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Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Extended Pause in Cardiac Surgeries and Leaders' Inadequate Planning of Intensive Care Unit Change and Negative Impact on Resident Education at the VA Eastern Colorado Health Care System in Aurora

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the VA Eastern Colorado Health Care System (facility), including the Rocky Mountain Regional VA Medical Center in Aurora, to review how facility leaders' actions may have impacted intensive care unit (ICU) coverage, patient care, and resident education.[1] Due to the breadth of the allegations and the reported impact on a multitude of clinical processes and services, the OIG initiated two separate, but simultaneous, healthcare inspections. The companion inspection focused on leadership and high reliability organization (HRO) principles, which are topics referenced in this report.[2]

On May 1, 2023, the OIG opened the healthcare inspection to assess allegations that in spring 2022, facility leaders implemented staffing changes that adversely affected the provision of cardiothoracic (CT) surgeries in the surgical ICU without adequate planning. In addition, facility leaders changed the medical ICU from an open unit to a closed unit in January 2023, without appropriate planning or discussion with service leaders and staff involved in ICU processes and patient care.[3] The change to a closed ICU allegedly resulted in a lack of resident supervision, an ineffective teaching environment for residents, and patient harm.[4]

1. Surgical ICU Changes Adversely Affected CT Surgeries

The OIG was unable to determine whether facility leaders implemented changes to the surgical ICU without adequate planning in April 2022. However, the OIG found that the subsequent lack of 24 hours a day, 7 days a week (24/7) ICU provider coverage for surgical patients adversely affected the provision of CT surgical services.[5]

In April 2022, five adult critical care nurse practitioners (ACCNPs) either transferred to another service, resigned, or retired, reportedly due to unfavorable changes to surgical ACCNPs'

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[1] ICU patients may include critically ill surgical and medical patients.

[2] Veterans Health Administration (VHA), "VHA High Reliability Organization (HRO) Glossary of Terms - Internal VA Use Only," May 2023. HRO principles focus on front line staff, processes and systems that impact patient care, preoccupation with failure, identification of root causes for a problem, commitment to resilience and reliance on subject matter experts.

[3] *Merriam-Webster.com Dictionary, "*cardiothoracic,*"* accessed September 19, 2023, https://www.merriam-webster.com/dictionary/cardiothoracic#medicalDictionary. Cardiothoracic means "specializing in the heart and chest." Veterans Health Administrations Chief Strategy Office, *2019 VHA Critical Care Survey Report*, January 2022. An open ICU model includes multiple physicians or teams, whether assigned to the ICU or not, to provide care to a patient in the ICU. A closed ICU model includes only the team specifically assigned to the ICU to manage all ICU patients.

[4] The OIG defined patient harm as a significant negative impact on the patient's care, including delays in care.

[5] The facility utilized the terms *cardiothoracic (CT)* and *cardiac* interchangeably when referring to the related surgical staff and surgical procedures. The OIG primarily utilizes CT throughout this report.

schedules.[6] Consequently, the loss of surgical ICU ACCNPs limited the 24/7 provider coverage necessary to care for CT patients, and CT surgical services were paused while the facility attempted to emergently hire providers.

First CT Surgical Pause: June 13—July 12, 2022

On June 13, 2022, the former Chief of Staff (COS) submitted an issue brief notifying Veterans Integrated Service Network (VISN) leaders of the inability to conduct cardiac surgeries due to "critical staffing shortages in [the] Intensive Care Unit (ICU) and Operation Room (OR) . . ."[7] The issue brief noted the "curtailment of operations" was anticipated to resolve within 14 days, disclosing that multiple clinical services were working together to "develop alternative coverage during [the] Advanced Cardiac Nurse Practitioner" shortage.

CT surgeries resumed in July 2022, with coverage plans in place, although facility leaders noted staffing was still a concern. While efforts were made to secure permanent 24/7 ICU provider coverage, the former chief of surgery, the former interim ICU director, and one surgeon provided overnight coverage (in addition to day shift duties) through early September 2022.

Extended CT Surgical Pause: September 2022—October 2023

In September 2022, the Surgical Work Group meeting minutes noted that efforts to secure ICU provider coverage of surgical patients were unsuccessful and CT surgeries would again be paused. CT surgical procedures were ultimately paused until October 2023, and during that time, all former CT surgical staff had either resigned (three) or were terminated (one). The OIG found the loss of 24/7 ICU provider coverage of surgical patients and the subsequent extended pause of CT surgeries ultimately led to loss of all facility cardiac surgical staff. The facility ultimately utilized contract CT surgical staff from the university [University of Colorado] to resume CT surgical procedures.

Failure to Notify VISN and VA Central Office of Second CT Surgical Pause

The OIG determined the newly appointed COS failed to notify VA Central Office, through the VISN, of the second pause in CT surgical services in September 2022 as expected.[8] Because of this failure to submit an issue brief on the curtailment, the facility was not prompted to, and did

[6] The ACCNPs' primary role, as defined in their functional statements, is "to provide direct care management of complex medical and surgical patients in consultation with critical care medical and surgical physicians." The OIG was unable to obtain clarification of the nature of the changes made to the surgical ICU in April 2022.

[7] Deputy Under Secretary for Health for Operations and Management (10N), "10N Guide to VHA Issue Briefs," updated June 26, 2017. Facilities submit issue briefs to inform VA leadership, through the VISN, of a situation, event, or issue, such as the curtailment of operations. Issue briefs should be submitted timely and include a brief statement of the issue and status and the actions, progress, and the date of resolution, when applicable. If the event is not resolved, updates to the original issue brief regarding progress should be provided.

[8] The new COS was hired and began employment at the facility in July 2022.

not provide, official status updates to the VISN or VA Central Office on the actions taken and progress toward resolution.

During the inspection, when the OIG inquired about the notification to and communications with VISN leaders and the VISN surgical consultant about the second CT surgical pause, the COS reported that the VISN and the National Surgery Office (NSO) were aware. However, the VISN surgical consultant denied awareness that CT surgery had resumed in July, then halted in September 2022. In July 2023, the VISN Director reported being unaware of the pause in the facility's CT surgical program and that no CT surgeries had been conducted since early September 2022. The VISN Director verified that although the VISN received a facility issue brief in June 2022 regarding CT curtailment and an update in July 2022 reporting the issue was resolved, no additional CT surgery issue briefs were received. VISN and VA leaders utilize issue briefs to stay informed of significant events that occur at a facility and provide opportunity for oversight of progress and resolution of such events.[9]

A review of emails revealed the COS requested the COS's administrative officer work with the former chief of surgery to prepare an issue brief detailing the curtailment of services. The former chief of surgery completed the issue brief template forms the following day, September 23, 2022, and, as requested, returned the forms to the COS and the COS's administrative officer. Following the receipt of the issue brief forms, the facility could not provide any evidence that further action was taken.

Failure to Notify and Engage the VISN and VA Central Office in Efforts to Resume CT Surgeries Following an 11-Month Pause

The OIG determined that the Facility Director, COS, deputy chief of staff inpatient operations (DCOS-IO), and the acting chief of surgery proceeded with plans to resume CT surgeries following the 11-month CT surgical pause and the loss of all facility CT surgical staffing without notifying and seeking approval from VISN and VA Central Office leaders. Although the COS reported that the VISN and NSO were aware of status of CT surgical services, she was unable to provide evidence of a formal notification. The OIG found that resuming CT surgical services after an extended pause met criteria for a major augmentation of clinical services and thus required the approval of the Under Secretary for Health or designee.[10] Further, the OIG found that the absence of a detailed, interdisciplinary evaluation and plan to be very concerning given that the last CT surgery was conducted nearly one year prior.

In late July 2023, the COS told the OIG the facility planned to resume CT surgeries with the first surgery scheduled on August 8, 2023. When questioned about the facility having a written plan

[9] Deputy Under Secretary for Health for Operations and Management (10N), "10N Guide to VHA Issue Briefs."
[10] VHA Directive 1043, *Restructuring of VHA Clinical Programs*, November 2, 2016.

to resume CT surgeries that included action items, responsible parties, and updates to the VISN, the COS stated, "I have not seen the detailed plan . . . I don't think there's a written plan."

The OIG escalated concerns about the facility's readiness to safely conduct a CT surgical procedure to the VISN Director on August 2, 2023, and requested follow-up. The VISN Director informed the OIG that facility leaders had not engaged the NSO in their plans to resume CT surgeries and made a formal request to the NSO to conduct a CT surgery program review prior to the facility restarting CT surgeries. Following the VISN Director's request, the NSO contacted the Facility Director and scheduled an "in person Consultative Site Visit" of the facility's CT surgery program on September 18, 2023. The first CT surgical procedure was conducted in late October 2023.

2. ICU Model Change Disrupted Patient Care and Resident Education

The OIG substantiated that leaders' actions to change the medical ICU from an open to a closed model (ICU model change) were made without adequate planning and input from service and section leaders and staff. The OIG found that there were preliminary efforts to plan for a change to a closed medical ICU in the fall of 2022 based on the COS's review of a 2021 Veterans Health Administration (VHA) assessment team's (VHA team) recommendation.

On January 3, 2023, the COS notified service leaders of the need to change medical ICU physician coverage from hospitalists to pulmonary and critical care medicine (PCCM) attendings and fellows due to a recent understanding that hospitalists' privileges did not include treating critically ill patients.[11]

Leaders Failed to Include Input from Service and Section Leaders and Staff

During an interview with the OIG, the COS reported that a closed ICU model was not a new concept for the facility. The COS explained that the VHA team including the VHA National

[11] The OIG reviewed the team's report, VHA, *Assessment of the Intensive Care Unit (ICU) to Include Summary and Recommendations*, March 26, 2021; "What is hospital medicine, and what is a hospitalist?" Society of Hospital Medicine, accessed October 23, 2023, https://www.hospitalmedicine.org/about/what-is-a-hospitalist/. "Practitioners of hospital medicine include physicians ("hospitalists") and non-physician clinicians" who provide hospital-based care. "Hospitalists typically undergo residency training in general internal medicine, general pediatrics, or family practice;" VHA Directive 1400.01, *Supervision of Physician, Dental, Optometry, Chiropractic, and Podiatry Residents*, November 7, 2019. Attendings are the supervising practitioners who have been approved by the facility "and associated training program." Fellows are physicians "in a program of accredited graduate education" who have completed eligibility requirements for board certification in a particular specialty;" VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was in effect at the time of the review until it was rescinded and replaced by VHA Directive 1100.21(1), *Privileging*, March 2, 2023, amended April 26, 2023. Privileging is a process by which a practitioner, is permitted to provide patient care independently, within the scope of the individual's license, based on clinical competence experience, education, and training. The two policies contain similar language related to privileging.

Director, Pulmonary and Critical Care, completed an assessment of the facility in 2021 and recommended a closed ICU model with PCCM attendings and ACCNPs providing all ICU overnight patient care coverage.[12] The VHA team cited in their report to the facility that hospitalists had responsibility for ICU patients, yet were not trained in critical care.[13]

When asked about planning for the ICU model change, the COS told the OIG that planning for the change had included facility section leaders since 2021. The COS reported that in October or November 2022, a facility workgroup began planning for the recommended ICU model change.[14] However, the OIG found the first documented discussion of a "single ICU model," or the change to a closed ICU model, occurred on December 22, 2022, with a goal of June 2023 implementation.

The COS reported that in early January 2023, the associate chief of staff for education (ACOS-E) asked the COS whether the hospitalists' privileges allowed them to treat critically ill patients. According to the COS, that same day, she determined the hospitalists' privileges outlined treatment for only general medical conditions and not critical care conditions and immediately acted to remove the hospitalists from the ICU. The COS did not consult with established service or section leaders or staff members prior to making the abrupt change.

During interviews with the OIG, section leaders, attendings, and fellows with program expertise reported they were not consulted regarding the abrupt decisions to remove hospitalists from providing care in the ICU or to accelerate the ICU model change. The section leaders reported that their input and solutions were disregarded after the change.

The OIG learned that facility leaders consulted with VHA leaders regarding hospitalists' privileges only after removing the hospitalists from providing care in the medical ICU. Through email correspondence, the OIG found that, on January 18, 2023, the DCOS-IO communicated with facility, section and service leaders, and hospitalists regarding hospitalists' privileges and ICU changes. The DCOS-IO stated that VHA's Office of General Counsel agreed with "the steps taken and recommended that we reach out to the national credentialing and privileging office for guidance." In addition, the Director, VHA Credentialing and Privileging gave the OIG evidence of email correspondence in which the DCOS-IO on January 18, 2023, asked for a meeting to discuss hospitalists' care practices. The DCOS-IO was referred to the National Program Director, VHA Hospital Medicine. The Director reported being unable to recall whether the requested meeting occurred. However, the OIG was provided with an email exchange between the DCOS-IO and VHA National Director of PCCM recommending a two-day critical care course for current hospitalists, which would support them providing care in the ICU. On January 27, 2023,

[12] VHA, *Assessment of the Intensive Care Unit (ICU) to Include Summary and Recommendations*. The facility ACCNPs provided on-site care 24/7 to surgical ICU patients.

[13] VHA, *Assessment of the Intensive Care Unit (ICU) to Include Summary and Recommendations*.

[14] The facility held 11 ICU Optimization Workgroup meetings from November 3, 2022, through January 26, 2023.

a section leader informed the DCOS-IO that the hospitalists had collectively decided not to pursue changes to their privileges.

In March 2023, further medical ICU provider coverage changes occurred including having PCCM attendings on-site 24/7. In correspondence dated April 19, 2023, the COS informed the Facility Director that recruiting for five additional PCCM attendings and expanding the surgical ACCNPs responsibilities to care for the medical ICU patients were in progress.

On May 17, 2023, surgical ACCNPs completed a two-day critical care course. Five days later the surgical ACCNPs were assigned to provide overnight coverage for the medical ICU patients, instead of second year ICU overnight residents (ICU residents), with on-call PCCM attendings and fellows for assistance as needed.[15]

Although a VHA team recommended the facility initiate a closed ICU model in March 2021, facility leaders implemented changes beginning on January 3, 2023, without adequate planning and involvement of facility subject matter experts. The OIG would have expected facility leaders to plan and involve service and section leaders and staff before implementing changes, in accordance with VHA HRO principles and The Joint Commission standards.

3. Lack of Resident Supervision and Ineffective Teaching Environment

The OIG substantiated that sudden implementation of a closed ICU model resulted in a lack of ICU resident supervision and an ineffective teaching environment for ICU residents. VHA policy states that the facility COS or designee ensures "the presence of a work environment that is consistent with quality patient care and the educational needs of residents that meet all applicable program requirements."[16]

The OIG determined that after the change was implemented, ICU residents did not have overnight on-site supervision and were instructed to rely upon TeleCritical Care. Through a service agreement between the facility and TeleCritical Care West Program (tele service agreement), physicians and nurses would provide 24-hour ICU care via live audio and video.[17] However, the OIG learned that residents were not provided with clear instructions for escalating patient concerns to PCCM attendings and fellows. Additionally, leaders failed to comply with VHA and Accreditation Council for Graduate Medical Education (ACGME) policies by

[15] According to email correspondence from the COS, the term on-call is that PCCM fellows and attendings were off-site during overnight hours and were paged.

[16] VHA Directive 1400.01.

[17] "TeleCritical Care-ICU of the future here today," *VA News*, July 13, 2021, https://news.va.gov/90854/telecritical-care-icu-future-today/; VA, *TeleCritical Care (TELECC) Interfacility Telehealth Service Agreement*, revised January 1, 2022.

implementing a change in the level of resident supervision without involving the residency program.

After the ICU model change was implemented, ICU residents reported concerns to program leaders as well as in program evaluations. Through document review and interviews with the OIG, ICU residents reported feeling insufficiently supported and increasingly concerned about not being able to perform their duties "well or safely." In May 2023, when the ACCNPs began providing overnight coverage for medical ICU patients and ICU admissions, the overnight ICU resident rotation was discontinued.[18]

Leaders Failed to Provide Clear Processes for TeleCritical Care

The OIG determined that facility leaders expected attendings, fellows, and residents, to utilize TeleCritical Care services to collaborate on ICU patient care, without providing written procedures or policy.

The OIG learned that beginning on February 6, 2023, TeleCritical Care providers were to assist the ICU residents with admissions and critical care assessment and treatment.

Staff reported to the OIG that the messaging of the expectation to use TeleCritical Care confused staff, and the change away from on-site hospitalist supervisors lacked written protocols, and failed to plan for resident supervision.[19] TeleCritical Care was implemented as the primary contact for ICU residents for approximately two months and was then changed to a PCCM attending.

The OIG concluded that the ICU model change and utilization of TeleCritical Care without providing procedures or policy negatively affected ICU resident supervision and work environment.

Failure to Involve Residency Program in Supervisory Change

The OIG found that facility leaders failed to comply with VHA policy by implementing a change in the level of resident supervision without the approval of the residency program. VHA policy requires that "a supervising practitioner must be approved by the program [director] of the residency program in order to supervise residents" and that a facility director verifies adherence to ACGME standards.[20] ACGME standards state that the residency program is to delineate when

[18] A service leader reported that a new week-long rotation was created for the residents to serve in the ICU during daytime hours.

[19] The ACOS-E provided the OIG with an unsigned facility standard operating procedure for use with overnight TeleCritical Care in the ICU dated February 28, 2023.

[20] VHA Directive 1400.01.

resident on-site supervision is needed.[21] The residency program director, based at VA or the affiliate institution, holds the designated authority and accountability for residency program operations.[22]

In a review of an email correspondence, the OIG found that although a section leader notified the residency program on January 3, 2023, of immediate "changes to the [resident] supervisory structures," during an interview with the OIG, the ACOS-E acknowledged the residency program leader was not consulted prior to removing the hospitalists from the ICU.

The OIG concluded that the Facility Director and COS failed to abide by VHA policy and ACGME requirements when the ICU resident supervision structure was altered without the approval of the residency program leader.

4. Alleged Patient Harm

The OIG did not substantiate that the ICU model change resulted in patient harm.[23] The OIG interviewed facility staff and reviewed the electronic health records of four patients who received care after the ICU model change. The OIG determined that PCCM fellows and ICU residents coordinated care, which met the needs of critically ill patients, as required. While the OIG did not substantiate patient harm, the OIG found that unclear guidance of when PCCM fellows must contact PCCM attendings may put patients at risk for adverse clinical outcomes.

5. Deficiency in Root Cause Analysis Process

The OIG identified a deficiency in the facility's completion of the root cause analysis.

The OIG determined that a root cause analysis team did not interview individuals vital to the patient's ICU care and treatment. A root cause analysis is a process used to identify the contributing factors to patient safety adverse events or close calls and focus on systems and processes rather than individuals.[24] VHA requires individuals directly involved with an adverse

[21] Accreditation Council for Graduate Medical Education, *ACGME Common Program Requirements (Residency)*, July 1, 2022. These requirements were in place during the time of the events discussed in this report. The requirements were revised on July 1, 2023. The revised 2023 requirements 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 as the 2022 requirements.

[22] VHA Directive 1400.01.

[23] The OIG defined patient harm as a significant negative impact on the patient's care, including delays in care.

[24] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This directive was replaced by VHA Directive 1050.1, *VHA Quality and Patient Safety Programs*, March 24, 2023. Unless noted, the requirements for patient safety reviews remains the same in both documents. A root cause analysis is a process used to identify the contributing factors to patient safety adverse events or close calls and focus on systems and processes rather than individuals.

event "be interviewed as part of the [root cause analysis] process and asked for suggestions about how to prevent the same or similar situations from happening again."[25]

During interviews with the OIG, an attending and a resident who were involved in the patient's care, told the OIG that the root cause team did not interview them.[26] The OIG concluded that omitting relevant ICU staff from the review was a missed opportunity to identify improvements in the provision of patient care and processes.

The OIG made one recommendation to the Under Secretary for Health to evaluate circumstances that led to VISN leaders' lack of awareness of the 11-month curtailment of CT surgeries; three recommendations to the VISN Director to evaluate circumstances that led to facility leaders' failure to submit plans to resume CT surgeries after an 11-month pause; ensure facility leaders implement HRO principles to plan for clinical operation changes that include input from stakeholders, service and section leaders, and staff; and require that the educational needs of the facility's residents are evaluated and maintained during service and program changes, including on-site supervision.

The OIG made two recommendations to the VA Eastern Colorado Health Care System Director to review and finalize the draft policy for call escalation and train attendings, fellows, residents, and staff members on the policy; and to review root cause analysis requirements for interviewing individuals relevant to the root cause analyses and ensure staff are trained accordingly.

VA Comments

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

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[25] VHA National Center for Patient Safety, *Guide to Performing Root Cause Analysis*, Version 11, October 2023.

[26] The OIG reviewed a list of facility staff interviewed by the RCA team and interviewed one of the two staff members on the list, in addition to two other staff members directly involved in the patient's intubation.

Contents

Abbreviations

ACCNP	adult critical care nurse practitioner
ACGME	Accreditation Council for Graduate Medical Education
ACOS-E	associate chief of staff for education
CT	cardiothoracic
COS	Chief of Staff
DCOS-IO	deputy chief of staff inpatient operations
EHR	electronic health record
HRO	high reliability organization
ICU	intensive care unit
NSO	VHA National Surgery Office
OIG	Office of Inspector General
PCCM	pulmonary and critical care medicine
TJC	The Joint Commission
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the VA Eastern Colorado Health Care System (facility), including the Rocky Mountain Regional VA Medical Center in Aurora, to review how facility leaders' actions may have impacted intensive care unit (ICU) coverage, patient care, and resident education. Due to the breadth of the allegations and the reported impact on a multitude of clinical processes and services, the OIG initiated two separate, but simultaneous, healthcare inspections. While this inspection focused on allegations related to the impact of facility leaders' actions on ICU provider coverage and patient care, the companion inspection focused on leadership and high reliability organization (HRO) principles.[1]

Background

The facility is part of Veterans Integrated Service Network (VISN) 19 and provides comprehensive health care through primary care, behavioral health, and specialized services, including cardiovascular and thoracic surgery. From October 1, 2022, through September 30, 2023, the facility served 101,411 patients and had a total of 215 operating beds, including 148 hospital beds and 18 ICU beds used for both medical and surgical post-operative patients. Additionally, the facility has seven outpatient clinics in Colorado.[2] The Veterans Health Administration (VHA) classifies the facility as a level 1a, highest complexity.[3]

Intensive Care Unit

An ICU is a location within a facility with designated beds that provides 24-hour a day specialized medical and surgical patient care, technology, and staffing "dedicated to the management of acute illnesses in which life or organ function may be in jeopardy."[4] Patients are often admitted to ICUs emergently, requiring complex care coordination. Patients who have undergone surgical procedures may be admitted for post-operative care. Pulmonary and critical care medicine (PCCM) physicians have specialized training to provide care to patients admitted

[1] VHA, "VHA High Reliability Organization (HRO) Glossary of Terms – Internal VA Use Only," May 2023. HRO principles focus on frontline staff, processes and systems that impact patient care, preoccupation with failure, identification of root causes for a problem, commitment to resilience, and reliance on subject matter experts.

[2] The facility's outpatient clinics are located in Alamosa, Aurora, Golden, Colorado Springs, Pueblo, La Junta, and Lamar, Colorado.

[3] VHA Office of Productivity, Efficiency and Staffing (OPES), "Facility Complexity Model Fact Sheet," January 28, 2021. 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.

[4] VA Eastern Colorado Health Care System Policy 118-54, *Intensive Care Units*, August 25, 2015. ICU patients may include, critically ill surgical and medical patients, patients who cannot be cared for on a general ward, and post-anesthesia recovery care surgical patients.

to an ICU. ICU teams collaborate for more frequent assessments and intensive or invasive monitoring; support of airway, breathing, or circulation; stabilization of acute or life-threatening medical problems; comprehensive management of injury or illness; and maximize comfort for terminally ill patients. ICUs may be structured as open or closed models. An open model "[i]ndicates that multiple physicians or teams, whether assigned to the ICU or not, are permitted to provide care to a patient in the physical space of the ICU." A closed model "[i]ndicates that only the ICU team specifically assigned to the ICU manages the patient's care for all patients admitted to the ICU."[5]

TeleCritical Care

TeleCritical Care physicians and nurses provide 24-hour ICU care via live audio and video.[6] To enhance availability of critical care expertise, providers from the TeleCritical Care West Program, Minneapolis VA Health Care System, Minnesota, collaborate with the facility ICU providers and staff to provide critical care services delivered electronically. Specifically, a service agreement between the facility and the TeleCritical Care West Program (tele service agreement) states TeleCritical Care providers "provide critical care telemedicine . . . and can therefore assist with the direct co-management of monitored patients," using audio and video teleconferencing equipment. TeleCritical Care services do not replace ICU staff who are "the ultimate authority for treatment plan decisions."[7]

Academic Affiliations and Residency Programs

Under federal law, VHA "shall develop and carry out a program of education and training of health personnel."[8] As one of four statutory missions, VHA conducts an education and training program for resident physicians and students from a variety of healthcare professions to enhance the quality and timeliness of health care.[9] In accordance with this mission, VA has collaborated with academic institutions "to train new health professionals to meet the rapidly evolving health care needs within VA and the Nation."[10] The facility trains more than 120 residents and 450 medical students every year and has multiple academic affiliations including the University

[5] VHA Chief Strategy Office, *2019 VHA Critical Care Survey Report*, January 2022.

[6] "TeleCritical Care—ICU of the future here today," *VA News*, July 13, 2021, https://news.va.gov/90854/telecritical-care-icu-future-today/.

[7] VA, *TeleCritical Care (TELECC) Interfacility Telehealth Service Agreement*, revised January 1, 2022. TeleCritical Care providers include physicians and nurses working within the scope of their respective licenses.

[8] 38 U.S.C. § 7302.

[9] "Office of Academic Affiliations," VA Office of Academic Affiliations, accessed August 7, 2023, https://www.va.gov/oaa/; VHA Directive 1400.01, *Supervision of Physician, Dental, Optometry, Chiropractic, and Podiatry Residents*, November 7, 2019. A resident physician provides health care in a medical training program and is supervised by an approved practitioner.

[10] "A History of VA's Academic Mission," VA Office of Academic Affiliations, accessed August 7, 2023, https://www.va.gov/OAA/75th-anniversary.asp.

of Colorado School of Medicine.[11] 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.[12] In addition, the associate chief of staff for education (ACOS-E) is responsible for ensuring the facility has "a process for identifying and remediating areas with insufficient resident supervision," and "assessing the quality of residency training programs and the quality of care provided by supervising practitioners and residents."[13]

Allegations and Related Concerns

On April 16, 2023, the OIG received a complaint alleging

- facility leaders implemented staffing changes to the surgical ICU without adequate planning in late spring of 2022, that adversely affected the provision of cardiac surgeries (referred to as cardiothoracic [CT] surgeries) and led to the CT section chief's resignation;[14]
- leaders made the medical ICU a closed unit, without appropriate planning, or discussion with service leaders and staff involved in ICU processes and patient care in January 2023;
- there was a lack of resident supervision and an ineffective teaching environment after leaders changed physicians responsible for medical ICU patients; and
- facility leaders' changes to the medical ICU resulted in patient harm.

On May 1, 2023, the OIG opened a healthcare inspection to assess the allegations. During the inspection, the OIG identified a deficiency in quality reviews conducted in response to reported patient care issues.

[11] "About Us," VA Eastern Colorado Health Care, accessed April 26, 2023, https://www.va.gov/eastern-colorado-health-care/about-us/.

[12] VHA Directive 1400.01; The facility's residency program reported that the residency program director is based with the affiliated university.

[13] VHA Directive 1400.01.

[14] *Merriam-Webster.com Dictionary*, "cardiothoracic," accessed September 19, 2023, https://www.merriam-webster.com/dictionary/cardiothoracic#medicalDictionary. Cardiothoracic means "specializing in the heart and chest."

Scope and Methodology

The OIG initiated the inspection on May 1, 2023, and conducted on-site visits June 20–23, 2023, July 13 and 18, 2023, with additional virtual interviews conducted through January 23, 2024.

The OIG interviewed VHA, VISN, and facility leaders; service and section leaders; attendings, fellows, and residents; and other staff members knowledgeable about the events and related processes.[15]

The OIG reviewed relevant VHA directives and handbooks, external standards, guidelines, and facility policies and procedures related to processes. The review also included facility committee agendas, meeting minutes, cardiology surgical attending reports, and reports in response to patient safety issues. Additionally, the OIG reviewed the electronic health records (EHRs) of four patients who were identified by facility staff as being potentially harmed by the change to a closed ICU model.

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

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

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

[15] VHA Directive 1400.01. Attendings are the supervising practitioners who have been approved by the facility "and associated training program." Fellows are physicians "in a program of accredited graduate education" who have completed eligibility requirements for board certification in a particular specialty. Specific titles of employees have been removed for confidentiality, excluding the facility leaders.

Inspection Results

1. Surgical ICU Changes Adversely Affected Cardiothoracic Surgeries

The OIG was unable to determine whether facility leaders implemented changes in April 2022 to the surgical ICU without adequate planning; however, the OIG found that the subsequent lack of ICU provider coverage 24 hours a day, 7 days a week (24/7) for surgical patients adversely affected the provision of cardiothoracic (CT) surgical services.

At that time, five surgical adult critical care nurse practitioners (ACCNP) left the surgery service limiting the 24/7 ICU provider coverage needed to care for cardiac surgical patients and adversely affecting the provision of CT surgeries.[16] As of August 2023, no CT surgical procedures had been performed at the facility for 11 months and all CT surgical staff had either resigned (three) or were terminated (one). The lack of permanency in key positions compounded by the Chief of Staff's (COS's) lack of sustained support contributed to the delayed resolution of 24/7 ICU provider coverage and the lengthy curtailment of services.

The facility's surgical program includes cardiovascular (heart and blood vessels) and thoracic (chest) surgical services. Per the surgical organizational chart, provided by the facility in draft form, the cardiac surgical program consisted of three full time equivalent employee positions including one section chief, one physician assistant, and one perfusionist. [17] However, the OIG learned through interviews that the Surgical Service actually had two facility perfusionist positions and also utilized contract cardiology surgeons and cardiac perfusionists to assist in the provision of patient cardiac surgical care. During interviews and document reviews, the OIG found the facility often referred to the cardiac surgical positions and services as cardiothoracic; CT will be used throughout this report.[18]

Through a review of documents provided by the acting chief of surgery, the OIG learned that in April 2022, five surgical ICU ACCNPs either transferred to another service, resigned, or retired. Although reportedly the departures were related to unfavorable changes to the surgical ACCNPs' schedules such as an increase in night shifts, the OIG was unable to verify the cause. A former surgical and ICU leader shared that as a consequence of losing the surgical ICU ACCNPs the 24/7 provider coverage necessary to care for CT patients was limited. The former deputy chief of

[16] The ACCNPs' primary role, as defined in their functional statements, is "to provide direct care management of complex medical and surgical patients in consultation with critical care medical and surgical physicians."

[17] "What does a cardiovascular perfusionist do?" Mayo Clinic College of Medicine and Science, accessed October 3, 2023, https://college.mayo.edu/academics/explore-health-care-careers/careers-a-z/cardiovascular-perfusionist/. Perfusionists are responsible for operating the heart-lung machine "during an open-heart surgery or any other medical procedure."

[18] "What is a cardiothoracic surgeon," Cleveland Clinic, accessed on October 11, 2023, https://my.clevelandclinic.org/health/articles/23263-cardiothoracic-surgeon. Cardiothoracic is a surgical specialty focusing on surgery of the heart, lungs, esophagus, and other parts of the chest cavity.

surgery explained that while urgently trying to secure 24/7 provider coverage, gap coverage measures were implemented which included the former chief of surgery providing overnight coverage for surgical patients.[19] Despite these efforts, the former deputy chief of surgery reported CT surgical services were paused while attempting to emergently hire providers.

First CT Surgical Pause June 2022

In accordance with VHA guidance, on June 13, 2022, the former COS submitted an issue brief notifying VISN leaders of the inability to conduct cardiac surgeries due to "critical staffing shortages in [the] Intensive Care Unit (ICU) and Operation Room (OR) . . ."[20] The issue brief, titled "Cardiothoracic (CT) Surgery Diversion" and categorized as a "curtailment of operations . . .clinical area closure," was anticipated to resolve within 14 days. The issue brief noted that surgery, anesthesiology, and critical care services were working together to "develop alternative coverage during [the] Advanced Cardiac Nurse Practitioner" shortage.

Per VHA, facilities submit issue briefs to inform VA leadership, through the VISN, of a situation, event, or issue, such as the curtailment of operations. Issue Briefs should be submitted timely and include a brief statement of the issue and status, as well as the actions, progress, and the date of resolution, when applicable. If the event is not resolved, updates to the original issue brief regarding progress should be provided.[21]

CT Surgeries Resume July 2022

On July 12, 2022, facility leaders sent an update to the June 13, 2022, issue brief to notify VISN and VA senior leaders that "Cardiothoracic procedures have completely resumed. While staffing is still a concern, a Service Level Agreement has been approved, and plans have been developed in coordination with multiple services to ensure adequate coverage can be provided." Per the facility's surgical report, CT surgeries resumed in July 2022.

In an interview with the former chief of surgery, the OIG learned that the plan for ICU coverage at that time primarily involved the former chief of surgery and one other provider covering the night shift in addition to their regular day shifts through early September 2022. The former interim ICU director also reported having volunteered to cover overnight shifts, without extra pay, to keep the cardiac surgery program active. The OIG reviewed an ICU coverage spreadsheet containing a list of physicians who voluntarily signed up to provide overnight coverage and

[19] During the site visit in June 2023, the OIG found the COS had detailed the former chief of surgery to a staff surgeon role and appointed an acting chief of surgery on January 30, 2023.

[20] Deputy Under Secretary for Health for Operations and Management (10N), "10N Guide to VHA Issue Briefs," updated June 26, 2017.

[21] Deputy Under Secretary for Health for Operations and Management (10N), "10N Guide to VHA Issue Briefs."

confirmed that the principal volunteers were the former chief of surgery, a staff surgeon, and the former interim ICU director.

While service line leaders and staff temporarily provided 24/7 ICU coverage to maintain CT surgeries, surgical service line leaders continued attempts to resolve ICU provider coverage shortages. The OIG reviewed a series of email correspondence that originated in May 2022 from the former CT section chief who was seeking resolution of the 24/7 ICU provider coverage. The former CT section chief, with the support of the former chief of surgery, developed and forwarded a proposal to hire two CT physician assistants to provide 24/7 ICU coverage, which would allow CT surgeries to resume. The proposal was sent by email to the former deputy chief of staff inpatient operations (DCOS-IO) who forwarded the proposal to the former COS and noted, "Given that our CT Surgery services are on a full divert I feel this worth pursuing aggressively." In June 2022, the former DCOS-IO emphasized the importance of resolving the issue by stating, " . . . having our Cardiac Surgery on diversion is big risk to our facility" via email to the former COS. The email correspondence dated June 27, 2022, cited that surgical leaders demonstrated continued attempts to secure a sustainable coverage plan and were open to "system-wide" solutions. In August 2022, the email chain was forwarded to the new COS who had begun facility employment in July.

During an interview, the OIG learned that despite surgical leaders' pursuit of securing provider coverage, efforts to secure 24/7 ICU provider coverage were unsuccessful; as such, temporary efforts by clinical service chiefs and physicians to provide overnight coverage were discontinued.

Extended Second CT Surgical Pause September 2022—October 2023

In September 2022, the Surgical Work Group meeting minutes noted that efforts to secure ICU provider coverage of surgical patients were unsuccessful and CT surgeries would be paused. This was the second CT surgical pause. The facility surgical report revealed the last CT surgical procedure was conducted on September 6, 2022.

Efforts to Secure Provider Coverage and Restart CT Surgery

Through interviews, correspondence with clinical leaders, and a review of meeting minutes, the OIG discovered a number of challenges clinical leaders experienced when trying to hire ACCNPs for 24/7 provider coverage of surgical ICU patients to restart the CT surgery program. The OIG reviewed 11 weekly interdisciplinary ICU Optimization Workgroup meeting notes from November 2022 through January 2023 that addressed surgical ICU provider coverage plans. As of November 10, 2022, three ACCNPs had been selected as ICU providers and two had accepted job offers, a third later accepted a job offer. However, per the agenda dated February 9, 2023, work group notes reported the three ACCNPs had not yet started employment

at the facility but appeared to be completing the onboarding process. Surgical Work Group committee meeting minutes noted that as of February 23, 2023, six of seven providers were "staffed in the ICU, which allows us around the clock coverage without any gaps."

Leadership Turnover Contributed to Prolonged Pause

The OIG opined that leadership and clinical vacancies in addition to the lack of permanency in key positions contributed to the delayed resolution of the 24/7 ICU provider coverage and the lengthy curtailment of CT surgical services.

Despite the frequency of the ICU Optimization Workgroup meetings, several clinical leaders cited additional challenges in resolving the provider coverage, including leadership turnover, a lack of support and priority from the COS, and hiring delays. One leader shared having worked with multiple chiefs of staff, chiefs of medicine, ICU directors, and nurse managers emphasizing "leadership turnover is important to highlight in light of us trying to build the clinical programs at [the facility]." The leader added, "we really needed the chief of staff to get nursing/ICU/surgery/cardiology all on the same page," and "we lacked support and transparency about decision-making at the chief of staff level." A second leader reported that despite inviting the COS to meetings "the COS wouldn't initially join, but then on TEAMs [virtual meeting call] would be on hold and then off, they went to other meetings. And so, it's very challenging for us to know if we were important or not, if we mattered or not" and " . . . We couldn't get any traction . . ." A third service leader stated the executive leadership was not engaged in the hiring process adding "the previous chiefs of staff, they'd have that done in a second, you know, in months," and "we didn't have access to the COS like in the old days." A fourth clinical leader explained that hiring providers predominantly for the night shift was a challenge, adding the "hiring cycle [is] not exactly fast at the VA . . .[and] we previously tried in three hiring cycles . . . in 2022."

Through a review of facility documents and email correspondence, the OIG learned that shortly following the first cardiac surgical pause a new COS was appointed in July 2022, and concurrently served with the former COS before the former COS resigned in August 2022. In late August 2022, the former DCOS-IO resigned from the facility. Additionally, there were a number of key positions that had been and remained vacant through the OIG's initial site visit in June 2023, including the chief of medicine (vacant since October 2020 according to the VISN Human Resources Officer) and the ICU director (estimated vacant since November 2021).[22]

[22] The OIG determined the ICU director position had been vacant since at least November 2021, based on a memorandum that appointed an interim ICU director at that time. Although the OIG asked VISN and facility staff, both reported the date as unknown. The OIG learned through correspondence and document review that an interim ICU director was appointed in November 2021 and remained in the interim role until the ACOS-E assumed the role in July 2023.

Further, the OIG noted additional clinical leadership disruptions. On December 18, 2022, and January 1, 2023, a new ACOS-E and a new DCOS-IO began employment at the facility, respectively. Through documents and interviews the OIG was informed on January 24, 2023, the new DCOS-IO relieved the interim chief of medicine of the position and concurrently served in both positions. Further, on January 30, 2023, facility leaders temporarily removed the former chief of surgery from the chief position, and the COS appointed a new acting chief of surgery. In April 2023, the former deputy chief of surgery voluntarily stepped down from the position and served as staff surgeon until resigning from VA on July 31, 2023. At the time of the OIG's site visit in June 2023, the former chief of surgery remained detailed to a staff surgeon position.

At the time of the OIG's July 2023 site visit, all facility cardiac surgical staff had resigned (one was terminated) from VA. The OIG learned through email correspondence and documents that, because of the low pay, one of the two perfusionists resigned in June 2022. In February 2023, the remaining perfusionist was terminated. In March 2023, the CT surgery section chief resigned and left federal employment. In June 2023, the CT physician assistant resigned. The OIG found the loss of 24/7 ICU provider coverage of surgical patients and the subsequent extended pause of CT surgeries ultimately led to loss of all facility cardiac surgical staff.

The OIG reviewed the facility's Surgical Work Group meeting minutes from October 2022 through August 2023. The OIG noted that following the former chief of surgery's removal and the appointment of an acting chief on January 30, 2023, no cardiac surgery updates were reported on the standing agenda item for February, March, April, or May 2023. Meeting minutes recorded cardiac surgery as "deferred" with one note in May stating an update would be presented in July. The OIG noted the COS, a voting member of the Surgical Work Group, did not attend the meeting in October or December 2022 or in March, April, May, July, or August 2023.

The OIG concluded that the lack of experienced and consistent leadership in critical clinical positions compounded by the COS's lack of sustained support contributed to the delayed resolution in securing 24/7 ICU provider coverage of surgical patients and the extended curtailment of CT surgical services.

Related Finding: Failure to Notify VISN and VA Central Office of Second CT Surgical Pause

The OIG determined the COS failed to notify VA Central Office, through the VISN, of the second pause in CT surgical services in September 2022. Although the former chief of surgery submitted preparatory briefing forms containing CT surgical pause information to the COS, the COS failed to submit an issue brief notifying VISN and VHA leaders of the curtailment of CT surgical services at the facility.

When the OIG inquired about the notification to and communications with VISN leaders and a VISN surgical consultant about the second CT surgical pause, the COS reported that the VISN

and the National Surgery Office (NSO) were aware. As evidence, the acting chief of surgery provided email correspondence with the VISN surgical consultant that took place in May of 2023. The OIG reviewed the email exchange and noted the VISN surgical consultant reached out to the acting chief of surgery to query if the facility was performing CT surgeries, and if not, was the status permanent or temporary.

When the OIG asked about the nature of the query and if an issue brief had been submitted by the facility, the VISN surgical consultant initially confirmed being aware of the CT surgical curtailment because of the facility issue brief submitted to the VISN in June of 2022. When asked if aware that the facility resumed CT surgeries in July 2022, the VISN surgical consultant responded, "I was not aware of either IB [issue brief] that resumed the program after June nor the IB [issue brief] that halted it once again in September. I was under the assumption it was a prolonged suspension."

When interviewed by the OIG on July 18 and 26, 2023, the VISN Director reported being unaware of either the pause in the facility's CT surgical program or that no CT surgeries had been conducted since early September 2022. Following the first interview, the VISN Director reviewed the issue briefs received from the facility and verified through email that, although the VISN received a facility issue brief in June 2022 regarding CT curtailment and an update in July 2022 reporting the issue was resolved, no additional CT issue briefs had been received. During a second interview, the VISN Director affirmed that facilities should report curtailments, diversions, and gaps in service and stated that reeducation was needed. Further, the VISN Director explained that an issue brief is part of the formal process in which the VISN notifies VA Central Office of what is happening in VA facilities across the country so VHA leaders are aware of service issues and can provide assistance.

In an interview, the former chief of surgery told the OIG that after a discussion in the Surgical Work Group about the ongoing issue of ICU provider coverage, CT surgeries went "offline." The former chief of surgery reported filling out the issue brief information on the curtailment of cardiac surgeries, as requested by the COS, and was under the impression that the issue brief had been submitted.

During an OIG interview, the COS recalled telling the COS's administrative officer that because a pause in CT surgeries was a curtailment of services an issue brief was needed. However, when asked to provide the issue brief to the OIG, the chief of quality, safety, and value, at the request of the COS, forwarded emails and preliminary issue brief forms. The OIG reviewed email correspondence between the former chief of surgery, COS, and the COS's administrative officer and found that on September 22, 2022, the former chief of surgery emailed the COS to follow up on what was needed to draft an issue brief about the status of cardiac surgery. The COS responded on the same day asking the COS's administrative officer to work with the former chief of surgery to prepare an issue brief for the curtailment of services, after which the administrative officer forwarded two issue brief template forms for the former chief of surgery to

complete stating, "Once complete, I will submit." The former chief of surgery completed the forms the following day, September 23, and returned the forms via email to the COS and the COS's administrative officer. The facility could not provide any evidence that the COS or the COS's administrative officer submitted an issue brief or that any further action toward this end was taken.

The OIG concluded that the COS was notified of the curtailment of CT surgical services, received the information needed to complete the issue brief from the former chief of surgery, but failed to notify VA Central Office, through the VISN, of the September 2022 pause of CT surgeries that would last nearly one year. Because the COS failed to submit an issue brief on the curtailment, the facility was not prompted to and did not provide official status updates noting actions taken and progress toward resolution.

Related Finding: Failure to Notify and Engage the VISN and VA Central Office in Efforts to Resume CT Surgeries Following an 11-Month Pause

The OIG determined that following the 11-month CT surgical pause and the loss of all facility CT surgical staffing, the Facility Director, COS, DCOS-IO, and the acting chief of surgery proceeded with plans to resume CT surgeries in August 2023, without notifying and seeking approval from VISN and VA Central Office leaders. The OIG found these conditions met criteria for a major augmentation of clinical services requiring the approval of the Under Secretary for Health or designee, as outlined in VHA policy.[23] Further, the OIG found that the absence of a detailed interdisciplinary evaluation and plan to be concerning given that the last CT surgery was conducted nearly one year prior.

Per VHA policy, "all proposals requiring restructuring, reduction, or augmentation of major clinical programs or services . . . must be approved by the Under Secretary for Health, or designee, through the Deputy Under Secretary for Health for Operations and Management and the Chief Officer, Patient Care Services."[24] VA's Central Office is responsible for working with VISNs "in the oversight and approval of bed changes, program restructuring, and changes in clinical services to coordinate and ensure that a full continuum of safe quality care is available. . . ."[25] "When a facility or VISN plans major augmentation to services or programs, a thorough clinical evaluation must be conducted to ensure competencies and skills of all clinical staff as well as necessary ancillary services needed."[26] Examples of major restructuring of clinical programs or services include but are not limited to the:

[23] VHA Directive 1043, *Restructuring of VHA Clinical Programs*, November 2, 2016.
[24] VHA Directive 1043.
[25] VHA Directive 1043.
[26] VHA Directive 1043.

- "Expansion of an existing surgery program to include thoracic or vascular surgery services, . . .[or] cardiac surgery"
- "Significant increase in the volume of existing procedures (i.e., more than 50 percent increase in baseline workload) expected to require additional equipment, space, staffing, and training"
- "Elimination of a major clinical program, such as. . . ., open heart surgery"[27]

VHA policy outlines the roles and responsibilities of the facility, VISN, and VA Central Office. The OIG outlined key roles and abbreviated responsibilities from the VHA policy below.

Facility-Level Responsibilities

The COS is responsible for assuring that a thorough clinical evaluation has been completed to "ensure that the competencies and skills of clinicians and staff of ancillary services required for any requested major clinical programs or services meet the standard of care." This includes review of related processes of care. Further, the COS is responsible for "providing a clinical review and evaluation for the proposed business plans." The Facility Director is responsible for ensuring the proposal request for restructuring clinical programs is completed on the required business plan and for submitting the proposal request to the VISN Director for review and approval.[28]

VISN Responsibilities

The VISN Chief Medical Officer is responsible for ensuring that a thorough clinical evaluation of the competencies, skills, and privileges of clinicians and ancillary service staff has been conducted. Further, the VISN Chief Medical Officer must ensure that a clinical evaluation of resources and processes of care is completed, a site visit through a responsible clinical program office (as applicable) is conducted, and a final clinical review and evaluation of the proposed plan is done and provided to VA Central Office. The VISN Director is responsible for reviewing and evaluating the facility's business plan proposal and submitting the approved proposal to VA Central Office. Further, the VISN Director is responsible for "initiating a request for a site review from the Office of Patient Care Services to ensure appropriateness of implementation of new or expanded clinical program."[29]

VA Central Office, Office of Patient Care Services Responsibilities

The Office of Patient Care Services is responsible for reviewing "the requests and business plans for restructuring, reduction, or augmentation of all major clinical programs or services at VA

[27] VHA Directive 1043.
[28] VHA Directive 1043.
[29] VHA Directive 1043.

facilities to ensure there are adequate clinical resources, and that standards of care and adherence to clinical policies are being addressed," and submitting the requests to the Deputy Under Secretary for Health for Operations and Management. Additional responsibilities include, "determining the need for on-site review prior to approval . . . [and] [a]ssembling an appropriate clinical team to conduct the on-site visit to review the facility requesting the new or expanded clinical program."[30]

Facility Leaders' Plan to Resume CT Surgical Services

During a review of a facility CT surgical report, the OIG noted a sharp decline in CT surgical procedures performed at the facility in April and May 2022 without sustained recovery. Specifically, 84 CT surgeries had been conducted at the facility in 2021, 34 CT surgeries in 2022, and zero CT surgeries from January through August of 2023 (see figure 1). Moreover, as of August 2023, when the COS, DCOS-IO, and acting chief of surgery planned to resume CT surgical services, it had been nearly 11 months since the last procedure had been performed.

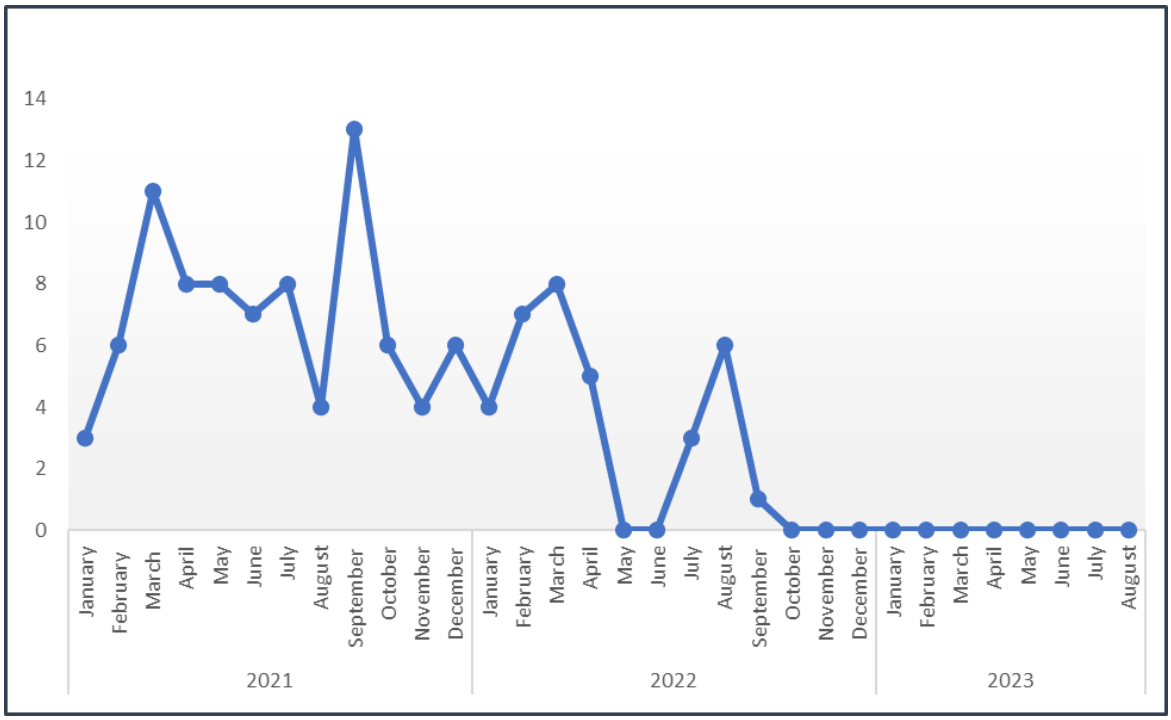

Figure 1. *The number of facility-conducted cardiac surgical procedures by month and year, spanning from January 1, 2021, through August 31, 2023.*
Source: OIG analysis of facility cardiac surgical report.

When the OIG interviewed a clinical leader in June 2023 concerning the restart of the CT surgical service, the leader stated, "I think everyone shares the recognition that CT surgery is important. I think everyone wants to have a CT surgery program rebooted here, internally. It's

[30] VHA Directive 1043.

more a question of focusing on developing a strategy to make that happen." When questioned by the OIG about a CT surgery action plan to restart the service, the acting chief of surgery stated, "we address things as they were encountered" and had "additional discussions in the Surgical Work Group."

On July 26, 2023, during an interview with the COS, the OIG learned the facility planned to resume CT surgeries with the first surgery scheduled on August 8, 2023; the COS explained that, contract CT surgical staff from the university would be conducting the surgery. When questioned about the facility having a detailed written plan to resume CT surgeries that included action items, responsible parties, and updates to the VISN, the COS stated, "I have not seen the detailed plan. . . .I don't think there's a written plan. I haven't seen any but will be happy to provide you with all the steps we have taken so far." The COS added " . . . there are multiple emails and multiple things. Would it be helpful if we can put it all together into one and provide . . . like a summary?" The following day, the OIG received a transcript of an interdisciplinary CT surgery restart meeting that took place during the Surgical Work Group on June 8, 2023.

From a review of the interdisciplinary meeting transcript, the OIG learned that concerns were brought forward from various disciplines including a contract CT surgeon, nursing leaders, and the COS. For example, the contract CT surgeon voiced being "somewhat uncomfortable about our operative room coverage," the need for a " consistent and reliable system," and a "much more robust system moving forward, not impairing our ability to start the program." The COS stated, "I understand what [contract CT surgeon] is saying to [*sic*] I think we are all feeling uncomfortably, but at the same time we have to start, because otherwise we just keep going in a hamster wheel and then the goal is that long term, we absolutely have coverage in every area. It doesn't matter where, so we are not again, constantly being in this stage of a whirlwind so, I appreciate, but we have to start somewhere."

Out of concern regarding the facility's readiness to safely conduct a CT surgical procedure, the OIG reached out to the VISN Director on August 2, 2023, and requested follow-up on concerns about the facility's readiness. The VISN Director informed the OIG by email that upon further inquiry to the facility, the VISN Director learned that facility leaders had not engaged NSO in their plans to resume CT surgeries. Subsequently, on August 3, 2023, the VISN made a formal request to NSO to conduct a cardiac surgery program review prior to the facility restarting CT surgeries. Further, the VISN Director shared having personally conveyed the expectation to the Facility Director that the facility would not conduct any CT surgery prior to an NSO review and a "green light" to proceed. NSO acknowledged the VISN Director's request for a program office review.

On August 3, 2023, the acting chief of surgery facilitated a "Cardiac Surgery Reboot" meeting that included facility, contract, and VISN staff to discuss efforts and identify concerns to be addressed prior to reinitiating CT surgical services. The OIG reviewed the meeting transcript and learned that the first surgical CT case was rescheduled from August 8 to August 22, 2023.

During the meeting, multiple participants expressed concerns about on-call schedules, limited weekend provider coverage, limited clinical cardiology staff and hiring priorities, nursing education and competencies, and potential safety issues.

Through a review of emails, the OIG learned that following the VISN Director's request for NSO to conduct a review, NSO contacted the Facility Director and scheduled an "in person Consultative Site Visit" of the facility's CT surgery program on September 18, 2023.[31] In early December 2023, the OIG queried facility leaders about the status of CT surgery and was informed that CT surgeries had resumed with the first procedure having been conducted in late October and two procedures having been completed in November of 2023.

The OIG concluded that neither the Facility Director nor the COS notified or engaged VISN or VA Central Office leaders in planning efforts to resume CT surgeries and did so only after the VISN Director requested an NSO program review. The Facility Director failed to complete and submit a request for restructuring clinical program proposal plan to the VISN Director for review and approval.

2. ICU Model Change Disrupted Patient Care and Resident Education

The OIG substantiated that leaders' actions to change the medical ICU from an open to a closed model (ICU model change) were made without adequate planning and input from service and section leaders and staff. The OIG found that while there were preliminary efforts to plan for a change to a closed ICU in the fall of 2022, which were based on the COS's review of a 2021 VHA assessment team's (VHA team) recommendation, facility leaders failed to ensure that a sustainable plan for patient care and resident supervision was in place at the time of the abrupt removal of hospitalists from the medical ICU on January 3, 2023. The COS notified service leaders of the need to change medical ICU physician coverage from hospitalists to PCCM attendings and fellows, due to a privileging concern, only hours prior to implementing the change.[32] Between January 3, 2023, when hospitalists were determined to not have privileges to care for critically ill patients in the medical ICU, and May 2023, when ACCNPs took over care

[31] The NSO report and recommendations are not included in this report; the OIG deferred to the VISN and NSO in the determination of the facility's readiness to conduct CT surgical procedures, related recommendations, and follow-up on any recommended actions.

[32] The OIG reviewed the team's report, VHA, *Assessment of the Intensive Care Unit (ICU) to Include Summary and Recommendations*; "What is hospital medicine, and what is a hospitalist?" Society of Hospital Medicine, accessed October 23, 2023, https://www.hospitalmedicine.org/about/what-is-a-hospitalist/. "Practitioners of hospital medicine include physicians ("hospitalists") and non-physician clinicians" who provide hospital-based care. "Hospitalists typically undergo residency training in general internal medicine, general pediatrics, or family practice;" VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was in effect at the time of the review until it was rescinded and replaced by VHA Directive 1100.21(1), *Privileging*, March 2, 2023, amended April 26, 2023. Privileging is a process by which a practitioner is permitted to provide patient care independently, within the scope of the individual's license, based on clinical competence experience, education, and training. The two policies contain similar language related to privileging.

of medical ICU patients overnight and residents no longer covered the ICU at night, facility leaders made frequent changes to the medical ICU coverage, which disrupted patient care and resident education.

VHA's HRO framework describes several integrated components within the three HRO pillars (Leadership Commitment, Culture of Safety, and Continuous Process Improvement) and guides leaders on the application of HRO principles to build a more reliable organization.[33] A successful HRO must be sensitive to front-line care processes, anticipate risk, commit to identifying root causes, be resilient, and value expert skill and knowledge.[34]

The Joint Commission (TJC) establishes that leaders are responsible for ensuring that hospitals are functioning effectively and that modified services or processes are well designed.[35] Planning and communicating are key systems that help provide a foundation to support hospital processes.[36] Hospital-wide planning activities are to focus on improving patient safety and quality of health care while including relevant individuals and resources.[37] Effective communication is essential among groups and individuals within a hospital and between the hospital and external stakeholders.[38]

Leaders Failed to Include Input from Service and Section Leaders and Staff

During an interview with the OIG and in email correspondence, the COS reported that on January 3, 2023, facility leaders took immediate action to remove hospitalists from providing critical care in the ICU, and all new admissions for critical care were assigned to the on-call PCCM attending.[39] Before January 3, 2023, on-site hospitalist attendings were responsible for admitting and transferring patients to the medical ICU and for managing patients during the day. Nocturnists admitted and provided care to medical ICU patients at night and supervised second year ICU overnight residents (ICU residents).[40] Facility leaders told the OIG that the PCCM

[33] VHA, "Leader's Guide to Foundational High Reliability Organization (HRO) Practices," March 24, 2022. This document is for internal VA use only.

[34] VHA Directive 1026.01, *VHA Systems Redesign and Improvement Program*, December 12, 2019.

[35] VHA Directive 1100.16, *Health Care Accreditation of VHA Facilities and Programs*, July 19, 2022. VHA requires compliance with TJC regulatory standards for the quality and safety of healthcare. The Joint Commission, *Standards Manual*, *E-dition*, LD.01.03.01 and LD.03.08.01, January 1, 2022.

[36] *Standards Manual*, LD.03.03.01 through LD.03.04.01.

[37] *Standards Manual*, LD.03.03.01.

[38] *Standards Manual*, LD.03.04.01.

[39] According to email correspondence from the COS, the term on-call meant that PCCM attendings and fellows were off-site during overnight hours and were paged.

[40] A facility staff member explained to the OIG that a nocturnist is a hospitalist who provides nighttime patient care, assists residents with clinical decision-making, and responds to patient emergencies.

attendings provided on-site consultation during rounds for ICU patients and PCCM attendings and fellows were on-call and available for patient care concerns overnight.

The COS reported that in early January 2023, the ACOS-E asked the COS whether the hospitalists' privileges allowed the hospitalists to treat critically ill patients. According to the COS, that same day, she determined that the hospitalists' privileges outlined treatment for only general medical conditions and not critical care conditions.[41] The COS acknowledged consulting with the DCOS-IO, who was scheduled to begin working at the facility on January 10, 2023, for "subject matter expertise," the day following the decision to remove the hospitalists. However, the COS did not consult established service or section leaders or staff members prior to making the abrupt change to remove hospitalists from providing care in the ICU. The COS stated the focus that day was to initiate a plan for safe patient care, and further work would be done for continued protection of patients as the lack of hospitalists' privileges for critical care treatment was perceived as a risk to providers and patients.

The COS reported that the closed ICU model was not a new concept and had been discussed among facility and service leaders for several months with a tentative implementation date of July 2023. The COS explained that the VHA team including the VHA National Director, Pulmonary and Critical Care completed an assessment of the facility's ICU in 2021. The VHA team recommended a closed model ICU utilizing PCCM attendings with ACCNPs providing all ICU overnight patient care coverage.[42] The VHA team cited in their report to the facility that hospitalists had responsibility for ICU patients yet were not trained in critical care.[43]

When asked about planning for the ICU model change, the COS told the OIG that planning for the change had included facility section leaders since 2021. When asked to provide additional details about the ICU model change, the COS reported that a facility ICU Optimization Workgroup with service leaders and stakeholders began planning in October or November 2022.

The OIG learned through a review of email correspondence that the first documentation of a discussion of a "single ICU model" or the change to a closed ICU model, occurred at an ICU Optimization Workgroup meeting on December 22, 2022, with a goal of June 2023 implementation.[44] January 5, 2023 Workgroup meeting notes included the topics of a "[h]ospital [m]edicine privilege concern" and university concerns with ICU resident supervision.

[41] The COS reported that the ACOS-E reviewed ICU care provided by the hospitalists. After assessing the documentation, the OIG found that the review included care provided from July–September 2022. The OIG reviewed patients included in the allegations from facility staff, which occurred after the ICU model change, and did not review patients included in the ACOS-E's review.

[42] VHA, *Assessment of the Intensive Care Unit (ICU) to Include Summary and Recommendations*, March 26, 2021. The facility ACCNPs provided on-site care 24/7 to surgical ICU patients.

[43] VHA, *Assessment of the Intensive Care Unit (ICU) to Include Summary and Recommendations*.

[44] The facility held 11 ICU Optimization Workgroup meetings from November 3, 2022, through January 26, 2023.

During interviews with the OIG, section leaders, attendings, and fellows with program expertise reported they were not consulted regarding the abrupt decisions to remove hospitalists from providing care in the ICU or to accelerate the ICU model change. Section leaders reported in interviews that they were directed by the COS to determine a new process for clinical decision-making to begin the evening of January 3, 2023, but their input and solutions were disregarded after the change. A section leader told the OIG of having to notify staff and residents of the immediate changes and transferring patient care to PCCM attendings. Some staff reported not being opposed to changing the medical ICU to a closed model, but that the actions were abrupt and without planning and stakeholder input. Staff also reported in interviews that the COS notified them of changes only hours before implementation and that the changes caused confusion.

Facility Leaders Consultation with VHA Leaders Regarding Hospitalists' Privileges

The OIG learned that facility leaders consulted with VHA leaders regarding hospitalists' privileges only after removing the hospitalists from providing care in the medical ICU. Through email correspondence, dated January 18, 2023, the DCOS-IO communicated with facility, section and service leaders, and hospitalists regarding hospitalists' privileges and ICU changes and stated that VHA's Office of General Counsel agreed with "the steps taken and recommended that we reach out to the national credentialing and privileging office for guidance." The Director, VHA Credentialing and Privileging gave the OIG evidence of email correspondence in which the DCOS-IO on January 18, 2023, asked for a meeting for discussion regarding hospitalists' care practices. The Director, VHA Credentialing and Privileging offered consultation and referred the DCOS-IO to the National Program Director, VHA Hospital Medicine, and could not recall whether the requested meeting occurred or being involved in further follow-up.

During an interview, the Director, VHA Credentialing and Privileging told the OIG that a facility director is responsible for granting privileges to providers and usually obtains clinical guidance from a facility's medical staff. The Director, VHA Credentialing and Privileging was unable to advise on specific questions related to whether the hospitalists could have privileges in the ICU and reported that factors such as other approved clinical privileges, clinical training, and consultant availability would be considered in privileging decisions. The Director, VHA Credentialing and Privileging also reported a practice of involving VHA program offices for clinical input.

The COS reported having a discussion on January 20, 2023, with the National Program Director, VHA Hospital Medicine, who was also a facility hospitalist, regarding a concern that hospitalists did not have privileges to provide critical care. The National Program Director, VHA Hospital Medicine told the OIG of involvement in correspondence with the COS about hospitalists' privileges, however, was not included in discussions regarding hospitalists no longer providing care in the medical ICU.

Additionally, according to the COS, the DCOS-IO and COS consulted with the VHA Chief Officer, Specialty Care Services approximately two weeks after the change to remove hospitalists from providing care in the ICU. According to the DCOS-IO's email correspondence, the VHA Chief Officer, Specialty Care Services "recommended a model where hospitalists could provide care in the ICU at three different levels" described as

- Level 1 – a hospitalist who provides all general medical care for acute illnesses and is not involved in the ICU,
- Level 2 – a hospitalist who provides general medical care and manages critical illness with competencies for critical care and procedures, and
- Level 3 – a hospitalist "requiring additional training, proctorship and competencies."

The DCOS-IO consulted with the VHA National Director, Pulmonary and Critical Care on January 26, 2023, for further guidance on hospitalists' privileges. The VHA National Program Director, Pulmonary and Critical Care reported that PCCMs usually support hospitalists in the ICU and recommended that hospitalists who regularly work in the ICU complete a two-day critical care course. On January 27, 2023, a section leader informed the DCOS-IO that the hospitalists had collectively decided not to pursue changes to their privileges.

Further ICU Provider Coverage Changes

The COS told the OIG of tasking the ACOS-E and a risk manager to review ICU practices on March 17, 2023, due to concerns regarding patient care and provider communication. In response, according to email correspondence the next day, the ACOS-E and risk manager observed ICU operations during the overnight shift. The ACOS-E and risk manager communicated concerns regarding intubation practices and provided recommendations to the COS and DCOS-IO that included revising provider coverage in the medical ICU.[45] The ACOS-E also offered possible solutions that included increasing ACCNP coverage and adding PCCM attending on-site 24-hour coverage. The COS subsequently held a meeting with facility leaders that day when it was determined the medical ICU needed a PCCM attending on-site 24/7 and, while recruiting PCCM attendings, ACCNPs would receive training on critical care medicine and invasive procedures. A section leader told the OIG that PCCM attendings were required to see overnight ICU patient admissions in person. This plan was unsustainable due to the inability for PCCM attendings to maintain ICU staffing coverage 24/7.

[45] *Merriam-Webster.com Dictionary*, "intubation," accessed February 20, 2019, https://www.merriam-webster.com/dictionary/intubated. Intubation is the insertion of a tube in the trachea to maintain the airway and provide ventilatory support.

In correspondence to the Facility Director on April 19, 2023, the COS stated that recruitment of five additional PCCM attendings and expanding the surgical ACCNPs responsibilities to care for all ICU patients including medical ICU patients were in process.

On May 17, 2023, surgical ACCNPs completed a two-day critical care course. Five days later instead of ICU residents assigned to provide overnight coverage for the medical ICU patients, ACCNPs were assigned with on-call PCCM attendings and fellows for assistance as needed.

During an interview with the OIG in July 2023, the COS reported efforts to improve on-site ICU staffing by approving three new PCCM attending positions and an ICU medical director. Later that month, the ACOS-E was appointed as the new ICU medical director in addition to having the ACOS-E position.

The OIG concluded that, although a VHA team recommended the facility initiate a closed ICU model in March 2021, facility leaders implemented changes beginning on January 3, 2023, without adequate planning and involvement of facility subject matter experts. In accordance with HRO principles and TJC standards, the OIG would have expected facility leaders to plan and involve service and section leaders and staff before implementing changes.

3. Lack of Resident Supervision and Ineffective Teaching Environment

The OIG substantiated that the ICU model change resulted in a lack of ICU resident supervision and an ineffective teaching environment for ICU residents. The OIG determined that although residents were instructed to rely upon TeleCritical Care providers, residents did not have on-site supervision or clear instructions for escalating patient concerns to PCCM attendings and fellows. Additionally, leaders failed to comply with VHA and Accreditation Council for Graduate Medical Education (ACGME) policies by implementing a change in the level of resident supervision without involving the residency program.

The OIG learned through an interview and review of an electronic communication, that the ICU residents were notified of the decision to remove hospitalists from the ICU and advised that PCCM attendings or fellows would provide overnight on-call off-site supervision the same day of implementation. After the change, ICU residents reported concerns to service leaders and in program evaluations citing lack of on-site supervision, increased patient safety risks, diminished resident education quality, and decreased overall satisfaction.

VHA policy states that the facility COS or designee ensures "the presence of a work environment that is consistent with quality patient care and the educational needs of residents that meet all applicable program requirements."[46]

[46] VHA Directive 1400.01.

Through document review and interviews with the OIG, ICU residents reported concerns of feeling insufficiently supported and increasingly concerned about not being able to perform "well or safely." More specifically, residents reported that they were not involved in decision-making, attendings and fellows were not consistently aware of changes to the workflow, and there was a lack of clarity regarding how residents should manage conflicting opinions from providers, such as PCCM, TeleCritical Care, and specialty care attendings.

A series of changes were made between January 3 and May 22, 2023, that affected the ICU workflow (see table 1).

Table 1: Timeline of Events Affecting ICU Workflow

Date	Event
January 3, 2023	COS identified concern with hospitalist privileging for patient management in ICU. Hospitalists removed from treating critical care patients in ICU. TeleCritical Care utilized for emergent issues or when PCCM attendings or fellows were unavailable or delayed.
January 3, 2023	Residency program notified "of changes to the [ICU resident] supervisory structures."
January 4, 2023	Residency program did not approve of ICU residents working overnight without on-site direct supervision.
January 17, 2023 approximate	Staff directed to initiate TeleCritical Care model starting on February 6, 2023.
February 3, 2023	Due to the plan for TeleCritical Care on February 6, 2023, and absence of guidance, the chief residents developed a workflow (resident ICU workflow) for overnight ICU patient admissions that outlined parameters for review of overnight admissions.
February 6, 2023	TeleCritical Care model initiated without an outlined protocol. ICU residents were to review all ICU patient admissions with a TeleCritical Care provider and to contact PCCM attendings or fellows with concerns or requests for assistance.
February 24, 2023	Chief residents updated the February 3, 2023 resident ICU workflow with information to call a PCCM fellow following a review of an admission with TeleCritical Care for any unstable ICU patient. Also, additional requirement to contact the PCCM attending if a fellow did not respond to the phone call in 15 minutes and for "major [patient] clinical changes."
March 7, 2023	Rounding with the TeleCritical Care providers was discontinued due to being "unhelpful."
March 18, 2023	Changes for ICU residents to consult with the PCCM attending who would evaluate all overnight admissions and transfers.
March 28, 2023	Chief residents updated the resident ICU workflow with a change that the PCCM attending or fellow will see all overnight ICU patient admissions in person and review ICU patient admission with ICU residents. Requirement added for an ICU resident to contact the PCCM attending directly if a patient required intubation.

Date	Event
April 5, 2023	ICU residents to contact a PCCM attending to determine if an overnight ICU patient admission required an in-person PCCM attending or fellow evaluation. A nocturnist was to contact the PCCM attending directly after evaluating a patient for ICU admission from the Emergency Department or a medical unit and determining a higher level of care was warranted, "taking the resident out of that chain of communication."*
April 7, 2023	Chief residents updated the ICU resident workflow with changes.
May 16, 2023	DCOS-IO notified staff of change for patient hand-off procedures from ACCNPs to daytime residents and that recruitment for ICU PCCM attendings was underway.
May 22, 2023	Surgical ACCNPs began providing overnight coverage for medical ICU patients and ICU admissions.
	ICU residents removed from providing overnight ICU patient care and a daytime ICU rotation was initiated.

Source: OIG analysis of facility staff interviews and documentation.

In an effort to address residents' concerns, a Service leader reported communicating weekly with facility leaders (ACOS-E and DCOS-IO) for several months beginning January 5, 2023.[47] Through interviews and a document review, the OIG learned that facility leaders' first attempt to address ICU residents' concerns included the use of TeleCritical Care services, which ICU residents reported did not provide a satisfactory solution for the lack of on-site supervision.

The OIG also learned that additional resident workflow changes occurred on March 28, 2023, when ICU residents were to contact a PCCM attending or fellow for all overnight ICU patient admissions and transfers. A PCCM physician would then evaluate the patient in person. A service leader and a section leader reported that this plan was not tenable for the limited number of PCCM attendings and fellows on staff, who were also working during the day. The document review further showed that on April 5, 2023, the ICU overnight residents were informed that a PCCM attending would instead determine by whom and when an in-person patient evaluation was needed. The OIG learned through review of electronic communications and interviews of a change to be initiated on May 22, 2023, when the ACCNPs began providing overnight coverage for medical ICU patients and ICU admissions; the overnight ICU resident rotation was discontinued.[48]

In an interview with the OIG, a section leader reported that adjustments in workflow were constant and there were no facility protocols for ICU residents to use TeleCritical Care or how to escalate concerns with on-call PCCM attendings or fellows. The staff member reported that, due to the absence of facility guidance, the chief residents developed and updated a resident workflow, which outlined parameters for contacting PCCM attending, fellow, and TeleCritical

[47] A service leader provided the feedback to the OIG and reported that the feedback was shared with facility leaders.

[48] A service leader reported that a new week-long rotation was created for the residents to serve in the ICU during daytime hours.

Care. An ICU resident reported to the OIG that the chief residents met with the ICU residents almost nightly during their rotations to ensure communication of the continuous changes to residents' ICU workflow.

The OIG reviewed ICU resident evaluations of the overnight rotation from July 4, 2022, through May 21, 2023, and determined satisfaction decreased for overnight ICU residents after the ICU model change (see figure 2).

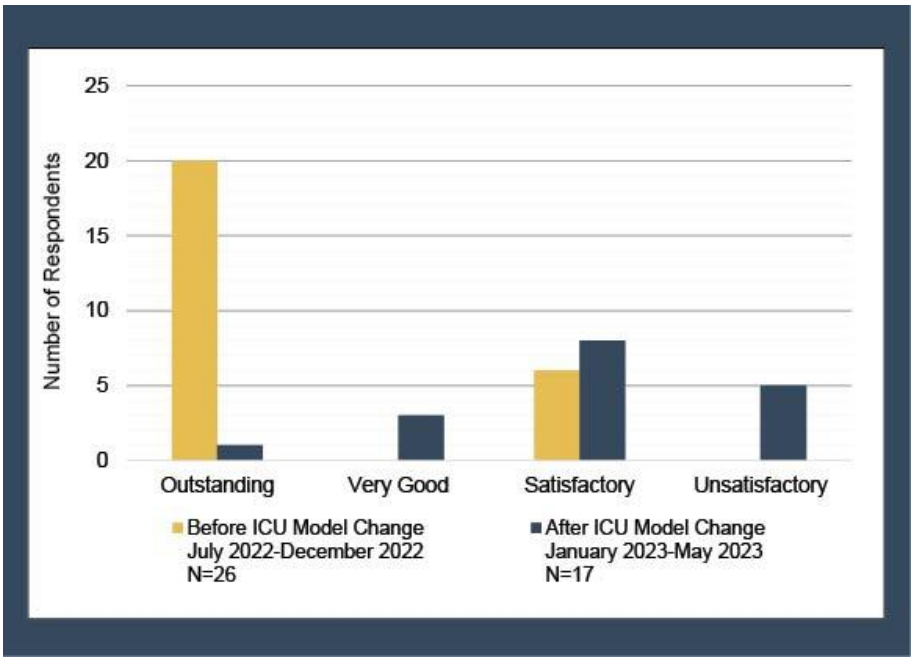

Figure 2. *Residents' Evaluation of ICU Overnight Rotation.*
Source: OIG analysis of ICU Resident Evaluations from July 4, 2022, through May 21, 2023.

The evaluations included ICU residents' narrative suggestions for improvement, such as the need for increased support and on-site supervision for procedures. Additionally, ICU residents noted concerns for patient safety issues and the ineffectiveness of virtual support provided by TeleCritical Care.

The OIG's review of email correspondences and interviews with section leaders, attendings, and a fellow noted similar concerns identified in ICU resident feedback regarding the impact of the ICU model change to the residency program.

Leaders' Failed to Provide Clear Processes for TeleCritical Care

The OIG determined that facility leaders expected attendings, fellows, and residents to utilize TeleCritical Care services to collaborate on ICU patient care, without providing written procedures or policy.

Through a document review and an interview with a section leader the OIG learned that beginning on February 6, 2023, TeleCritical Care providers would assist the ICU residents with

admissions and critical care assessment and treatment. Specifically, ICU residents were to contact TeleCritical Care providers first to review treatment of medical ICU patients and then consult with on-call PCCM attendings or fellows and other specialty consultants as needed.

Staff reported to the OIG that the messaging of the expectation to use TeleCritical Care was confusing and lacked written protocols. For example, a section leader told the OIG there was no plan for resident supervision and an expectation that TeleCritical Care providers could provide supervision, which the OIG learned was against VHA policy and the tele service agreement. As stated in VHA policy and the tele service agreement, residents may not be supervised by TeleCritical Care providers.[49]

The ACOS-E provided the OIG with an unsigned facility standard operating procedure for use of overnight TeleCritical Care in the ICU dated February 28, 2023. Staff reported that, due to the absence of facility guidance, the chief residents developed workflows, which outlined parameters for contacting PCCM attendings or fellows and TeleCritical Care. A section leader acknowledged that the decision to use TeleCritical Care was based on the successful use in other VA medical centers, and was implemented as the primary contact for ICU residents for approximately two months and was then changed to a PCCM attending.

The OIG concluded that the ICU model change and utilization of TeleCritical Care, without providing procedures or policy, negatively affected ICU residents supervision and work environment. Additionally, TeleCritical Care providers were utilized for overnight resident supervision, which was against VHA policy and the tele service agreement. Residents reported decreased satisfaction and the need for increased support and on-site supervision for overnight ICU patient care. Further, establishment of procedures for utilizing TeleCritical Care would have been an important element in planning and would have equipped the ICU residents with an understanding of the relationship between the facility ICU and TeleCritical Care.

Failure to Involve Residency Program in Supervisory Change

The OIG determined that facility leaders failed to comply with VHA policy by implementing a change in the level of resident supervision without the approval of the residency program. VHA policy requires that "a supervising practitioner must be approved by the program [director] of the residency program in order to supervise residents."[50] VHA also requires that facilities abide by ACGME standards, which state that the residency program is to delineate when resident on-site

[49] VHA Directive 1400.01; VA, *TeleCritical Care (TELECC) Interfacility Telehealth Service Agreement*.
[50] VHA Directive 1400.01.

supervision is needed.[51] Further, VHA states that facility directors are responsible for verifying the facility's adherence to ACGME standards "for all matters pertaining to the resident training program, including the level of supervision provided."[52]

In a review of an email correspondence, the OIG found that a section leader notified the residency program on January 3, 2023, after facility leaders communicated to staff the "changes to the [resident] supervisory structures." In interviews, the OIG learned that the residency program was not involved in the decision to remove on-site supervision and that "supervision of the [residents] is really the discretion of the [residency] program director and [the supervision of residents] has to meet . . . the requirements of the program." The OIG reviewed email correspondence from the day after hospitalists were removed from providing care in the ICU (January 3, 2023), in which the COS and ACOS-E were informed by the residency program that ICU residents working overnight without on-site direct supervision was not allowed.

During an interview with the OIG, the ACOS-E acknowledged the residency program leader was not consulted prior to removing the hospitalists from the ICU, recalling

> the decision [to remove the hospitalists] by [the] COS . . . was I think late in the day . . . we did not really have a lot of stakeholders that could have been brought in for that discussion that did not happen . . . but gradually we talked to [the residency program] about what changes were happening.

The Facility Director reported to the OIG the expectation for the COS to manage resident education supervision and related policies. The OIG confirmed, through email correspondences, that facility leaders and the residency program jointly decided to remove ICU residents from overnight patient care in May 2023.

The OIG concluded that the Facility Director and COS failed to abide by VHA policy and ACGME requirements when the ICU resident supervision structure was altered without the approval of the residency program leader.

[51] VHA Directive 1400.01. VHA specifically notes that per ACGME, a residency program leader must approve a supervising practitioner. Accreditation Council for Graduate Medical Education, *ACGME Common Program Requirements (Residency)*, July 1, 2022. These requirements were in place during the time of the events discussed in this report. The requirements were revised on July 1, 2023. The revised 2023 requirements 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 as the 2022 requirements.

[52] VHA Directive 1400.01.

4. Alleged Patient Harm

The OIG did not substantiate that the ICU model change resulted in patient harm to the four patients reviewed.[53] The OIG determined that PCCM fellows and ICU residents coordinated care that met the needs of critically ill patients.

TJC requires coordination of patient care and treatment within a time frame that meets the patient's needs, recognition of and response to changes in patient condition, and patient assessment and reassessment by qualified staff.[54]

The OIG interviewed facility staff and reviewed the EHRs of four patients identified by facility staff who received care after the ICU model change.[55] During interviews, seven providers reported care concerns for a patient (Patient 1), including unavailability of on-site physician support for ICU residents, unclear escalation of physician support for earlier interventions, and inadequate ICU resident support from TeleCritical Care providers.

Patient 1's care illustrates the confusion over who was responsible for clinical decision-making and the lack of support for an ICU resident during a patient's rapid decline.

> *Patient 1 was a 72-year-old with a history of atrial fibrillation, gout, and hyperlipidemia who presented to the Emergency Department in early winter of 2023 with a three and a half week history of shortness of breath and a dry cough.[56] The patient was found to have atrial fibrillation with a rapid heart rate and was given intravenous fluids and a medication for heart rate control. The Emergency Department attending consulted the cardiologist who recommended withholding additional heart rate control medication. After discussion with the ICU overnight resident the patient was admitted to the medical ICU for further management. A computerized tomography scan showed changes concerning for heart failure and possible pneumonia.[57] Upon arrival to the medical ICU, after consultation with a cardiologist, the patient received additional heart rate control medications and antibiotics. The ICU resident discussed the admission with a*

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[53] The OIG defined patient harm as a significant negative impact on the patient's care, including delays in care.

[54] The Joint Commission *Standards Manual*, *E-dition*, PC.02.02.01, PC.02.01.19, and PC.01.02.05, March 14, 2021.

[55] The OIG provides two of the four patients to illustrate examples of processes in the ICU at the times of the events.

[56] "Atrial fibrillation," Mayo Clinic, accessed June 9, 2020, https://www.mayoclinic.org/diseases-conditions/atrial-fibrillation/symptoms-causes/syc-20350624. Atrial fibrillation is an irregular heart rate; *Merriam-Webster.com Dictionary*, "gout," accessed September 21, 2023, https://www.merriam-webster.com/dictionary/gout. Gout is "a metabolic disease marked by a painful inflammation of the joints, deposits of urates in and around the joints, and usually an excessive amount of uric acid in the blood,"; "Nutritional Services for Pediatric Gastrointestinal Conditions," Johns Hopkins All Children's Hospital, accessed May 14, 2020, https://www.hopkinsallchildrens.org/Services/Nutrition/Psediatric-Gastrointestinal-Conditions. Hyperlipidemia is a condition of abnormal or elevated cholesterol levels.

[57] "CT scan," Mayo Clinic, accessed May 15, 2020, https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675. A computerized tomography scan is a series of x-ray images that uses computer processing to diagnose disease or injury.

TeleCritical Care provider who made a medication recommendation for diuresis and atrial fibrillation rate control.[58] The TeleCritical Care provider did not place any orders in the patient's chart. The ICU resident ordered the recommended medication.

The ICU resident documented receiving a call approximately 90 minutes later stating that the patient was experiencing respiratory distress.[59] Per the ICU resident's documentation, the patient appeared in respiratory distress and was sitting on the edge of the bed receiving oxygen. The TeleCritical Care recommended placing the patient on additional non-invasive ventilation support.[60] The patient's respiratory status declined. When the patient became unresponsive, a respiratory therapist intubated the patient. While the patient was declining, an ICU resident called the PCCM fellow to communicate the change in the patient's clinical status. The PCCM fellow started driving to the hospital to further assist with management.

Shortly after intubation, the patient experienced a cardiac arrest.[61] The nocturnist presented to the patient's bedside to assist with patient management and documented that the patient had return of a sustained heartbeat and circulation after receiving medications and chest compressions. The nocturnist then helped to stabilize the patient with the ICU resident until the PCCM fellow arrived. After arriving to the ICU, the PCCM fellow took over the care of the patient and continued managing the patient's care overnight. The following morning, the PCCM attending, who had not been contacted the previous night, and the cardiology and renal consult teams saw the patient and made recommendations for continued care. However, given the patient's worsening clinical condition and poor prognosis, the family decided to withdraw care. The patient expired shortly thereafter in the early afternoon.

During an interview with the OIG, an ICU resident expressed that during Patient 1's rapid decline, the TeleCritical Care attending's input was not helpful. A PCCM attending reported that fellows had been directed to contact the PCCM attending when the fellow was required to come to the facility for a patient who was intubated. However, the PCCM attending reported not being

[58] *Merriam-Webster.com Dictionary*, "diuresis," accessed October 17, 2023, https://www.merriam-webster.com/dictionary/diuresis. Diuresis is an increased excretion of urine.

[59] *Merriam-Webster.com Dictionary*, "acute respiratory distress syndrome," accessed September 19, 2023, https://www.merriam-webster.com/dictionary/acute%20respiratory%20distress%20syndrome#medicalDictionary. Respiratory decline or failure is the onset (often sudden) of rapid breathing and very low levels of oxygen in the blood.

[60] "non-invasive ventilation," Indian Journal of Critical Care Medicine, accessed January 6, 2024, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7085817/pdf/ijccm-24-S61.pdf. Non-invasive ventilation involves the delivery of oxygen into the lungs (ventilation) without the use of intubation tubes into the airway.

[61] "Sudden Cardiac Arrest," Mayo Clinic, accessed February 1, 2019, https://www.mayoclinic.org/diseases-conditions/sudden-cardiac-arrest/symptoms-causes/syc-20350634. Cardiac arrest "is the abrupt loss of heart function, breathing, and consciousness."

contacted and that "this was a patient that I needed to be . . . by the bedside making decisions" and proposed that the TeleCritical Care attending's involvement in the care may have been a reason for not being called.

The OIG determined that the on-call PCCM fellow provided timely response to the resident in accordance with the COS's expectation that PCCM attendings and fellows respond to calls within 15 minutes and be available in the facility within 60 minutes. The TeleCritical Care attending was available to support the ICU resident, and the nocturnist responded to the code as expected. However, for Patient 1, the PCCM attending was not contacted as expected. While the OIG did not substantiate patient harm, the OIG found that unclear guidance for call escalation may put patients at risk for adverse clinical outcomes.

In October 2023, the COS provided the OIG a draft facility policy to improve call escalation by residents and fellows to an ICU attending provider.[62] The OIG reviewed the draft policy and found intubation identified as a condition that would warrant a resident or fellow to notify an attending.[63] The OIG would expect facility leaders to ensure the draft policy is finalized and that attendings, fellows, residents and staff are trained on the policy.

During interviews with the OIG, five providers involved in a second patient's (Patient 2) care reported a concern related to unavailability of on-site physician support for ICU residents and unclear escalation of physician support for earlier interventions.

Patient 2's care illustrates an on-site nocturnist's support for an ICU resident during the patient's rapid decline.

> *Patient 2 was a 73-year-old with past medical history significant for terminal esophageal cancer, anemia, and malnutrition who was admitted to the facility medical ICU in late winter 2023 with altered mental status, which improved with intravenous fluids and correction of electrolyte disturbances.[64] The patient was transferred to a medical unit the following day. Five days later, a medical resident caring for the patient documented the cancer was not treatable and that the patient's care would focus on comfort and independence. The patient started consuming a clear liquid diet. Later that evening, the patient had an aspiration event and was found by a registered nurse with vomitus on the pillow, cough, and increasing oxygen requirements. The patient improved with*

[62] Facility Draft Policy MCP – 11-55, *Call Escalation of Communication*, October 2023.

[63] Facility Draft Policy MCP – 11-55.

[64] "Anemia," accessed October 31, 2019, https://www.mayoclinic.org/diseases-conditions/anemia/symptoms-causes/syc-20351360?p=1. Anemia is a lack of "healthy red blood cells to carry adequate oxygen to [the] body's tissues;" "electrolyte imbalance," Cleveland Clinic, accessed October 17, 2023, https://my.clevelandclinic.org/health/symptoms/24019-electrolyte-imbalance. "An electrolyte imbalance occurs when certain mineral levels in [the] blood get too high or too low."

supplemental oxygen and airway suctioning.[65] *However, 15 minutes later, the registered nurse documented that the patient had another episode of vomiting and required more oxygen and that the resident and nocturnist came to the patient's bedside and decided to transfer the patient to the medical ICU. The nocturnist documented that the PCCM fellow was called regarding the change in the patient's clinical status. The nocturnist made several unsuccessful attempts to contact the patient's family member to update them of the patient's clinical change and to clarify the patient's wishes for medical intervention.*

Upon arrival to the ICU, the patient experienced a change in mental status and became less responsive with a drop in blood pressure. The on-call PCCM fellow documented receiving a call about the patient's change in mental status and drop in blood pressure. The PCCM fellow communicated to the nocturnist and ICU resident a plan to come to the hospital, inform the PCCM attending, and advised to delay intubation of the patient until their arrival to the bedside. The PCCM fellow documented receiving a call five minutes later with the update that the patient had further vomiting and was asked for permission to intubate the patient. The PCCM fellow agreed with the need for intubation and the respiratory therapist was able to intubate the patient. The PCCM fellow managed the patient's care upon arriving to the ICU. The patient continued to decline and died the same afternoon after the family decided to withdraw care.

The OIG found that a nocturnist completed an assessment and made emergent treatment decisions during Patient 2's clinical deterioration. The OIG concluded that patient harm did not occur despite the ICU model change because of the nocturnist's involvement and responsiveness to the patient's rapidly changing clinical status.

5. Deficiency in Root Cause Analysis Process

The OIG reviewed the facility's patient safety reports, a root cause analysis, and EHR documentation related to Patient 1's care and identified a deficiency in the facility's completion of the root cause analysis. Specifically, the OIG determined that the root cause analysis team did not interview individuals vital to Patient 1's ICU care and treatment.[66]

[65] "Aspiration," US National Library of Medicine, MedlinePlus, accessed March 1, 2019, https://medlineplus.gov/ency/article/002216.htm. Aspiration is "breathing in a foreign object." Airway suctioning is "a medical procedure that removes substances" from the airway.

[66] The OIG found that a root cause analysis was not completed for Patient 2.

VHA promotes reporting adverse events and close calls as the primary mechanism to identify system vulnerabilities.[67] Review of reported events provide opportunities for evaluation of root causes and contributing factors, which guide actions to prevent recurrence.[68] A root cause analysis is a process used to identify the contributing factors to patient safety adverse events or close calls and focus on systems and processes rather than individuals.[69] VHA provides guidance for conducting a root cause analysis including how to appoint and train a team, establish the sequence of events using facts, and gather relevant information.[70] VHA requires individuals directly involved with an adverse event "be interviewed as part of the [root cause analysis] process and asked for suggestions about how to prevent the same or similar situations from happening again."[71]

The Facility Director chartered a root cause analysis of Patient 1's ICU care. During interviews with the OIG, an attending and a resident who were involved in the patient's care told the OIG that the root cause analysis review team did not interview them.[72] When the OIG asked whether the staff members involved in Patient 1's treatment were interviewed by the root cause analysis team, a service leader reported that typically a review team interviews providers involved in the care.

The OIG found differing reports related to attendings, or residents' participation in the review of Patient 1's care and had concerns that the facility's review analysis and findings were made without interviewing relevant providers. The OIG concluded that omitting relevant providers from the review was a missed opportunity to identify improvements in the provision of patient care and processes.

Conclusion

The OIG was unable to determine whether facility leaders made changes to the surgical ICU without adequate planning in April 2022. However, the OIG found that the lack of 24/7 ICU provider coverage for surgical patients adversely affected the provision of CT surgical services

[67] VHA, *VHA National Center for Patient Safety Guidebook for JPSR Business Rules and Guidance*, November 2021. VHA encourages facility staff to identify and report adverse events, utilizing a web-based reporting system. VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This directive was replaced by VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. Unless noted, the requirements for patient safety reviews remains the same in both documents. The directive states that "Adverse events are untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm directly associated with care or services delivered by VA providers."

[68] VHA National Center for Patient Safety, *Guide to Performing Root Cause Analysis*, Version 11, October 2023.

[69] VHA National Center for Patient Safety, *Guide to Performing Root Cause Analysis,* Version 11.

[70] VHA National Center for Patient Safety, *Guide to Performing Root Cause Analysis*, Version 11.

[71] VHA National Center for Patient Safety, *Guide to Performing Root Cause Analysis*, Version 11.

[72] The OIG reviewed a list of facility staff interviewed by the RCA team and interviewed one of the two staff members on the list, in addition to two other staff members directly involved in the patient's intubation.

and led to the resignation of the section chief of CT surgery. As of August 2023, no CT surgical procedures had been performed at the facility for 11 months, and all CT surgical staff had either resigned or were terminated.

In April 2022, five ACCNPs either transferred to another service, resigned, or retired, which limited the 24/7 provider coverage necessary to care for CT patients. CT surgeries were paused from June to July 2022 while attempting to emergently hire providers. Efforts to secure ICU provider coverage for surgical patients were unsuccessful and in September 2022, there was a second CT surgery pause.

The OIG determined the COS failed to notify VA Central Office, through the VISN, of the second pause in CT surgical services. Although the former chief of surgery submitted preparatory briefing forms containing CT surgical pause information to the COS, the COS failed to submit an issue brief notifying VISN and VHA leaders of the curtailment of CT surgical services at the facility.

The Facility Director, COS, DCOS-IO, and the acting chief of surgery proceeded with plans to resume CT surgeries following an 11-month CT surgical pause and the loss of all facility CT surgical staffing, without notifying or seeking approval from VISN and VA Central Office leaders. The OIG found these conditions met criteria for a major augmentation of clinical services requiring the approval of the Under Secretary for Health or designee, as outlined in VHA policy. Further, the OIG found that the absence of a detailed, interdisciplinary evaluation and plan to be concerning and escalated concerns about facility's readiness to safely conduct a CT surgical procedure to the VISN Director in August 2023. The VISN Director requested NSO conduct a CT surgery program review prior to restarting CT surgeries; the consultative site visit was scheduled for September 2023 and CT surgeries resumed in late October 2023.

Facility leaders' actions to change the ICU model were made without adequate planning and input from service and section leaders and staff. The COS notified service leaders that due to a privileging concern there was a need to change medical ICU physician coverage from hospitalists to PCCM attendings and fellows. The notification occurred only hours prior to implementing the change. In accordance with HRO principles and TJC standards, the OIG would have expected facility leaders to plan and involve service and section leaders, and staff before implementing the change to a closed ICU model.

The OIG substantiated that the sudden implementation of a closed ICU model resulted in a lack of ICU resident supervision and ICU residents' reliance on on-call attendings or fellows rather than on-site nocturnists, and created an ineffective work environment that failed to meet the educational needs of the ICU residents. Relatedly, the OIG determined that an expectation to utilize TeleCritical Care services to assist overnight admissions and critical care decision-making in the ICU, was implemented by facility leaders without providing written procedures or a policy. Additionally, facility leaders failed to comply with VHA policy and ACGME

requirements by implementing a change in the level of resident supervision without approval of the residency program.

The OIG reviewed resident evaluations of the overnight rotation from July 4, 2022, through May 21, 2023, and determined there was decreased resident satisfaction with the overnight rotation after the ICU model change. The evaluations included ICU residents' narrative suggestions for improvement such as the need for increased support and on-site supervision for procedures, concerns for patient safety issues, and the ineffectiveness of virtual support provided by TeleCritical Care.

The OIG did not substantiate that the ICU model change resulted in patient harm. The OIG determined that PCCM fellows and ICU residents coordinated care, which met the needs of critically ill patients. However, the OIG found that despite the expectation for a PCCM fellow to contact a PCCM attending for a patient who has been intubated, the attending for Patient 1 was not contacted. While the OIG did not substantiate patient harm in the cases reviewed, the OIG found that unclear guidance for when PCCM fellows must contact PCCM attendings may put patients at risk for adverse clinical outcomes. Patient harm did not occur for Patient 2, despite the ICU model change because of the nocturnist's involvement and responsiveness during the patient's rapidly changing clinical status.

The OIG found differing reports related to attendings or residents' participation in the review of Patient 1's care and had concerns that the facility's root cause analysis and findings were made without interviewing relevant providers.

Recommendations 1–6

1. The Under Secretary for Health evaluates the circumstances that led to Veterans Integrated Service Network leaders' lack of awareness of the 11-month curtailment of cardiothoracic surgeries and takes action as needed to ensure effective Veterans Integrated Service Network oversight of facility clinical operations.

2. The Veterans Integrated Service Network Director evaluates the circumstances that led to the failure of VA Eastern Colorado Health Care System leaders to submit a proposal request and business plan to resume cardiothoracic surgeries after an 11-month pause to the Veterans Integrated Service Network Director for review and approval and takes action as needed.

3. The Veterans Integrated Service Network Director ensures facility leaders implement high reliability organization principles to plan for clinical operation changes that include stakeholders, service and section leaders, and staff input.

4. The Veterans Integrated Service Network Director ensures that the educational needs of the facility's residents are evaluated and maintained during service and program changes, including on-site supervision, as required by Veterans Health Administration directive.

5. The VA Eastern Colorado Health Care System Director reviews and finalizes Facility Draft Policy 11-55 titled *Call Escalation of Communication* and trains attendings, fellows, residents, and staff members on the policy.

6. The VA Eastern Colorado Health Care System Director reviews root cause analysis requirements for interviewing individuals relevant to root cause analyses and ensures staff are trained accordingly.

Appendix A: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: June 5, 2024

From: Under Secretary for Health (10)

Subj: Office of Inspector General (OIG) Draft Report, Extended Pause in Cardiac Surgeries and Leaders' Inadequate Planning of Intensive Care Unit Change and Negative Impact on Resident Education at the VA Eastern Colorado Health Care System in Aurora

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on OIG's draft report on Extended Pause in Cardiac Surgeries and Leaders' Inadequate Planning of Intensive Care Unit Change and Negative Impact on Resident Education at the VA Eastern Colorado Health Care System in Aurora. The Veterans Health Administration (VHA) is committed to ensuring that high reliability principles are implemented to ensure a strong culture of safety and continuous improvement. VHA concurs with recommendation 1 made to the Under Secretary for Health and provides an action plan in the attachment. Veterans Integrated Service Network 19 provides the responses to recommendations 2-4 and the Eastern Colorado Health Care System provides the responses to recommendations 5-6.

2. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at VHA10BGOALACTION@va.gov.

(*Original signed by:*)

Shereef Elnahal M.D., MBA

VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan

OIG Draft Report, Extended Pause in Cardiac Surgeries and Leaders' Inadequate Planning of Intensive Care Unit Change and Negative Impact on Resident Education at the VA Eastern Colorado Health Care System in Aurora (OIG Project Number 2023-02179-HI-1368)

Recommendation 1. The Under Secretary for Health evaluates the circumstances that led to Veterans Integrated Service Network leaders' lack of awareness of the 11-month curtailment of cardiothoracic surgeries and takes action as needed to ensure effective Veterans Integrated Service Network oversight of facility clinical operations.

VHA Comments: Concur

The Assistant Under Secretary for Health for Operations will perform an evaluation into the circumstances that led to Veterans Integrated Service Network leaders' lack of awareness of the 11-month curtailment of cardiothoracic surgeries and will take any necessary actions as a result of that assessment. This evaluation will include interviews with staff and a review of policies. There have been changes in key leadership positions and the Network Director has established oversight expectations to include the establishment of an Oversight Officer role and the creation of a communication matrix to ensure the sharing of information and decision-making.

Status: In Progress Target Completion Date: October 2024

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: April 2, 2024

From: Director, Rocky Mountain Network (10N19)

Subj: Office of Inspector General (OIG) Draft Report, Extended Pause in Cardiac Surgeries and Leaders' Inadequate Planning of Intensive Care Unit Change and Negative Impact on Resident Education at the VA Eastern Colorado Health Care System in Aurora

To: Office of the Under Secretary for Health (10)
Director, Office of Healthcare Inspections (54HL09)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. We are committed to ensuring Veterans receive quality care that utilizes the high reliability pillars, principles, and values including leadership commitment, sensitivity to operations, and deference to expertise. We appreciate the opportunity to review and comment on the Office of Inspector General (OIG) report, Extended Pause in Cardiac Surgeries and Leaders' Inadequate Planning of Intensive Care Unit Change and Negative Impact on Resident Education at the VA Eastern Colorado Health Care System in Aurora.

2. Based on a thorough review of the report by VISN 19 Leadership, I concur with the recommendations and submitted action plans of Eastern Colorado Health Care System and VISN 19. These recommendations will be used to strengthen our processes and improve the care that is provided to our Veterans.

3. I would like to thank the Office of Inspector General for their thorough review and if there are any questions regarding responses or additional information required, please contact the VISN 19 Quality Management Officer.

(*Original signed by:*)

Sunaina Kumar-Giebel, MHA
Director, VA Rocky Mountain Network (10N19)

[**OIG comment**: The OIG received the above memorandum from VHA on June 7, 2024.]

VISN Director Response

Recommendation 2

The Veterans Integrated Service Network Director evaluates the circumstances that led to the failure of VA Eastern Colorado Health Care System leaders to submit a proposal request and business plan to resume cardiothoracic surgeries after an 11-month pause to the Veterans Integrated Service Network Director for review and approval and takes action as needed.

_X _Concur

____Nonconcur

Target date for completion: April 2024

Director Comments

The Network Director evaluated the circumstances pertaining to the resumption of cardiothoracic surgeries after an 11-month pause. The medical center identified that clinical vacancies had the potential to impact patient safety, necessitating the decision to pause cardiothoracic surgeries. After the medical center was able to successfully recruit key clinical positions for the cardiothoracic (CT) surgery program, the VISN provided oversight of facility plans through review by the Chief Surgical Consultant (VCSC). The VCSC confirmed with the Veterans Health Administration (VHA) National Surgery Office (NSO) that VHA Directive 1043 processes were not required for program restart but offered a consultative site visit. In early August 2023, the VISN requested the NSO complete an on-site CT program review and directed the medical center to not resume the program until the review was completed. At completion of its review, NSO supported facility plans for resuming the CT surgery program and provided guidance to the facility and VISN, beginning in October 2023. The VISN provided oversight to verify appropriate actions were taken to reinstate the CT surgery program in accordance with NSO guidance and existing national policies.

Additional actions by the VISN to prevent recurrence included process changes to communicate planning for clinical restructuring, new service, expansion of services, or restart of medical services and tracking through the VISN Oversight Officer. A site visit by the VISN or program office may be completed after review by VISN subject matter experts, when indicated. The VISN requests closure of this recommendation on publication.

OIG Comments

The VISN concurred with the recommendation and developed an acceptable action plan. The OIG considers this recommendation open to allow for time for the submission of documentation to support closure.

The OIG notes the VISN response included misinformation related to the VCSC's oversight of the facility's plans to resume the CT surgery program. As detailed in the report, when asked for evidence of VISN level awareness and engagement, facility leaders provided a brief email exchange initiated by the VCSC to the facility's acting chief of surgery in May 2023 (eight months after the second surgical pause) inquiring whether the facility was performing CT surgeries, and if not, whether the status was permanent or temporary. After being informed of concerns by the OIG in July and August 2023, the VISN Director acted promptly to ensure the facility's readiness to perform CT surgeries.

Recommendation 3

The Veterans Integrated Service Network Director ensures facility leaders implement high reliability organization principles to plan for clinical operation changes that include stakeholders, service and section leaders, and staff input.

_X _Concur

____Nonconcur

Target date for completion: October 2024

Director Comments

The Network Director will provide oversight as facility structures and processes are developed to include key stakeholders in shared decision-making to ensure open communication and collaboration occurs across facility levels. By engaging diverse groups in the planning phase, leaders can proactively identify and address concerns and leverage opportunities. The VISN High Reliability Officer will coordinate with the facility High Reliability Officer to attend applicable stakeholder meetings, support the development of communication plans associated with any changes in operations and ensure the VISN has visibility on facility's shared decision-making process.

Recommendation 4

The Veterans Integrated Service Network Director ensures that the educational needs of the facility's residents are evaluated and maintained during service and program changes, including on-site supervision, as required by Veterans Health Administration directive.

_X _Concur

____Nonconcur

Target date for completion: December 2024

Director Comments

The Network Director will ensure the residents' education needs are evaluated and maintained as required by VHA policy. The Associate Chief of Staff for Education (ACOS-E) and the residency program site directors will establish a regular cadence of meetings with VA and University facility executives, program directors, and key clinical leaders to set appropriate program and facility expectations. The Office of Academic Affiliations (OAA) conducted a site visit at the Eastern Colorado Health Care System and the University of Colorado in January 2024 to evaluate and create actions to improve the communication and relationship with the affiliate. As part of the action plan from OAA, the ACOS-E will alert the affiliate educational leadership of any significant changes in program management. Additionally, education leadership from the VA and University will meet at least quarterly to assess the status of resident learning and satisfaction. The Interim Director and Chief of Staff have met with leadership from the University and both sides continue to participate to ensure a collaborative relationship which benefits residents and Veteran patients. Finally, the ACOS-E will develop a local standard operating procedure (SOP) which defines the procedures to be followed for the monitoring of resident supervision and assignment of facility-level responsibility for monitoring inpatient, outpatient, procedural (including operating room care), emergency, and consultative care involving residents. The SOP will also outline the procedures to review patient safety, risk management, and quality improvement data involving residents to include results of health records and other locally derived quality management data, incident reports, tort claims, risk events including adverse events and "near misses," patient complaints, externally-derived quality management data such as External Peer Review Program (EPRP), and reports by accrediting and certifying bodies.

Appendix C: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: May 9, 2024

From: Interim Director, VA Eastern Colorado Health Care System (554/00)

Subj: Office of Inspector General (OIG) Draft Report, Extended Pause in Cardiac Surgeries and Leaders' Inadequate Planning of Intensive Care Unit Change and Negative Impact on Resident Education at the VA Eastern Colorado Health Care System in Aurora

To: Director, Rocky Mountain Network (10N19)

1. We appreciate the opportunity to work with the Office of Inspector General's Office of Healthcare Inspections as we continuously strive to improve the quality of healthcare for America's Veterans.

2. The Facility Director response to Recommendations 5 and 6 are provided on the attached document.

3. VA Eastern Colorado Health Care System and its leadership are committed to implementing high reliability principles to ensure a strong culture of safety and continuous improvement. Immediate and thorough actions have been initiated so that when the responsible provider is not able to be reached, the next senior provider is called (call escalation). Call escalation is addressed with a newly implemented policy in alignment with the principle of preoccupation with failure to mitigate potential risk.

4. VA Eastern Colorado Health Care System considers quality review and oversight to be vital to continuous improvement of processes and the care we provide. Root Cause Analyses (RCA) are one of the important quality management processes which ensure improvement and compliance. To meet compliance standards, these RCAs will be monitored through the governance structure and shared with the VISN Patient Safety Officer and Quality Management Officer. This tracking of RCA compliance aligns with the HRO principle of deference to expertise, so that all RCA team members will be knowledgeable and appropriately trained in pursuit of reducing the risk of harm. VA Eastern Colorado Health Care System is committed to our journey as a HRO and upholding a strong culture of safety.

(*Original signed by*:)

Amir Farooqi, FACHE
Interim Director

[**OIG comment**: The OIG received the above memorandum from VHA on June 7, 2024.]

Facility Director Response

Recommendation 5

The Eastern Colorado Health Care System Director reviews and finalizes Facility Draft Policy 11-55 titled *Call Escalation of Communication* and trains attendings, fellows, residents, and staff members on the policy.

_X _Concur

____Nonconcur

Target date for completion: August 2024

Director Comments

The Veterans Affairs (VA) Eastern Colorado Health Care System (ECHCS) developed medical center policy (MCP) 11-55 Call Escalation of Communication to standardize VA ECHCS' processes and procedures for the escalation of communication to promote patient safety/positive patient outcomes. The policy underwent extensive review among subject matter experts and stakeholders and was finalized March 2024.

ECHCS completed multiple dissemination actions on the new MCP call escalation procedures and has two planned training actions:

1. ECHCS used the "Did You Know" email to disseminate the new MCP, which includes quick blurbs directly from the MCP, the two repository locations for all-staff access to the MCP, as well as instructions for the wide audience to share with staff and disseminate through huddles and staff meetings.

2. ECHCS announced the new policy on the Daily Management System (DMS) electronic huddle boards, ensuring bilateral communication through the tiered huddle system.

3. ECHCS posted notification of the new policy in the all-staff accessed Rocky Mountain Minute weekly publication for VA ECHCS.

4. ECHCS disseminated an algorithm visual from policy in a "Quality Patient Safety Tid-bit" communication by the Chief, Quality and Patient Safety Service to the all-staff email group as part of continuous mission readiness efforts.

5. In addition to the above actions, ECHCS is planning for facility leadership to provide education on MCP 11-55 at the next Nursing Town Hall and at the next All Medical Staff meeting no later than July 31, 2024. The meeting is held virtually and recorded for staff who cannot attend.

To support the closure of this recommendation, ECHCS will provide OIG with documentation of the final MCP and attendance at the planned trainings.

The standardized MCP and the dissemination/training to all staff on the procedures for call escalation communication aligns with the HRO principle of "preoccupation with failure" by ensuring VA ECHCS learns from identified vulnerabilities and seeks to mitigate current and future risks.

Recommendation 6

The Eastern Colorado Health Care System Director reviews root cause analysis requirements for interviewing individuals relevant to root cause analyses and ensures staff are trained accordingly.

_X _Concur

____Nonconcur

Target date for completion: November 2024

Director Comments

The ECHCS Interim Director completed reviewing requirements for interviewing individuals relevant to root cause analyses. The ECHCS Patient Safety Managers (PSMs) will continue to charter and facilitate root cause analyses (RCAs) for all patient safety reports (PSRs) that result in a safety assessment code (SAC) score of 3 or more, in alignment with VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023.

The following requirements will be monitored for compliance and the results of the monitoring will be reported to leadership for awareness and action as appropriate:

1. Each RCA team member must complete the ECHCS Patient Safety RCA training course or must watch the RCA training video from National Center for Patient Safety.

2. Each RCA team member must sign and return the RCA Team Member Appointment Letter to Patient Safety, which certifies that one of the two trainings has been completed prior to the participant's first RCA meeting.

OIG Contact and Staff Acknowledgments

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