern with the methodology used to monitor compliance, which placed the responsibility for ensuring completion of operative notes on PACU nurses. The associate chief nurse provided the OIG with documentation indicating that from March through December 2023, the chief surgical nurse monitored compliance through random sampling of operative cases. However, in January 2024, deputy chief of staff 2 assigned PACU nurses the responsibility for tracking the surgical cases without an operative note prior to discharge from the PACU. The associate chief nurse explained that PACU nurses documented the cases without an operative note and the PACU manager divided this by the total number of cases through the PACU to calculate the compliance rate. The updated monitoring method revealed compliance rates of 99.5 percent in both January and February 2024.

The OIG questions the reliability of the methodology used to measure compliance, which relies on nursing staff identifying cases of noncompliance, but without a retrospective audit to ensure that missing documentation is consistently captured. The OIG would expect Surgery Service leaders to provide direct oversight of surgeon compliance with operative documentation requirements, including conducting audits to verify completion of operative notes prior to patient transfer, rather than assigning responsibility to other clinical staff. Variables including nursing staff turnover and workload demands could affect how consistently PACU nurses identify missing documentation. If missing documentation is not identified, compliance may appear

[73] The associate chief nurse for surgery and perioperative services provided documentation of postoperative note compliance monitoring from March 2023 through February 2024.

falsely high and increase the risk that important clinical information is unavailable to clinicians after an operative procedure.

4. Deficiencies in Information Security Practices and Protection of Patient Privacy

The OIG substantiated that facility leaders failed to ensure adherence to information security practices. Specifically, anesthesiology attending physicians provided unauthorized VA computer access to anesthesiology residents practicing in operating rooms. The OIG found deputy chief of staff 2 was aware unauthorized access was occurring, but the OIG was unable to determine if attending physicians provided unauthorized access at the direction of deputy chief of staff 2, as alleged by the complainant. Further, the OIG did not substantiate the complainant's allegation that routine patient privacy violations occurred in the surgical waiting area.

Unauthorized Access to VA Computer Systems

VHA requires that all facilities "must ensure that appropriate administrative, technical, and physical safeguards are established to ensure the security and confidentiality of personally identifiable information and records" including VA computer systems.[74] To obtain authorization to access VA computer systems, all system users must review and adhere to the "Rules of Behavior."[75] The "Rules of Behavior" describe "the minimal rules with which individual users must comply" including prohibiting users from unauthorized access and granting access to others.[76] Once computer access is authorized, "health care providers may access [the] EHR to facilitate and document medical care."[77]

During interviews, the OIG learned that current and former anesthesia attending physicians provided unauthorized computer access in the operating room to anesthesia residents who lacked computer access at the start of a clinical rotation.[78] The attending physicians and an anesthesia resident described that attending physicians used their computer login credentials to facilitate resident access to the VA computer system and two electronic medical record programs so residents could view patient records and document anesthesia care. The attending physicians reported instances of leaving the operating room while a resident was logged into their account, allowing unauthorized and unmonitored computer access. In an interview, an attending physician told the OIG of signing the EHR documentation after clinical care was provided, and noting that the documentation inaccurately reflected the care was provided by the attending physician and

[74] VHA Directive 1605.01, *Privacy and Release of Information*, July 24, 2023.

[75] VA Directive 6500, *VA Cybersecurity Program*, February 24, 2021.

[76] VA Information Security Rules of Behavior for Organizational Users.

[77] VHA Directive 1605.01.

[78] The OIG also interviewed attending surgeons and residents and an anesthesiologist who did not work in the operating room, and all denied providing or receiving unauthorized computer access.

not the resident. Due to concerns regarding unauthorized computer access, the OIG shared this finding with the Chief of Staff immediately and with facility and VISN leaders during the on-site exit briefing.

Attending physicians reported an awareness that providing unauthorized access violated VA rules, but that they did so to avoid delaying scheduled patient care. Further, attending physicians expressed a perception that providing unauthorized access was known and permitted by facility leaders, though none could recall being directed by facility leaders to provide unauthorized access to residents.

Deputy chief of staff 2 told the OIG of awareness upon starting employment as an anesthesiologist at the facility in 2015 that residents had not had reliable access to VA computer systems on the first day of their clinical rotation. When residents lacked computer access, deputy chief of staff 2 described logging into the computer system and allowing resident access to facilitate supervised anesthesia care and associated documentation. Further, residents were previously able to resolve computer access barriers in one day, but in January 2023, resolution began to take longer and deputy chief of staff 2 reported this access issue to the facility education service.

In March 2023, deputy chief of staff 2 moved from the chief of anesthesiology and perioperative pain service (anesthesiology) role to an acting deputy chief of staff role. The new acting chief of anesthesiology told the OIG that challenges with timely computer access for residents continued. Deputy chief of staff 2 reported learning "a few weeks" prior to the OIG on-site inspection that attending physicians were continuing to log residents into the computer system but were unable to remain in the operating room due to staffing limitations, and asked the new permanent chief of anesthesiology to stop the practice. Deputy chief of staff 2 denied instructing anesthesiologists in the operating room to provide unauthorized access to residents and an OIG review of electronic communication did not find evidence of instruction to attending physicians to provide residents with unauthorized access.

The associate chief of staff for education told the OIG that despite improvement efforts, residents routinely experienced barriers to accessing VA computers and computer programs at the beginning of VHA rotations and that resolution time frames were variable.[79] Further, the associate chief of staff for education reported no awareness of residents documenting medical care under another clinician's name and stated that it "is not an acceptable workaround" when residents lack computer access. After learning from the OIG that unauthorized computer access was being provided to residents, the associate chief of staff for education met with facility and

[79] The associate chief of staff for education reported factors affecting authorized computer access at the start of a clinical rotation included trainees not returning information required to initiate computer access, communication being sent to an incorrect email address, user account deactivation due to lack of activity between VA rotations, delays with trainee onboarding, and unexpected access removal at the national level.

affiliate stakeholders to review computer access requirements, requested support from the facility privacy officer to review compliance within the anesthesia service, and planned to continue work to reduce lapses in computer access for residents.

The OIG also interviewed VISN and OAA leaders who acknowledged resident computer access challenges exist at the VISN and national levels. Both VISN and OAA leaders reported that national information technology policy does not always adequately address individual facility resident onboarding processes. Consequently, residents may have difficulty obtaining computer access by the first day of a VA rotation. OAA leaders told the OIG that concerns related to computer access requirements had been communicated to higher-level VHA leaders but that no changes were made.

The OIG found anesthesiology attending physicians provided unauthorized and unmonitored computer access to anesthesia residents to facilitate documentation of anesthesia care. This created an opportunity for unauthorized access to additional VA computer systems and may have resulted in an inaccurate record in the EHR of who provided care and treatment to a patient and what elements of the care a resident provided. The OIG learned attending physicians facilitated the unauthorized access due to a perception that facility leaders were aware and that the lack of resident access would delay patient care. The OIG found unreliable computer access on the first day of a VHA rotation was not limited to the facility and was highlighted as a concern at both the VISN and national levels.

Alleged Privacy Violations in the Surgical Waiting Area

To safeguard patient health information, VHA requires that employees "be conscious of when and where it is appropriate to discuss issues involving individually identifiable health information" and "[s]peak quietly when discussing a patient's condition with family members in a waiting room . . . or in other public areas."[80]

The OIG observed the surgical waiting area (for families and friends of surgical patients) and noted the waiting area was a large open space with multiple rows of chairs located near offices and the intensive care unit. Additionally, the OIG viewed an alcove adjacent to the waiting area and a room with a locked door labeled "COVID testing room."[81]

Facility surgeons told the OIG of concerns with accessing private space to provide postoperative surgical updates. However, the surgeons denied awareness of privacy complaints and explained how private spaces for sensitive discussions could be accessed as needed. The chief of surgery

[80] VHA Directive 1605.01. Protected health information is "individually identifiable health information transmitted or maintained in any form or medium by a covered entity, such as VHA."

[81] The OIG did not witness any interactions between facility staff and the individuals in the waiting area.

told the OIG of a renovation plan to create dedicated space for private discussions adjacent to the surgical waiting room using the space previously utilized for COVID screening.[82]

The OIG learned no privacy complaints related to the surgical waiting area were reported to the privacy officer during the inspection review period.

5. Facility Leaders Failed to Resolve Reported Patient Safety Concerns

The OIG did not substantiate that facility leaders were unresponsive to patient safety concerns raised by the SICU providers. When facility leaders learned of patient safety concerns, prompt action was taken to review the concerns and develop action plans. However, the OIG found concerns with implementation, monitoring of outcomes, and communication related to the action plans.

VHA affirms that facility leaders are responsible for promoting quality and patient safety and "safeguarding a climate of bidirectional communication . . . [to] empower staff members to continually improve systems, processes and organizational alignment."[83] VHA utilizes high reliability organization principles to promote patient safety by "recommitting leadership to safety and reliability, instilling a Culture of Safety, and training staff members in Continuous Process Improvement methods to ensure . . . [VHA] function[s] as a continuous learning and improvement organization that meaningfully engages its staff members."[84] Continuous process improvement involves "both identification of the root cause(s) of errors and staff member feedback" to improve patient safety.[85] Additionally, the Institute for Healthcare Improvement asserts that measuring outcomes "is a critical part of knowing if we have made a difference, what the impact of the changes are, if we have met our aim, and future action to take" and that "it is

[82] During the interview with the OIG, the chief of surgery reported being unaware of a renovation timeline.

[83] VHA Directive 1050.01(1), *VHA Quality and Patient Safety Programs*, March 24, 2023, amended March 5, 2024. VHA Directive 1050.01, *VHA Quality and patient Safety Programs*, March 24, 2024, has the same or similar language as the amended version unless otherwise noted in this report; "HRO Pillar: Leadership Commitment," VHA Journey to High Reliability, accessed June 5, 2024, https://dvagov.sharepoint.com/sites/vhahrojourney/Shared%20Documents/Forms/Edit_View.aspx?id=%2Fsites%2Fvhahrojourney%2FShared%20Documents%2FHRO%20Pillar%20Leadership%20Commitment%20Fact%20Sheet%2Epdf&viewid=32b04def%2D7ab4%2D49bc%2D8b03%2Dcae5efd6603c&parent=%2Fsites%2Fvhahrojourney%2FShared%20Documents. (This site is not publicly accessible.)

[84] High Reliability Organization Elevator Speech Guide, November 2021; "HRO," VHA Journey to High Reliability, accessed June 7, 2024. A high reliability organization (HRO) is an organization that "experiences fewer than anticipated accidents or events of harm, despite operating in highly complex, high-risk environments." HRO principles include sensitivity to operations, preoccupation with failure, reluctance to simplify, commitment to resilience, and deference to expertise.

[85] "HRO Pillar: Continuous Process Improvement," VHA Journey to High Reliability, accessed June 5, 2024, https://dvagov.sharepoint.com/:b:/r/sites/vhahrojourney/Shared%20Documents/HRO%20Pillar%20Continuous%20Process%20Improvement%20Fact%20Sheet.pdf?csf=1&web=1&e=pq6YP8. (This site is not publicly accessible.)

vital to include the people [who] . . . will be impacted by the improvement to have a voice in deciding what measures are important."[86]

Prompt Development of Action Plans

The OIG reviewed email communication and learned that in mid-February 2023, the complainant sent an email to facility leaders requesting a meeting be scheduled within a few weeks to discuss concerns about the Surgery Service that affected the SICU. Facility leaders responded the same day indicating they appreciated the concerns being raised and initiated a plan to meet in early March to hear the concerns in person. Additionally, in an email to the complainant, deputy chief of staff 2 indicated speaking with the director of the SICU to determine if a safety issue was present that would "warrant an emergency meeting" and determined an emergency meeting was not indicated. Deputy chief of staff 1 requested interim communication from the complainant about specific patient safety concerns in order to address safety concerns in real time. The complainant told the OIG of attending a meeting in March 2023 with facility leaders to discuss concerns described in this report.[87] On the day the meeting occurred, deputy chief of staff 2 wrote an email summary of the discussed concerns, and the Chief of Staff reported a plan to convene a committee to "evaluate, triage, and work through these concerns . . . in a logical and systematic manner." The committee was established the same month and a spreadsheet was used to track the concerns, proposed solutions, and actions.[88] The OIG reviewed the spreadsheet and found a majority of the concerns had action plans developed within one month and all action plans were developed within two months.

The OIG found facility leaders took prompt action to learn of concerns about the Surgery Service from the SICU providers and then established a committee that developed corresponding action plans.

Concerns with Implementation, Monitoring of Outcomes, and Communication of Action Plans

The OIG reviewed the spreadsheet used by the committee to track the proposed solutions and action plans to determine if the plans addressed the concerns raised by the SICU providers. The spreadsheet contained 17 separate concerns with 19 proposed solutions and corresponding

[86] "Model for Improvement question: How will we know that a change is an improvement?," Institute for Healthcare Improvement, accessed June 6, 2024, https://www.ihi.org/resources/how-to-improve/model-for-improvement-establishing-measures.

[87] Concerns raised by the complainant to facility leaders during the meeting in March did not include concerns related to information security and protection of patient privacy.

[88] The facility patient safety specialist reported the committee did not take formal minutes and instead used a spreadsheet to track action items and progress.

actions. As of April 2024, the spreadsheet indicated that all but one of the concerns had been closed.

The OIG reviewed the actions and monitoring of outcomes on the spreadsheet and identified concerns with facility leaders' failure to

- ensure assigned corrective actions were carried out,
- develop and implement outcome measures to determine if corrective actions were effective,
- establish short-term mitigation plans when a long-term corrective action was incomplete, and
- communicate the status of the action plans to the staff who raised the concerns.

The OIG found the spreadsheet included action plans for concerns identified by the OIG, and one particular issue reflected multiple OIG concerns.[89] Specifically, in the March 2023 meeting, a concern was raised involving cardiac surgery patients being admitted to the SICU late in the afternoon when fewer resources were available to manage postoperative complications. The committee proposed a solution to begin cardiac surgery earlier in the day so patient admissions would occur earlier when more resources would be available. The spreadsheet indicated the proposed solution would be implemented and monitored by the SWAG committee. The OIG reviewed SWAG committee meeting minutes and learned that cardiac surgery start times were discussed in late May 2023 with a decision to start cardiac surgeries at 7:15 a.m. on Mondays and Tuesdays and 8:15 a.m. on Thursdays beginning in early June.

The OIG reviewed SWAG committee minutes from June 2023 through January 2024 and found no documentation that earlier cardiac surgery start times were implemented as planned or that the proposed solution resolved the original concern. Further, the OIG found no evidence that the target outcome was measured as planned.[90] The OIG questions if solely measuring cardiac surgery start times would have effectively evaluated resolution of the original concern. After more than one year, this action plan remained incomplete with no interim mitigation identified to address the original concern on either the spreadsheet or in the SWAG committee meeting minutes.

During interviews, current and former clinical SICU staff reported that adequate resources for postoperative management of cardiac surgery patients continued to be of concern and that the

[89] While one example is discussed in this report section, additional examples of the bulleted concerns were discussed earlier in this report: compliance with surgical complexity designation requirements, supervision of PGY-1 surgical residents, and postoperative documentation.

[90] The SWAG committee shifted focus to starting all surgeries on time, which addresses an operating room efficiency metric the facility would like to improve rather than the concern regarding late afternoon admissions following complex surgical procedures.

facility leaders' response to patient safety concerns in the SICU did not result in any appreciable improvement.[91]

Current and former SICU providers reported a perception that the committee focused on policy compliance rather than improving patient care and that staff were not informed of outcomes related to the concerns that had been raised. The Chief of Staff stated that communication with staff who raised the concerns was challenging, and reported an expectation that service leaders would communicate committee progress and related outcome measures to their staff. The chief of surgery reported an attempt to communicate progress and engage one of the staff members who raised concerns but that the staff member was not receptive to the communication.

During interviews with the OIG, former SICU providers described leaving their positions almost nine months after the meeting in March due to facility leaders not resolving raised concerns and associated distress related to the perception the unresolved concerns resulted in "substandard care."

The OIG found concerns with facility leaders' implementation and monitoring of the identified corrective actions related to issues raised by the SICU providers. Facility leaders did not ensure that the action plans developed by the committee were carried out or measured to evaluate if the action plans resolved the raised concerns. The lack of follow through and communication about progress from facility leaders led to a perception by SICU providers that concerns were not being addressed. For some staff, this resulted in distress due to a belief that the unresolved concerns resulted in "substandard care" and contributed to staff resignations.

Conclusion

The OIG substantiated the facility lacked required infrastructure for vascular and non-vascular interventional radiology, cardiac catheterization, and interventional neuroradiology. While the chief of surgery initiated waivers for these requirements, a lack of awareness of available services, unclear direction about waiver requirements, deficient tracking and communication of the waiver request status, and lack of VISN oversight led to delays in submission and approval of the waiver requests. Additionally, the OIG identified concerns related to reliance on patient transfers, engagement and communication between Surgery Service and blood bank, and failure to disclose an adverse patient outcome.

The OIG learned of existing transfer challenges that could delay patient transfers for acute or emergent medical conditions and identified a concern with the failure to monitor timeliness of

[91] The OIG reviewed patient safety reports from March 2023 to February 2024 and morbidity and mortality data from October 2022 through December 2023 specific to cardiac surgeries and did not find evidence of outcomes that required further review. The chief of surgery and the deputy chief of staff 2 told the OIG of recruitment efforts for SICU intensivists, including two recent new hires, but the chief of surgery noted efforts were challenging due to the small size of the unit and low patient acuity.

patient transfers related to approved waivers. While facility leaders described efforts to address delays in patient transfers, the OIG would expect that facility leaders would have monitored transfer delays upon submitting the waiver requests to identify any transfer delays and contributing factors and ensure safe and timely patient care.

Blood bank services and blood products were available as required but the OIG identified a concern with a lack of engagement and communication between Surgery Service and blood bank staff and leaders. Consistent Surgery Service representation on the BURC may improve communication of changes to blood product needs and minimize miscommunication about blood product availability.

The OIG did not substantiate the facility lacked Surgery Service coverage or qualified inpatient coverage as required for an *inpatient complex* facility. However, facility leaders failed to consider an institutional disclosure despite awareness that a delay in surgical treatment may have contributed to patient B's death.

The OIG was unable to determine if facility leaders failed to ensure that on-site supervision was provided to PGY-1 surgery residents as required by VHA. The OIG found inconsistencies with interpretation of VHA policy related to the supervision of PGY-1 surgery residents among facility providers and VISN and program office leaders. Although facility leaders implemented an SOP for PGY-1 surgery resident supervision, the SOP did not address on-site supervision for surgical patient management, and the level of interaction between hospitalists and PGY-1 surgery residents may not meet VHA's definition of supervision. The OIG is concerned that varying interpretations between policy and OAA guidance is likely to result in nonstandardized supervision for residents across VHA.

While surgeons were not consistently completing required operative notes, Surgery Service and facility leaders took action to monitor and improve compliance with operative documentation completion as required by facility bylaws and The Joint Commission standards. However, the OIG identified a concern with the methodology used to monitor compliance, which placed the responsibility for ensuring completion of operative notes on PACU nurses without a retrospective audit to ensure that missing documentation is consistently captured.

The OIG substantiated facility leaders failed to ensure adherence to information security practices when anesthesiology attending physicians provided unauthorized VA computer access to anesthesiology residents practicing in operating rooms. While deputy chief of staff 2 was aware of the practice, the OIG was unable to determine if deputy chief of staff 2 directed the unauthorized access. Unreliable computer access on the first day of a VHA rotation was a concern at both the VISN and national levels.

The OIG did not substantiate that facility leaders were unresponsive to patient safety concerns raised by SICU providers. However, facility leaders did not ensure completion of the action

plans or evaluation of the effectiveness of the actions, which led to a perception by SICU providers that concerns were not being addressed.

Recommendations 1–12

1. The Lieutenant Colonel Charles S. Kettles VA Medical Center Director ensures that service chiefs responsible for required invasive procedure infrastructure services ensure the completion of the annual review of infrastructure and that existing infrastructure is accurately reported.

2. The VA Healthcare System Serving Ohio, Indiana, and Michigan Network Director ensures that requirements and processes for invasive procedure complexity infrastructure waiver requests are clearly communicated to facility leaders.

3. The VA Healthcare System Serving Ohio, Indiana, and Michigan Network Director reviews the process for tracking invasive procedure complexity infrastructure waiver requests, and takes actions as needed to avoid delays in review and submission.

4. The Under Secretary for Health ensures that guidance provided to Veterans Integrated Service Network and facility leaders regarding the invasive procedure complexity infrastructure waiver request process is clear and consistent with Veterans Health Administration Directive 1220(1).

5. The Lieutenant Colonel Charles S. Kettles VA Medical Center Director confirms that acute and emergent patient transfer times related to waived infrastructure requirements are tracked and monitored, identifies trends or adverse patient outcomes, and takes actions as warranted.

6. The Lieutenant Colonel Charles S. Kettles VA Medical Center Director directs the chief of surgery, or designee, to attend blood utilization review committee meetings per facility requirements, and ensures compliance.

7. The Lieutenant Colonel Charles S. Kettles VA Medical Center Director reviews the care provided to patient B to confirm compliance with Veterans Health Administration Directive 1004.08, determines if an institutional disclosure is warranted, and takes action as required.

8. The Under Secretary for Health reviews Veterans Health Administration Directive 1400.01 to confirm that the supervision of PGY-1 surgery residents and guidance provided to Veterans Health Administration facilities aligns with Veterans Health Administration policy and Accreditation Council for Graduate Medical Education program requirements.

9. The Lieutenant Colonel Charles S. Kettles VA Medical Center Director ensures that operative documentation is completed per facility policy, reviews the methodology for monitoring operative documentation compliance, and takes action as necessary.

10. The Lieutenant Colonel Charles S. Kettles VA Medical Center Director reviews and monitors staff and health professional trainee compliance with the rules of behavior as it applies to authorized access to all VA computer programs including clinical applications.

11. The Under Secretary for Health evaluates the process for granting authorized access to VA computer systems for health profession trainees and takes steps to ensure access is provided by the start of trainee rotations at VA facilities.

12. The VA Healthcare System Serving Ohio, Indiana, and Michigan Network Director ensures the corrective actions developed by facility leaders to address surgical intensive care unit patient safety concerns are completed and evaluated for effectiveness.

Appendix A: Invasive Procedure Complexity Infrastructure Requirements Waiver Requests

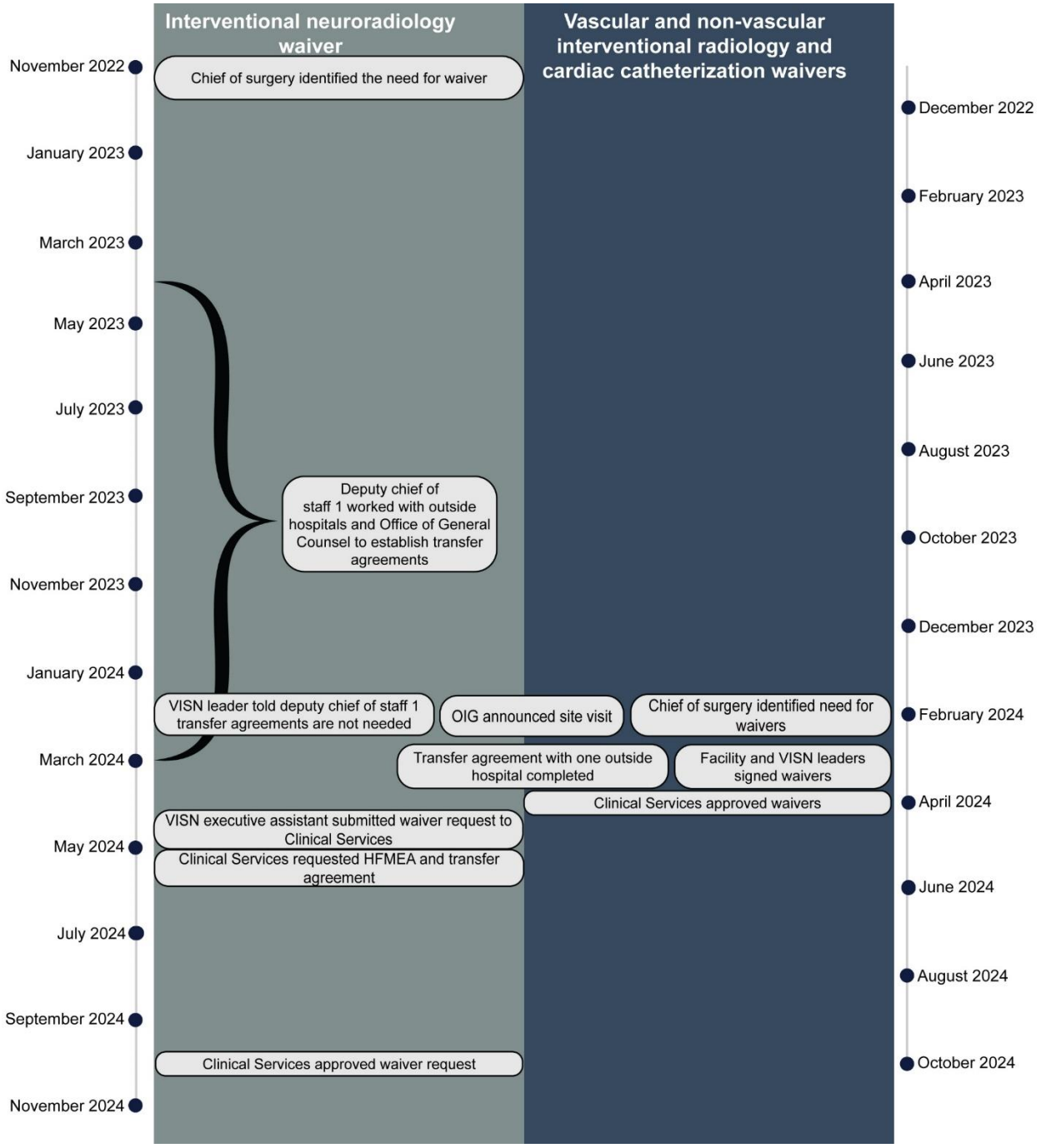

Figure A.1. *Timeline for the facility's invasive procedure complexity infrastructure requirements waiver requests.*
Sources: Documentation provided by Clinical Services staff, VISN and facility staff and leaders, and OIG interviews.

Appendix B: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: November 22, 2024

From: Office of the Under Secretary for Health (10)

Subj: Healthcare Inspection—Deficiencies in Invasive Procedure Complexity Requirements, Surgical Resident Supervision, Information Security, and Leaders' Response at the VA Ann Arbor Healthcare System in Michigan

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on OIG's draft report on invasive complexity requirements, surgical resident supervision, information security, and leaders' response at the Department of Veterans Affairs (VA) Ann Arbor HCS.

2. The Veterans Health Administration concurs with recommendations 4, 8, and 11 and provides an action plan in the attachment. The Veterans Integrated Service Network 10 and VA Ann Arbor Healthcare System will provide action plans in response to recommendations 2, 3, and 12 and 1, 5, 6, 7, 9, and 10, respectively.

3. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at vha10oicgoalaction@va.gov.

(Original signed by:)

Shereef Elnahal, M.D., MBA
[OIG comment: The OIG received the above memorandum from VHA on December 12, 2024.]

Office of the Under Secretary for Health Response

VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan

OIG Draft Report, Deficiencies in Invasive Procedure Complexity Requirements, Surgical Resident Supervision, Information Security, and Leaders' Response at the VA Ann Arbor HCS
(OIG Project Number 2024-00234-HI-1431)

Recommendation 4: The Under Secretary for Health ensures that guidance provided to Veterans Integrated Service Network and facility leaders regarding the invasive procedure complexity infrastructure waiver request process is clear and consistent with Veterans Health Administration Directive 1220(1).

VHA Comments: Concur. The Office of the Assistant Under Secretary for Health for Clinical Services will ensure that guidance provided to Veterans Integrated Service Network (VISN) and facility leaders aligns with the principles and overall direction of VHA Directive 1220(1), Facility Procedure Complexity Designation Requirements to Perform Invasive Procedures in Any Clinical Setting. Clinical Services will ensure updated guidance and direction, created through the interdisciplinary Clinical Services Waiver Council and Integrated Clinical Structuring Integrated Project Team, is available and communicated to VISNs and facilities to clarify the waiver requirements and process for submission. Clinical Services will continue to oversee a certification of Department of Veterans Affairs (VA) medical facility Invasive Procedure Complexity Designations and compliance for each VA medical facility performing invasive procedures in relation to available infrastructure. This information will continue to be posted annually and available for VA Medical Center, VISN, and national review.

Status: In progress Target Completion Date: November 2025

Recommendation 8: The Under Secretary for Health reviews Veterans Health Administration Directive 1400.01 to confirm that the supervision of PGY-1 surgery residents and guidance provided to Veterans Health Administration facilities aligns with Veterans Health Administration policy and Accreditation Council for Graduate Medical Education program requirements.

VHA Comments: Concur. The Office of Academic Affiliations concurs with the need to review existing policy and guidance to support deconfliction of information. Directive 1400.01 is in revision. Appropriate supervision for PGY-1 residents will be based on Accreditation Council for Graduate Medical Education requirements. Once the revised directive is published, VA Ann Arbor Health Care System will determine if any existing standard operating procedures require revision or should be sunset and will act as necessary.

Status: In progress Target Completion Date: February 2025

Recommendation 11: The Under Secretary for Health evaluates the process for granting authorized access to VA computer systems for health profession trainees and takes steps to ensure access is provided by the start of trainee rotations at VA facilities.

VHA Comments: Concur. The goal of the Office of Academic Affiliations is that Health Professions Trainees (HPTs) are fully onboarded, trained, and provisioned to begin care for Veterans on the first day of their educational experience. To that end, in April 2024, the new Account Provisioning/Deprovisioning System (APDS) was mandated for use by all HPTs onboarded after that date. APDS allows complete visibility of an HPT as they progress through onboarding, including assigning required information technology systems. All 191 VA facilities that support HPTs have access to the system, and nearly 70,000 trainees were registered during fiscal year 2024. This system meets and exceeds all GAO 18-124 goals for better data and tracking of physician trainees for recruitment and retention purposes.

APDS streamlined the process of granting authorized access to VA computer systems for HPTs. This allows the Under Secretary for Health to have real-time information on the process of HPTs through onboarding.

Status: Complete Completion Date: April 2024

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

Appendix C: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: December 11, 2024

From: Veterans Integrated Service Network (VISN) 10 Network Director, VA Healthcare System Serving Ohio, Indiana, and Michigan

Subj: Office of Inspector General (OIG) Draft Report: Deficiencies in Invasive Procedure Complexity Requirements, Surgical Resident Supervision, Information Security, and Leaders' Response at the VA Ann Arbor Healthcare System in Michigan

To: Assistant Inspector General for Healthcare Inspections (54)
Executive Director, Office of Integrity and Compliance (10OIC)

1. Thank you for the opportunity to review and comment on the draft report regarding invasive procedure complexity requirements, surgical resident supervision, information security, and leaders' response at the Department of Veterans Affairs (VA) Ann Arbor Healthcare System in Michigan.

2. I have reviewed and concur with the comments and action plans detailed in the response, which have been developed by leaders and subject matter experts from VISN 10 and the VA Ann Arbor Healthcare System.

3. If you have any questions or require further information, please contact the VISN 10 Deputy Quality Management Officer.

(*Original signed by:*)

Laura E. Ruzick
Network Director

[OIG comment: The OIG received the above memorandum from VHA on December 12, 2024.]

VISN Director Response

Recommendation 2

The VA Healthcare System Serving Ohio, Indiana, and Michigan Network Director ensures that requirements and processes for invasive procedure complexity infrastructure waiver requests are clearly communicated to facility leaders.

_X _Concur

____Nonconcur

Target date for completion: September 2024

Director Comments

The Veterans Integrated Service Network (VISN) 10 Deputy Chief Medical Officer/VISN Chief Surgical Consultant (VCSC) reviewed VHA Directive 1102.01(2) and VHA Directive 1220(1) with each Surgical Chief during annual VISN Surgical Workgroup Site Visits completed over July-September 2024. This review included the requirements and processes for invasive procedure complexity infrastructure waiver requests.

The status of submitted waivers was reviewed to reflect if they had been approved indefinitely, approved for a 12-month period, were still under review, or were denied. Any discrepancies were reflected in the site visit report and applicable sites were advised to submit waivers as warranted. Additionally, all sites are responsible for ensuring that the Invasive Procedure Infrastructure Inventory Tool is updated with complexity requirements annually through communication with the Office of the Assistant Under Secretary for Health for Clinical Services (Clinical Services).

OIG Comments

The OIG considers this recommendation closed.

Recommendation 3

The VA Healthcare System Serving Ohio, Indiana, and Michigan Network Director reviews the process for tracking invasive procedure complexity infrastructure waiver requests, and takes actions as needed to avoid delays in review and submission.

_X _Concur

____Nonconcur

Target date for completion: September 2024

Director Comments

The VISN surgical leadership team reviewed the process for tracking invasive procedure complexity infrastructure waiver requests and determined that a new tool was needed. In December 2023, the VISN surgical leadership team developed and implemented a new tracking tool that is updated with information provided by facility reports to the monthly VISN 10 Surgical Workgroup and VISN 10 Surgery Integrated Clinical Community meetings, along with any updates reported from Clinical Services. Additionally, VISN surgical leadership implemented quarterly contact with a Clinical Services representative to request updates on the status of pending waivers.

OIG Comments

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

Recommendation 12

The VA Healthcare System Serving Ohio, Indiana, and Michigan Network Director ensures the corrective actions developed by facility leaders to address surgical intensive care unit patient safety concerns are completed and evaluated for effectiveness.

_X _Concur

____Nonconcur

Target date for completion: March 2025

Director Comments

The review of corrective actions to address surgical intensive care unit patient safety concerns will be added as a standing agenda item to the existing quarterly meeting between VISN and facility surgical leaders beginning with the November 2024 meeting. The facility will report on action plan progress, to include status of assigned corrective actions, effectiveness of completed actions, and how the status of the action plan is being communicated to applicable stakeholders. This enhanced visibility will allow VISN leaders to provide support and address barriers as needed.

Appendix D: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: December 11, 2024

From: Medical Center Director, Department of Veterans Affairs (VA) Ann Arbor Healthcare System (506/00)

Subj: Office of Inspector General (OIG) Draft Report: Deficiencies in Invasive Procedure Complexity Requirements, Surgical Resident Supervision, Information Security, and Leaders' Response at the VA Ann Arbor Healthcare System in Michigan

To: Veterans Integrated Service Network (VISN) 10 Network Director, VA Healthcare System Serving Ohio, Indiana, and Michigan (10N10)

1. Thank you for the opportunity to review and comment on the draft report regarding invasive procedure complexity requirements, surgical resident supervision, information security, and leaders' response at the VA Ann Arbor Healthcare System in Michigan.

2. I concur with the draft report and OIG's recommendations.

3. The VA Ann Arbor Healthcare System is committed to providing the highest level of care possible to the Nation's Veterans and is eager to incorporate these valuable recommendations to further our maturation into a high-reliability organization.

4. Comments regarding the contents of this memorandum may be directed to the VA Ann Arbor Healthcare System Chief of Quality Management and Survey Readiness Coordinator.

(*Original signed by*:)

Ginny L. Creasman, PharmD, FACHE
Medical Center Director
VA Ann Arbor Healthcare System

[OIG comment: The OIG received the above memorandum from VHA on December 12, 2024.]

Facility Director Response

Recommendation 1

The Lieutenant Colonel Charles S. Kettles VA Medical Center Director ensures that service chiefs responsible for required invasive procedure infrastructure services ensure the completion of the annual review of infrastructure and that existing infrastructure is accurately reported.

_X _Concur

____Nonconcur

Target date for completion: February 2025

Director Comments

The Facility will track surgical complexity directive requirements according to VHA Directive 1220(1) through the facility Surgical Work Action Group committee (SWAG) and review compliance with the attestation of requirements from relevant Service/Section Chiefs annually at the beginning of each calendar year. The services listed on the Invasive Procedure Infrastructure Inventory Tool (IPIIT) for Inpatient Complex will be engaged and expected to present on their areas of oversight. Additionally, any gaps in coverage requiring waivers and current waivers with expiration timelines will be tracked through SWAG and documented in the minutes.

Recommendation 5

The Lieutenant Colonel Charles S. Kettles VA Medical Center Director confirms that acute and emergent patient transfer times related to waived infrastructure requirements are tracked and monitored, identifies trends or adverse patient outcomes, and takes actions as warranted.

_X _Concur

____Nonconcur

Target date for completion: May 2025

Director Comments

As a standing monthly agenda item, the facility Bed Utilization Committee (BUC) will monitor inpatient transfers to a higher level of care for waived surgical complexity infrastructure requirements, identify if there are delays in timeliness of transfer for urgent or emergent clinical needs, review for adverse patient outcomes, and take corrective action as warranted. Concerns will be escalated to leadership as needed via regular reporting from BUC to the Executive Committee of the Medical Staff, which is chaired by the Chief of Staff.

Recommendation 6

The Lieutenant Colonel Charles S. Kettles VA Medical Center Director directs the chief of surgery, or designee, to attend blood utilization review committee meetings per facility requirements, and ensures compliance.

_X _Concur

____Nonconcur

Target date for completion: December 2024

Director Comments

The Chief of Surgery or designee is listed on the Blood Utilization Review Committee (BURC) charter as a voting member and will attend meetings regularly. BURC meeting minutes will demonstrate attendance as required. The Medical Center Director will address any barriers to attendance or absences from the BURC with the Chief of Surgery and Chief of Staff.

Recommendation 7

The Lieutenant Colonel Charles S. Kettles VA Medical Center Director reviews the care provided to patient B to confirm compliance with Veterans Health Administration Directive 1004.08, determines if an institutional disclosure is warranted, and takes action as required.

_X _Concur

____Nonconcur

Target date for completion: April 2024

Director Comments

On April 9, 2024, a review of the care provided to patient B was completed. The review included confirming compliance with VHA Directive 1004.08 and determining if an institutional disclosure was warranted. An institutional disclosure meeting was scheduled with patient B's family on April 16, 2024; however, the patient's family cancelled due to personal reasons. Attempts to reschedule this meeting were made by the Clinical Risk Program Manager in alignment with VHA Directive 1004.08 requirements and documented in the electronic medical record.

OIG Comments

The OIG considers this recommendation closed.

Recommendation 9

The Lieutenant Colonel Charles S. Kettles VA Medical Center Director ensures that operative documentation is completed per facility policy, reviews the methodology for monitoring operative documentation compliance, and takes action as necessary.

_X _Concur

____Nonconcur

Target date for completion: May 2025

Director Comments

The Associate Chief Nurse of Surgery, in collaboration with Quality Management, will review the current methodology for monitoring operative documentation and create a monthly auditing plan to ensure timely completion of postoperative documentation in compliance with The Joint Commission Standards and local policy. This will be reported at SWAG committee and action taken to achieve compliance as necessary.

Recommendation 10

The Lieutenant Colonel Charles S. Kettles VA Medical Center Director reviews and monitors staff and health professional trainee compliance with the rules of behavior as it applies to authorized access to all VA computer programs including clinical applications.

_X _Concur

____Nonconcur

Target date for completion: June 2025

Director Comments

The facility Office of Integrity and Compliance will coordinate with the Privacy Officer and Information System Security Officer to complete random, monthly, facility-wide audits of staff (including health professional trainees) to monitor compliance with the rules of behavior and report these findings regularly to facility leadership. Closure will be requested when audit results demonstrate sustained compliance with the rules of behavior as it applies to authorized access to all VA computer programs, including clinical applications.

OIG Contact and Staff Acknowledgments

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