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OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

VHA's Response following Cardiac Catheterization Lab Closure at the Samuel S. Stratton VA Medical Center in Albany, New York

HEALTHCARE INSPECTION | REPORT #19-09129-76 | FEBRUARY 17, 2021

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess an allegation that the Cardiac Catheterization Lab (CCL) was closed due to significant concerns of risk to patients at the Samuel S. Stratton VA Medical Center (facility) in Albany, New York.[1]

The OIG received the allegation in summer 2019. Following an inquiry from the OIG regarding the allegation, the facility confirmed closure of the CCL and informed the OIG of reviews initiated to study CCL operations. The OIG requested additional information regarding the reviews; however, Veterans Integrated Service Network (VISN) staff who reviewed the facility's response did not respond to two subsequent requests.[2] Therefore, in early 2020, rather than making additional contacts with the Veterans Health Administration (VHA), the OIG opened a healthcare inspection to assess the multiple reviews and to ensure continuity of care for patients.

The OIG substantiated that the CCL was closed due to significant concerns of risk to patients and determined the closure was in response to a combination of issues including use of improper clinical procedural techniques, personnel disputes, and a hostile work environment. In June 2019, the Chief of Medicine informed facility leaders of issues in the CCL possibly affecting patient care. In July 2019, a facility fact-finding review identified concerns with communication and team dynamics among CCL staff, potentially affecting patient safety. As a result, facility leaders suspended all procedures in the CCL. Veterans in need of cardiology services no longer available due to the CCL closure were referred to community providers.

The OIG found that VISN and facility leaders acted promptly to obtain unbiased assessments when they arranged for an external review of the CCL by the National Cardiology Program Office (NCPO).[3] The NCPO made recommendations addressing a variety of concerns related to the clinical judgment and technical skills of the CCL cardiologists, including the development of a mechanism for improving the selection of cases appropriate for the facility services available to support the CCL, and ensuring that procedural complications were reported.

Based on one of the NCPO recommendations, facility leaders convened an administrative investigation board (AIB) on August 6, 2019, to review allegations of potential patient care

[1] "What is a Cardiac Catheterization Lab?" accessed June 9, 2020, https://www.ama-assn.org/specialty/interventional-cardiology. The CCL is a unit in the facility where interventional cardiologists (cardiologists with subspecialty training who treat cardiovascular disease with imaging, catheters, and specialized tools) insert catheters (thin, flexible tubes) through veins or arteries to access the heart and treat cardiovascular disease. American Medical Association, Interventional Cardiology.

[2] The facility prepared a response that lacked the facility leader's signature. This response was not forwarded to the OIG. While awaiting the signature, the VISN employee responsible for sending it to the OIG assumed a new role, and no one at the VISN tracked the failure to produce the response.

[3] The NCPO provides subject matter expertise to VA leaders on policy and strategy development in areas of cardiovascular topics. The NCPO lacks operational authority over the field.

concerns resulting from unprofessional relationships among CCL staff.[4] The AIB found that CCL staff comments undermined a cardiologist's reputation, and the marital relationship between a CCL physician and CCL nurse had not been properly reported, which created a tense and uncomfortable work environment in the CCL.[5] The AIB made five recommendations addressing the administrative structure and staffing of the CCL, training needs, assessment of clinical competence, and support services for staff.

In response to concerns raised by the NCPO regarding the clinical judgment and technical skills of CCL cardiologists, the Chief of Medicine initiated management reviews of the three CCL interventional cardiologists.[6] The reviews did not identify areas of concern for Cardiologist 1; however, the Chief of Medicine recommended additional educational activities and a more robust ongoing professional practice evaluation for Cardiologist 1.[7] For Cardiologists 2 and 3, the management review identified areas of concern. Cardiologist 2 was noted to select cases that were more complex than the facility had the surgical capability to support. In response, the Chief of Medicine recommended a focused professional practice evaluation for cause for Cardiologist 2.[8] For Cardiologist 3, the management review identified concerns in technical skills and interpretation of results for treatment recommendations. The Chief of Medicine proposed a plan to place Cardiologist 3 on a focused professional practice evaluation for new privileges should the CCL reopen at a later date.[9] CCL privileges for all three cardiologists were administratively removed due to the closure of the CCL.

The OIG determined that between the reviews of patient care completed by the NCPO team and the management reviews initiated by the Chief of Medicine, a thorough assessment of the CCL cardiologists' clinical competence was made by clinicians independent of the facility and well versed in interventional cardiology.

[4] Administrative investigations collect evidence to identify individual and process deficiencies needing correction. The AIB works at a facility level and is a group of people with the knowledge and expertise to sufficiently review the items of concern. The NCPO works at a national level and focused on the cardiovascular issues. Because the NCPO lacks operational authority over the field, it deferred items of concern related to unprofessional behavior to the AIB for further examination.

[5] As a result of the AIB, the Chief of Human Resources advised the CCL nurse married to the CCL physician be reassigned to another unit based on national guidelines advising married couples not work together or report to the same chain of command.

[6] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A management review is conducted within VA for purposes other than confidential quality assurance. These reviews are not protected by 38 U.S.C. 5705 and may be used for administrative investigations.

[7] VHA Directive 1190. "The ongoing monitoring of privileged providers to confirm the quality of care delivered and ensures patient safety."

[8] VHA Directive 1190. A focused professional practice evaluation for cause, like a performance improvement plan, allows a provider the opportunity to improve.

[9] VHA Directive 1190. A focused professional practice evaluation documents a provider's competency in practicing assigned privileges.

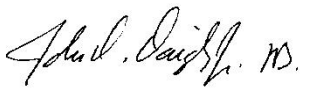
Based on the results of the external review by the NCPO, clinical care reviews coordinated by the facility, and the findings of the AIB, VISN and facility leaders decided that the CCL should remain closed indefinitely. A closure request was submitted to VHA in November 2019 and approved by VHA's Executive in Charge in January 2020.

According to the NCPO, its role is typically confined to advising VHA and facilities on policy matters. In this instance, the offering of recommendations by NCPO extended beyond policy matters and addressed operations, including the safe resumption of interventional cardiology at the facility. The OIG concluded that it would be prudent for VHA to appoint a specialty leader in interventional cardiology, whose responsibilities would extend to operational matters, who could ensure that VHA provides quality interventional cardiology services. VHA facilities without local subject matter expertise in highly specialized medical services could similarly benefit from VHA centralized specialty care subject matter expertise to assist in operational matters.

The OIG made three recommendations: two recommendations to the Under Secretary for Health regarding the designation of a VHA specialty leader in interventional cardiology and one recommendation to the VISN Director to review the circumstances that led to the failure to respond to an OIG request for additional information.

Comments

The Executive in Charge for the Office of the Under Secretary for Health and the VISN Director concurred with the recommendations and provided acceptable action plans (see appendixes B and C).[10] The OIG considers all recommendations open and will follow up on the planned and recently implemented actions to allow time for the facility to submit documentation of actions taken and to ensure they have been effective and sustained.



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[10] Recommendations directed to the Under Secretary for Health were submitted to the Executive in Charge who had the authority to perform the functions and duties of the Under Secretary for Health. Effective January 20, 2021, he was appointed to Acting Under Secretary for Health with the continued authority to perform the functions and duties of the Under Secretary.

Contents

Abbreviations

AIB	administrative investigation board
CCL	Cardiac Catheterization Lab
COS	Chief of Staff
FPPE	focused professional practice evaluation
NCPO	National Cardiology Program Office
OIG	Office of Inspector General
QMO	Quality Management Officer
VA	Veterans Administration
VAMC	Veterans Administration Medical Center
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted an inspection to assess an allegation that the Cardiac Catheterization Lab (CCL) was closed due to significant concerns of risk to patients at the Samuel S. Stratton VA Medical Center (facility) in Albany, New York.

Background

The facility is part of the New York/New Jersey VA Health Care Network, Veterans Integrated Service Network (VISN) 2, and serves 22 counties of upstate New York, western Massachusetts, and Vermont. Designated as Level 1c (high-level complexity), the facility provides primary and specialty care and is affiliated with Albany Medical College residency programs.[1] From October 1, 2018, through September 30, 2019, the facility served 35,748 patients.

CCL

A CCL is a hospital unit where, in lieu of surgery, cardiologists insert thin, flexible tubes or catheters, through veins or arteries to access the heart and treat cardiovascular disease. Using imaging equipment, the CCL team also assess how well blood flows to and from the heart.[2] From October 1, 2018, through September 30, 2019, 220 procedures were completed in the CCL with a staff of three cardiologists, three nurses, and two technicians.

Interventional Cardiology

Interventional cardiology is a specialty service performed by cardiologists who use imaging, catheters, and specialized tools to treat cardiovascular disease. This cardiology subspecialty requires a minimum of a one-year interventional cardiology fellowship in addition to the training required for the cardiology specialty. Cardiologists who perform invasive procedures in a CCL work with CCL nurses, who care for patients upon arrival, and CCL technicians, who assist cardiologists with procedures.[3]

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[1] VHA Office of Productivity, Efficiency, & Staffing. *Facility Complexity Level Model Fact Sheet*. "The Facility Complexity Model classifies VHA facilities at levels 1a, 1b, 1c, 2, or 3 with level 1a being the most complex and level 3 being the least complex." A level 1c facility has "medium-high volume, medium risk patients, some complex clinical programs, and medium sized research and teaching programs."

[2] "What is a Cardiac Catheterization Lab?" The Society for Cardiovascular Angiography and Interventions, accessed March 16, 2020, http://www.secondscount.org/treatments/treatments-detail-2/what-is-cardiac-catheterization-lab#.Xm9vX7CP42w.

[3] "Interventional Cardiology," American Medical Association, accessed June 9, 2020, https://www.ama-assn.org/specialty/interventional-cardiology. "What is a Cardiac Catheterization Lab?" The Society for Cardiovascular Angiography and Interventions, accessed June 9, 2020, https://www.ama-assn.org/specialty/interventional-cardiology.

Allegation and Related Concerns

On July 17, 2019, the OIG received an allegation that the CCL was closed due to significant concerns of risk to patients. On August 6, 2019, the OIG sent a case referral to the VISN requesting details related to the CCL closure, including the expected time frame for when the CCL would reopen, the process for veterans to receive CCL services during the closure, and the results of any reviews of patient care.

The VISN responded on October 7, 2019, explaining that facility leadership suspended activities in the CCL on July 3, 2019, following a fact-finding review initiated after the Chief of Medicine raised concerns with CCL operations on June 20, 2019. The VISN's response noted that complete restoration of CCL operations was dependent upon completion of an administrative investigation board (AIB) and recommendations of the National Cardiology Program Office (NCPO).[4]

The OIG reviewed the response and on November 25, 2019, requested additional information from the VISN specific to the AIB and NCPO external reviews. When the VISN did not respond, the OIG sent a second request for the information on January 15, 2020. The OIG followed with a third request on January 24, 2020, to which no response was received.

On January 28, 2020, the OIG opened a healthcare inspection to assess the allegation that the CCL was closed due to significant concerns of risk to patients and to review the actions taken following the closure of the CCL, including

- Disseminating information to staff and providers about the CCL closure, and
- Ensuring continuity of care for affected patients.

The OIG assessed multiple reviews requested by the facility related to CCL operations and patient care in the CCL as well as subsequent action plans:

- NCPO review of CCL operations and clinical care
- Facility's assessment of clinical competence for CCL physicians
- AIB findings related to allegations of a hostile work environment in the CCL
- Disposition of recommendations made in the internal facility fact-finding review NCPO, and facility AIB reports

[4] Administrative investigations collect evidence to identify individual and process deficiencies needing correction. The AIB works at a facility level and is a group of people with the knowledge and expertise to sufficiently review the items of concern. The NCPO works at a national level and focused on the cardiovascular issues. Because the NCPO lacks operational authority over the field, it deferred items of concern related to unprofessional behavior to the AIB for further examination. The NCPO team provide subject matter expertise to VA leaders on policy and strategy development in areas of cardiovascular topics.

During the inspection, the OIG identified concerns related to the lack of operational oversight authority granted to Veterans Health Administration's (VHA) national program offices.

The OIG also reviewed the failure of the VISN and facility to respond to OIG's request for additional information associated with an open case referral.

Scope and Methodology

The OIG initiated the inspection on January 28, 2020. From April 16, 2020, through May 21, 2020, the OIG interviewed staff involved with the closure of the CCL and actions taken following the closure to include the Facility Director, Chief of Staff (COS), Chief of Medicine, Chief of Quality Management, VISN Quality Management Officers, and the NCPO Director. In lieu of interviews, the OIG sent questions to the NCPO site visit team and received a written response. An on-site visit was not conducted for this inspection given ongoing concerns with travel and the potential spread of COVID-19.

The OIG reviewed relevant VHA and facility directives, handbooks, and policies. In addition, an internal fact-finding review, NCPO report, AIB report, and selected patient cases were reviewed. The OIG reviewed emails provided by the facility and VISN documenting communication between VHA's Central Office, the VISN, facility leaders and staff related to topics including the OIG case referral and closure of the CCL.[5]

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

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

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

[5] VHA's Central Office is in Washington, DC, and is the headquarters for VHA services, which provide centralized program direction to field facilities.

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

Inspection Results

1. Closure of the CCL

The OIG substantiated that the CCL was closed due to significant concerns of risk to patients. The OIG found that facility leaders took timely action when closing the CCL thereby reducing potential risk to patients.

In June 2019, the Chief of Medicine informed facility leaders of issues in the functioning of the CCL including quality of care and staff conduct concerns possibly affecting patient care. In July 2019, facility leaders suspended all procedures in the CCL. Veterans in need of cardiology services that were no longer available due to the CCL closure were referred to community providers.[6] VHA's Executive in Charge approved a request to discontinue catheter-based diagnostics and interventional cardiology services at the facility on January 15, 2020.

Closure Timeline

On June 20, 2019, the Chief of Medicine sent a memorandum to the COS, notifying him of risks to patients due to improper flushing of intra-arterial lines and issues related to personnel disputes, including a hostile, threatening working environment among staff in the CCL.

On June 21, 2019, after learning of the Chief of Medicine's concerns, facility leaders initiated a fact-finding review. The review was completed on July 2, 2019, and resulted in nine recommendations related to communication and team dynamics among CCL staff, potentially affecting patient safety (see appendix D).

Following the fact-finding review and in consultation with VISN leaders, facility leaders suspended activity in the CCL on July 3, 2019, to reduce potential risk to patients and allow time for facility leaders to conduct further reviews. On September 9, 2019, facility leaders reopened the CCL for some cardiac procedures including cardioversions and pacemaker implantation and

[6] VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety and Value*, August 2, 2013. This directive was in effect at the time of the events discussed in this report. It was rescinded on October 24, 2019. According to VHA directive, leaders in VHA must ensure that veterans are provided with high-quality health care, identify early warning signals of potential problems, and communicate information throughout the facility. VA MISSION Act of 2018, Pub. L. No. 115-182, § 132 (2018). If veterans are not ensured continuity of care at VHA facilities, the Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018 (MISSION Act) states that medical services will be also be provided to veterans through community health care providers, ensuring continuity of care.

management.[7] Catheter-based diagnostics and interventions remained on hold pending completion of an external review of the CCL. On November 4, 2019, the Facility Director submitted a proposed restructuring document to the VISN requesting closure of the CCL. Plans were put in place to relocate those procedures still done in the CCL to the operating room and cardiology procedure clinic space effective December 1, 2019. On January 15, 2020, VHA's Executive in Charge approved the proposed restructuring plan to discontinue catheter-based diagnostics and interventional cardiology services at the facility.

Communication of Closure

The OIG found that facility leaders communicated the CCL closure to CCL staff and facility providers. Facility leaders updated CCL staff of the status of reviews and CCL plans from when CCL operations were suspended in July 2019 to the final decision to close the CCL.

In November 2019, the COS met with CCL staff and informed them that VHA, VISN, and facility leaders decided to close the CCL indefinitely. Staff were informed of plans to relocate all remaining procedures out of the CCL effective December 1, 2019.[8] In late January 2020, after receiving approval from VHA's Executive in Charge to discontinue catheter-based cardiology services at the facility, the COS directed administrative staff to send an email to all physicians, social workers, pharmacists, nurses, and managers notifying them of the changes in the cardiology service. The email outlined those services available for veterans and made clear that diagnostic and interventional cardiology procedures were unavailable at the facility.

Continuity of Patient Care

Following the suspension of CCL services, facility staff identified those patients affected by the closure and took action to ensure continuity of care was maintained.

The COS told the OIG that interventional cardiology was readily available in the community and noted the facility's affiliation with Albany Medical Center. Facility staff planned for patients scheduled, or in future need of, catheter-based diagnostic or therapeutic procedures at the facility to be offered care at another VA or put in contact with the facility's Community Care program for referral to community providers. Facility patient advocates reported no complaints from veterans related to cardiac care in the community.

The OIG determined that the closure of the CCL was done in response to significant concerns of risks to patients that were alleged to be a combination of improper clinical procedural techniques,

[7] The CCL resumed transesophageal echocardiography, cardioversions, the placement of implantable cardiac defibrillators, pacemakers, and battery changes.

[8] CCL staff at the facility continued to provide non catheter-based CCL procedures including cardioversion, echocardiography, stress testing, and pacemaker implantation and management. Procedures that required a monitored environment were initially done in the CCL but then moved to the operating room on December 1, 2019.

issues related to personnel disputes, and a hostile, threatening working environment. In response to the concerns, facility leaders took timely action and closed the CCL. The closure was communicated to staff, and patients in need of CCL services were referred to the community for care. The closure of the CCL afforded leaders the time to further address the areas of concern thereby reducing potential risk to patients.

2. Reviews Completed Following CCL Closure

The OIG found that following the CCL closure, VISN and facility leaders arranged for an external review by NCPO of the CCL to further understand the issues resulting in the closure of the CCL and recommend actions moving forward. In response to NCPO findings, facility leaders coordinated a review of the clinical care provided by CCL cardiologists and initiated an AIB.

VHA's directive provides policy for VISNs when considering major programmatic changes to clinical programs.[9] The directive states that the facility COS is responsible for ensuring that a site visit is conducted by the responsible clinical program office, such as the NCPO, if and when needed. The facility COS is also responsible for ensuring that clinicians and staff in clinical programs, such as the CCL, are evaluated to ensure their skills and competencies meet the standard of care.

External Review by NCPO

On July 3, 2019, the Facility Director notified the VISN Director of the unplanned closure of the CCL and submitted an issue brief to the VISN two days later on July 5, 2019. After receiving the facility notification on July 3, 2019, the VISN Chief Medical Officer emailed the NCPO Director on the same day to request a consultation regarding concerns with the CCL at the facility. On July 8, 2019, the NCPO Director called the VISN Chief of Medicine and facility COS to discuss an NCPO evaluation of the CCL. The NCPO conducted a site visit at the facility on July 23, 2019, and issued its final report on September 30, 2019.

NCPO is a specialty care service program office that guides strategic development and policy relating to cardiology programs throughout VHA. The NCPO evaluates and informs VISN and facility leaders regarding the opening and closing of invasive cardiac programs such as CCLs. The NCPO Director serves as a subject matter expert for VHA leaders but in this role, lacks operational authority over the field.

The NCPO team that conducted the site visit consisted of two interventional cardiologists and a registered nurse with specialty credentials in interventional cardiology. The team arrived at the facility on July 23, 2019; interviewed CCL staff, VISN, and facility leaders; inspected the CCL equipment; reviewed CCL staff competencies, and CCL policies. They also requested the last

[9] VHA Directive 1043, *Restructuring of VHA Clinical Programs*, November 2, 2016.

20 consecutive cases from each of the three cardiologists working in the CCL as well as a list of complications in the CCL for the last three years to review after the site visit was completed.

The NCPO team issued two reports to the facility; the first report issued on August 2, 2019, described the site visit findings, and the final report issued on September 30, 2019, included the clinical care review of the three cardiologists' cases. In total, the two NCPO reports included 17 major and six minor recommendations (see appendix D).[10] Because the NCPO lacks operational authority, the NCPO recommendations were consultative, and facility leaders were not required to act on them. The major recommendations addressed a variety of concerns related to the clinical judgment and technical skills of the CCL cardiologists including the development of a mechanism for improving the selection of cases appropriate to be done in the facility's CCL and ensuring that procedural complications are reported. The minor recommendation included the appointment of a new CCL medical director and nurse manager, clear reporting structure for non-physician staff, and the development of protocols.

Clinical Care Reviews in Response to NCPO Findings

The NCPO notified the Facility Director and COS of clinical care review results that raised concerns about the clinical judgment and technical skills of the CCL cardiologists. In response to the concerns identified by the NCPO, the Chief of Medicine initiated management reviews of the three CCL cardiologists and took administrative action when warranted.

VHA Directive 1190 states that when clinical care reviews of a provider's performance are conducted as management reviews, they are not protected or confidential and can be used to assess a provider's performance.[11] The results of a management review can affect a provider's privileges or personnel status and result in a focused professional practice evaluation (FPPE) or an FPPE for cause. An FPPE documents a provider's competency in practicing assigned privileges, while an FPPE for cause is similar to a performance improvement plan and gives the provider the opportunity to improve.

Each of the three cardiologists was notified of the review of their practice based on concerns regarding their professional conduct and clinical competence with potential to affect patient care. Eleven randomly selected cases from each cardiologist were sent to interventional cardiologists outside of the facility for an independent and unbiased review. The reviews, like those done by NCPO, found concerns with the clinical judgment and technical skills of the cardiologists. The results identified no actionable areas of concern for Cardiologist 1; however, the Chief of Medicine recommended additional educational activities and a more robust ongoing professional

[10] The NCPO advised that patient care in the CCL would not resume until the major recommendations are addressed. Per the NCPO, minor recommendations are important; but would not necessarily need to be accomplished before care resumes in the CCL.

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

practice evaluation. For Cardiologists 2 and 3, the management review identified actionable areas of concern. Cardiologist 2 was noted to select cases that were more complex than the facility had the surgical capability to support. In response, the Chief of Medicine recommended an FPPE for cause for this cardiologist. For Cardiologist 3, the management review identified concerns in technical skills and interpretation of results for treatment recommendations. The Chief of Medicine proposed this cardiologist's CCL privileges be administratively removed due to the closure of the CCL with a plan to place the cardiologist on an FPPE for new privileges should the CCL reopen at a later date. Based on the management review findings, the recommendations for two of the cardiologists will become relevant if the CCL is reopened.

Following the closure, CCL cardiologists continued to provide inpatient consultations and see patients in outpatient clinics. As catheter-based procedures were no longer offered at the facility, the COS recommended, and the Facility Director approved, removal of the cardiologists' catheter-based privileges.

The OIG determined that the Chief of Medicine and COS took appropriate steps to initiate management reviews assessing the clinical competence of the CCL physicians, and planned to ensure clinical oversight and reprivileging of the cardiologists should the CCL reopen.

AIB in Response to NCPO Findings

One of the major recommendations in the NCPO's initial report suggested conducting an administrative investigation into allegations of a hostile work environment in the CCL. On August 6, 2019, facility leaders followed the NCPO team's suggestion and convened an AIB to inquire into allegations of undermining the professional reputation of staff resulting in potential care concerns and unprofessional relationships among CCL staff. The AIB completed its review on October 2, 2019.

In a 2002 directive, VA indicated that administrative investigations are performed to gather facts and evidence for significant incidents or issues within VA facilities. The information collected is analyzed to determine what took place and to identify system issues in need of resolution. The authority requesting the investigation is to act based on the results of the investigation.[12]

The AIB found that staff made comments that undermined a cardiologist's reputation, and that the marital relationship between a CCL physician and CCL nurse had not been properly reported and created a tense and uncomfortable work environment in the CCL.[13] The AIB made five recommendations addressing the administrative structure and staffing of the CCL, training needs,

[12] VA Directive 0700, *Administrative Investigations*, March 25, 2002.

[13] As a result of the AIB, the Chief of Human Resources advised the CCL nurse married to the CCL physician be reassigned to another unit based on national guidelines advising married couples not work together or report to the same chain of command.

assessment of clinical competence, and support services for staff (see appendix D). Findings from the AIB led to two admonishments; one for failure to report clinical care concerns through appropriate channels and another for a leader failing to take action when aware of clinical and conduct concerns. While not a recommendation in the final report, it was noted that the Chief of Human Resources advised the CCL nurse married to the CCL physician be re-assigned to another unit.

Based on the results of the external review by the NCPO review, and clinical care reviews coordinated by the facility and the AIB, facility and VISN leadership decided that the CCL should remain closed indefinitely and submitted a clinical restructuring request to VHA in November 2019 that was approved by the VHA's Executive in Charge.

The OIG's review found that facility and VISN leaders responded timely to obtain unbiased assessments of the CCL. The OIG determined that between the reviews of patient care completed by the NCPO team and the management reviews initiated by the Chief of Medicine, a thorough assessment of the CCL cardiologists' clinical competence was made by clinicians independent of the facility and well versed in interventional cardiology. The combined input of the reviews provided facility and VISN leadership with targeted information on opportunities for improvement in the CCL and guidance to consider when determining the future of the CCL.

3. Status of Review Recommendations

The OIG found that facility leaders received and reviewed the internal fact-finding review, NCPO, and AIB reports including the recommendations made in each.

In total, 37 recommendations were made. Some of the recommendations were targeted at actions the facility would only take if the CCL were open or planning to be reopened. The OIG reviewed the status of each recommendation and found that all were either completed or on hold until, and if, facility leaders plan to reopen the CCL. The Facility Director and COS told the OIG that any progress toward reopening the CCL has been halted due to the COVID-19 pandemic.

If, at a future time, the facility leaders decide to resume CCL procedures, the facility and VISN will need to submit a new proposal for clinical restructuring through VHA.[14]

4. Role of National Cardiology Program Office

According to NCPO, its role is typically confined to advising VHA and facilities on policy matters. In this instance, the offering of recommendations by NCPO extended beyond policy matters and addressed operations, including the safe resumption of interventional cardiology at

[14] VHA Directive 1043.

the facility. The OIG determined that other VHA facilities could similarly benefit from specialty care subject matter expertise to assist in operational matters.

The NCPO is aligned under the Deputy Under Secretary for Health for Policy and Services, Office of Specialty Care Services. The NCPO Director provides subject matter expertise to VHA leaders on policy and strategy development in areas of cardiovascular topics. The NCPO is consultative and does not have the authority to enforce compliance with recommended actions or provide operational oversight to facility programs.

Leaders in specialty care services, such as those in the NCPO, are not involved in the determination of the quality of medical practice of a given specialty at a specific facility. Program specialty leaders weigh in on the organizational structure of specialty sites at facilities at times of initial setup or major changes but are not involved in the process of selecting the clinicians to staff the service.

The VISN recognized the need for subject matter expertise to review the facility CCL and contacted the NCPO to request a site visit. The NCPO site visit team included individuals with knowledge related to interventional cardiology and the operation of CCLs. The NCPO team issued two reports that summarized their observations to VISN and facility leaders and made recommendations specific to the alignment of clinical assignments with the capabilities of the facility, the ideal candidates for leadership positions, and the management of clinical performance issues.

After reviewing the selected patient cases, the NCPO team identified a gap between the services available at the facility and those that may be needed for patient treatment. Each facility has CCL staff with different clinical skill sets and capabilities, and not all VHA facilities with a CCL provide complex cardiac care. For example, the facility CCL offered catheter-based procedures but did not have the staff or infrastructure to provide coronary artery bypass grafts. Therefore, depending on preprocedural risks, the facility may have been unable to care for higher risk patients on-site. A VHA specialty leader in interventional cardiology charged with reviewing clinicians considered for hire in the CCL could ensure that clinicians' skill sets and interests match the clinical needs and capabilities of a facility to benefit the facility and patients served.

To effectively manage a CCL, its leaders need training and experience to develop expertise in a CCL environment. Both the CCL medical director and nurse manager lacked CCL experience. A VHA specialty leader in interventional cardiology involved with the selection of CCL leaders may have identified the need for an interventional cardiologist (rather than diagnostic) to oversee the CCL and the nurse manager's lack of CCL experience.

The clinical competence of a provider affects the patient care he or she provides. If concerns are identified, plans to provide ongoing review of clinical competence are ideally developed by individuals trained in the specialty area and include elements of review to ensure an adequate specialty assessment is achieved. The NCPO team outlined several clinical care concerns in their

final report. The report included recommended steps forward that the facility intends to follow; however, the facility was not required to do so. Requiring facilities to consult with national specialty leaders, including cardiology, when preparing FPPEs completed for cause may provide the expertise to identify the elements to assess clinical competence specific to the given specialty.

The appointment of a VHA specialty leader in interventional cardiology, whose responsibilities would extend to operational matters, could ensure that VHA provides quality interventional cardiology services.

5. Failure to Respond to the OIG

The OIG determined that the facility provided the VISN with a response to the OIG's 2019 request for additional case referral information; however, the VISN failed to transmit the response to the OIG.

On August 6, 2019, the OIG requested information from the VISN related to the complaint alleging that the CCL was closed due to significant concerns of risks to patients. The VISN response dated October 7, 2019, confirmed closure of the CCL on July 3, 2019. The response informed the OIG of an NCPO on-site visit on July 23, 2019, and that the NCPO review involved selected CCL cases for clinical review. The response also noted that an AIB review was initiated on August 21, 2019, and completed on October 2, 2019.[15]

On November 25, 2019, the OIG requested additional case referral information from the VISN specific to the external reviews including copies of the NCPO and AIB reports with the recommendations, action plans, and a status update on all recommendations. The facility submitted its response to the request for additional case referral information to the VISN on December 2, 2019. However, the facility prepared response lacked the facility leader's signature, and the VISN employee responsible returned the response to the facility. While awaiting the signature, the VISN employee did not track and identify the failure to produce the response to the OIG. The OIG did not receive a response from the VISN and resubmitted requests on January 15 and January 24, 2020. As no response was received by January 28, 2020, rather than making additional contacts with VHA, the OIG opened an inspection.

According to VA directive, VA facilities are responsible for performing an independent review of OIG case referral allegations and providing a written response to the OIG within 60 days or requesting an extension, if needed.[16] In this specific VISN, the OIG case referral process begins

[15] The response to the OIG stated the AIB was initiated on August 21, 2019. The AIB charge letter was dated August 6, 2019, with an amendment on August 15, 2019. Interviews for the AIB were conducted from August 21 through August 23, 2019.

[16] VA Directive 0701, *Office of Inspector General Hotline Complaint Referrals*, January 15, 2009.

when an administrative member of the VISN action group sends the referral to a facility action group. A member of the facility action group assumes responsibility for working with subject matter expert(s) in the areas of concern, coordinating the facility response for review by the facility director, and returning to the VISN action group. The VISN Quality Management Officer (QMO) reviews the response prior to sending the response to the OIG within the prescribed six-week time frame.

During an interview with the VISN QMO and Deputy QMO (Deputy), the OIG learned that at the time of the case referral in question, an executive assistant in Quality Management coordinated the receipt of OIG case referrals and the submission of approved case referral responses. This individual left the position on November 15, 2019, and the Deputy assumed those tasks. The Deputy described being new to the role, still learning the responsibilities of the position, and being unfamiliar with VISN processes. VISN staff sent the OIG request for additional case referral information to the Facility Director and the facility's Quality Management staff on November 25, 2019. On December 2, 2019, a facility administrative officer sent the facility response, with the additional information requested by the OIG to the VISN; however, the VISN's Deputy did not forward the response to the OIG.

When asked about the VISN's process for managing OIG case referrals, the Deputy described a person-dependent process with no standardized mechanism for tracking OIG referrals. The VISN is in the process of implementing a new document tracking system using a VA platform.[17] The QMO and Deputy see this as an improvement to their current process. They stated that after the OIG case referrals are loaded into the VA platform, the system will notify the individuals responsible for action at the appropriate times.

The OIG determined that the VISN's failure to respond to the OIG's request for additional case referral information was the result of the departure of the VISN employee responsible for the person-dependent process. The newly appointed VISN Deputy assumed those duties while in the process of learning a new role, which likely contributed to the gap in tracking this item and the failure to respond to the OIG.

Conclusion

The OIG substantiated that the CCL was closed due to significant concerns of risk to patients. and determined that the risk to patients was reduced through closure of the CCL.

Facility leaders communicated the CCL closure to facility staff and updated staff with the status of reviews and plans for CCL operations. Following the suspension of CCL services, facility staff identified those patients affected by the closure and took action to ensure continuity of care

[17] The VA platform is the Light Electronic Action Framework, or LEAF, a web application that helps streamline day-to-day processes and facilitate information workflows between administration and providers.

was maintained. VISN and facility leaders arranged for an external review by NCPO of the CCL to further understand the issues resulting in the closure of the CCL and recommend actions moving forward. In response to NCPO findings, facility leaders coordinated a review of the clinical care provided by CCL cardiologists and initiated an AIB.

Between the NCPO review of patient care and the management reviews, the OIG determined that interventional cardiologists independent of the facility completed a thorough assessment of the CCL cardiologists' clinical competence. Additionally, the OIG found that facility leaders received and reviewed the internal fact-finding review, NCPO, and AIB reports including the recommendations. The OIG reviewed the status of each recommendation and found that all were either completed or on hold until and if facility leaders plan to reopen the CCL.

According to the NCPO, their role is typically confined to advising VHA and facilities on policy matters. In this instance, the offering of recommendations by NCPO extended beyond policy matters and addressed operations, including the safe resumption of interventional cardiology at the facility. The OIG concluded that it would be prudent for VHA to appoint a specialty leader in interventional cardiology, whose responsibilities would extend to operational matters, who could ensure that VHA provides quality interventional cardiology services. VHA facilities without local subject matter expertise in other highly specialized medical services could similarly benefit from VHA centralized specialty care subject matter expertise assisting in operational matters.

Recommendations 1–3

1. The Under Secretary for Health should publish written guidance that clarifies roles and responsibilities of the national Cardiology program office, Veterans Integrated Service Networks, and Chief Medical Officers to review and opine on interventional cardiologist applicant's qualifications for employment in those cases when facilities lack local interventional cardiology expertise and the facility's Chief of Staff seeks subject matter expert opinion. [18]

2. The Under Secretary for Health should outline general parameters and triggers for facilities without local interventional cardiology expertise to engage appropriate subject matter experts in interventional cardiology to advise responsible facility leadership regarding data needed to conduct a focused professional practice evaluation for cause.

3. The Veterans Integrated Service Network Director reviews circumstances that led to the failure to respond to an Office of Inspector General request for additional information and alters the person-dependent process accordingly to ensure future OIG referrals are responded to timely and completely.

[18] Recommendations directed to the Under Secretary for Health were submitted to the Executive in Charge who had the authority to perform the functions and duties of the Under Secretary for Health . Effective January 20, 2021, he was appointed to Acting Under Secretary for Health with the continued authority to perform the functions and duties of the Under Secretary.

Appendix A: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: December 21, 2020

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

Subj: OIG Draft Report: Veterans Health Administration's Response following Cardiac Catheterization Lab Closure at the Samuel S. Stratton VA Medical Center in Albany, New York

To: Assistant Inspector General for Office of Healthcare Inspections (54)

1. Thank you for the opportunity to review the Office of Inspector General draft report, Veterans Health Administration's Response following Cardiac Catheterization Lab Closure at the Samuel S. Stratton VA Medical Center in Albany, New York.

2. I concur with the draft report and provide the attached actin plan to address the two OIG recommendations. Recommendation 1 addresses the need for guidance clarifying the national Cardiology program office roles and responsibilities. Recommendation 2 speaks to the need for appropriate subject matter experts to advise facility leadership regarding data required to conduct "for cause" evaluations.

3. If you have any questions, please email Karen Rasmussen, M.D., Director, GAO-OIG Accountability Liaison Office at VHA10EGGOALACTION@va.gov.

(Original signed by:)

Richard A. Stone, M.D.
Attachment

Executive in Charge Response

Recommendation 1

The Under Secretary for Health should publish written guidance that clarifies roles and responsibilities of the national Cardiology program office, Veterans Integrated Service Networks, and Chief Medical Officers to review and opine on interventional cardiologist applicant's qualifications for employment in those cases when facilities lack local interventional cardiology expertise and the facility's Chief of Staff seeks subject matter expert opinion.

Executive in Charge Comments

Concur. VHA's national Cardiology program office will collaborate with other VHA offices and Veterans Integrated Service Networks (VISN) to develop and publish written guidance that clarifies roles and responsibilities of the national Cardiology program office, VISNs, and Chief Medical Officers to review and opine on interventional cardiologist applicants' qualifications for employment in those cases when facilities lack local interventional cardiology expertise and the facility's Chief of Staff seeks subject matter expert opinion.

Status: In progress **Target Completion Date**: November 2021

Recommendation 2

The Under Secretary for Health should outline general parameters and triggers for facilities without local interventional cardiology expertise to engage appropriate subject matter experts in interventional cardiology to advise responsible facility leadership regarding data needed to conduct a focused professional practice evaluation for cause.

Executive in Charge Comments

Concur. VHA's national Cardiology program office will collaborate with other VHA offices and Veterans Integrated Service Networks to develop and publish written guidance that outlines general parameters and triggers for facilities without local interventional cardiology expertise. VHA will engage appropriate subject matter experts in interventional cardiology to advise responsible facility leadership regarding data needed to conduct a focused professional practice evaluation "for cause."

Status: In progress **Target Completion Date**: November 2021

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: November 3, 2020

From: Director, New York/New Jersey VA Health Care Network (10N2)

Subj: Draft Report: Healthcare Inspection—Review of the Cardiac Catheterization Lab Closure at the Samuel S. Stratton VA Medical Center, Albany, New York

To: Director, Office of Healthcare Inspections (54HL05)

Cc: GAO/OIG Accountability Liaison (GOAL) Office
OIG 54 CR00

1. Thank you for the opportunity to review the Draft Report: Healthcare Inspection—Review of the Cardiac Catheterization Lab Closure at the Samuel S. Stratton VA Medical Center, Albany, New York. I appreciate the Office of Inspector General's oversight and the extensive work done as part of this review.

2. I acknowledge there were improvements to be made and have already taken action to resolve the identified recommendation.

(*Original signed by*:)

Joan E. McInerney, MD, MBA, MA, FACEP
Network Director, VISN 2

VISN Director Response

Recommendation 3

The Veterans Integrated Service Network Director reviews circumstances that led to the failure to respond to an OIG request for additional information and alters the person-dependent process accordingly to ensure future OIG referrals are responded to timely and completely.

Concur.

Target date for completion: Completed.

Director Comments

The QMO recognized the reliance on a human dependent process to manage OIG responses as a vulnerability and took appropriate action to remedy the issues. The gap in process, which was identified prior to the OIG review led to the implementation of an automated document management system as a solution. VISN 2 moved all OIG Hotline case and non-case referrals to be managed via the Light Electronic Action Framework (LEAF) platform. The VA-approved platform provides a secure method to manage responses from the initial notification to the final VISN review and approval. At the completion of VISN approval, VISN reviewer emails the response to OIG. At the time of the OIG review, the VISN 2 OIG LEAF platform was in development to better manage the inquiries efficiently. The process was successfully piloted with one site from May 29th to June 30th and launched at all VISN 2 facilities as the only method for processing OIG responses since August 3, 2020. Using one platform allows for timely management of responses without having to rely on outlook email and calendars to manually track status of requests. LEAF leverages Artificial Intelligence (AI) to run real time reports at the click of a button to provide referral response status, pending actions, comment and approval history. LEAF reduces the potential for human error with less manual entry and more automated reports allowing for more complete capture of data. To ensure a consistent practice across all sites, training was provided to over 40 staff including Medical Center Directors and/or their designees, facility Quality Managers and others responsible at the VISN and facilities to address OIG responses.

Since LEAF implementation, we have closed 20 OIG case and non-case referrals on average in 37 days. Prior to LEAF, the average completion from start to finish was approximately 65 days. The data shows significant improvement in time management and does not fully account for all improved efficiencies we may have gained on this platform.

OIG Comment

The OIG considers this recommendation to be open and will follow up on the recently implemented actions to allow time for the facility to submit documentation of actions taken and to ensure they have been effective and sustained.

Appendix C: Review Recommendations and Status

Table C.1. Fact-Finding Review Recommendations (July 2, 2019)

Recommendation	Facility Response	Status
"Formal Cath Lab meetings with all staff present, occurring on a regular basis to discuss Lab Operations, safety issues, program and staff development and for team building purposes will enhance team functioning."	"Staff meetings were occurring from July 2019-October 2019. The staff were then re-assigned to different areas in the facility and the Cath Lab was closed. Once plans for re-establishing the opening of the Cardiac Cath Lab have begun, staff meetings will re-started."	"Closed until plans are made to re-open the Cardiac Cath Lab"
"While 'time out's' are reported as routinely occurring, staff have all agreed that a process for routinely discussing preparation and set up for procedures between the Physician and the staff on the day's procedural setup would improve communication and process, safety and timeliness."	"A pre-procedure and a post-procedure briefing sheet were created for all staff to use in November 2019. The provider initiates "Time Out" per VAMC policy and the Cath Lab Tech/RN [registered nurse] will document in "real" time in MAC-Lab documentation."	"Completed"
"Staff have agreed that a process for a brief post-procedure discussion should be available to any staff person for the team to address concerning the procedure."	"During a Cardiac Cath Lab staff meeting, discussion occurred regarding when to report or discuss an issue. Quality specialist gave staff the OR post-op Briefing checklist and the Cath lab staff developed their own post-procedure de-brief checklist using the Operating Room checklist as guidance. They trialed a draft in September 2019 and revised the document in November 2019 based on user feedback."	"No longer using as the Cath lab is closed"

Recommendation	Facility Response	Status
"Cath Lab Leadership requires a clearer delineation of the person(s), who are leadership, some consideration on the preferred leadership style, (passive, collaborative, regimented,) and accountability. There has been a cultural shift in expectation with staff turnover. Current Nursing manager is stretched between assignments and there are multiple layers in nursing management, Associate Manager, Manager, Assistant manager which leads to a lot of process on issue review and resolution. The Chief cardiology [s]erves as the current Lead with verbalized plans for a Director of the Cath Lab, not yet named. Historically, there has been a Nurse Manager working with the [CCL] staff in the lab and providing immediate feedback on questions and concerns. This person was also a go-between with [p]Physicians to address issues. That may have some merit going forward."	"Current Nurse Manager is currently managing a medical-surgical unit and the telemetry techs. Once plans for re-establishing the opening of the Cardiac Cath, the Albany VAMC will recruit for a dedicated Medical Director of the Cath Lab as a part of the re-opening structure plan Once plans for re-establishing the opening of the Cardiac Cath Lab, the Albany VAMC will recruit for a dedicated Cath Lab Nurse Manager as a part of the re-opening structure plan."	"Completed"
"Formal Team Meetings with an agenda will improve team functioning."	"Staff meetings were occurring from July 2019- October 2019. The staff were then re-assigned to different areas in the facility and the Cath Lab was closed. Once plans for re-establishing the opening of the Cardiac Cath Lab have begun, staff meetings will re-started."	"Closed until plans are made to re-open the Cardiac Cath Lab"
"A review of Nursing Staff Guideline reports for Cath Lab staff may be useful in utilizing staff at the top of their training."	"Upon establishing the re-opening of the Cardiac Cath Lab, Quality Specialist and Nursing Education will work with the Cardiac Cath staff to research and develop policies and protocols to allow the staff to be utilized at the top of their education and training."	"Closed until plans are made to re-open the Cardiac Cath Lab"

Recommendation	Facility Response	Status
"Cath Lab staff report excellent training practices as a team exercise in places they worked previously and would like to see some replication here."	"Upon establishing the re-opening of the Cardiac Cath Lab, Quality Specialist and Nursing Education will work with the Cardiac Cath staff to research and develop team building exercises to replicate for the team."	"Closed until plans are made to re-open the Cardiac Cath Lab"
"Revamp Orientation Safety training on addressing the above listed findings so that there is agreement on terminology, protocols, reporting and feedback mechanisms and timeframes."	"Upon establishing the re-opening of the Cardiac Cath Lab, Quality Specialist and Nursing Education will work with the Cardiac Cath staff to research and develop protocols and feedback mechanisms. Prior to the Cath Lab closing, the staff, along with the Quality Specialist, were updating policies and briefing sheets."	"Closed until plans are made to re-open the Cardiac Cath Lab"
"Make Cath Lab Metrics information available to all staff."	"Upon establishing the re-opening of the Cardiac Cath Lab, a unit tracking board will be installed so that data will be displayed for the staff. The data will also be communicated in the Cath Lab staff meetings."	"Closed until plans are made to re-open the Cardiac Cath Lab"

Source: The recommendation column is from the fact-finding review completed on July 2, 2019. The facility response and status columns are from the facility's response to the OIG inquiry on the status of the recommendations.

Note: In this appendix, Cath Lab, Cardiac Cath Lab, and Lab all refer to the CCL (cardiac catheterization lab).

Table C.2. NCPO Review Major Recommendations (August 2, 2019)

The NCPO advised that patient care in the CCL not resume until the following recommendations are addressed.

Recommendation	Facility Response	Status
"Conduct a formal, thorough and complete administrative investigation of the allegations of hostile work environment in the Albany Cath Lab. We defer to VISN 2 regarding how best to conduct this investigation. If serious concerns are identified which might impact patient safety or quality of care, then the facility should address prior to re-opening of the Cath Lab."	"Formal Administrative Investigation was conducted. Board letters and staff letters were given on August 15, 2019. The Administrative Investigation team conducted the Administrative Investigation from August 21-23, 2019. Final report was received on October 2, 2019."	"Completed"
"Review by the site visit team and/or the CART [Clinical Assessment Reporting and Tracking] Quality Committee of 20 consecutive procedural cases for each of the three physicians who perform procedures in the Albany Cath Lab."	"NCPO Review Completed see NCPO review recommendations from September 30, 2019 report."	"Completed"
"Review by the site visit team and/or the CART Quality Committee of selected cases flagged by the Albany Quality Management team due to quality of care concerns."	"NCPO Review Completed see NCPO review recommendations from September 30, 2019 report."	"Completed"
"Physicians should not perform radial access catheterization procedures without either completion of an interventional cardiology fellowship, or without formal training in the technique of radial access for cardiac catheterization."	"Upon re-opening of the Cardiac Cath Lab, Albany COS and Chief of Medicine will ensure that all providers who receive privileges for catheter-based procedures in the Cath Lab will be competent in techniques of radial access for cardiac catheterizations."	"Closed until plans are made to re-open the Cardiac Cath Lab"

Source: The recommendation column is from the NCPO report completed on August 2, 2019. The facility response and status columns are from the facility's response to the OIG inquiry on the status of the recommendations.

Note: In this appendix, Cath Lab, Cardiac Cath Lab, and Lab all refer to the CCL (cardiac catheterization lab).

Table C.3. NCPO Review Minor Recommendations (August 2, 2019)

The NCPO advised that patient care in the CCL could resume pending resolution of the major recommendations above; however, these additional minor recommendations should be addressed as soon as possible.

Recommendation	Facility Response	Status
"Appoint a physician Medical Director of the Cath Lab. The Medical Director should be a board-certified interventional cardiologist with at least 2 years of experience."	"Upon establishing the re-opening of the Cardiac Cath Lab, the Albany VA will recruit for a dedicated Medical Director of the Cath Lab as a part of the re-opening structure plan. This individual will be a board-certified interventional cardiologist with at least 2 years of experience."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"Appoint a Cath Lab Nurse Manager with Cath Lab nursing experience, who has no additional duties other than management of Cath Lab nursing."	"Upon establishing the re-opening of the Cardiac Cath Lab, the Albany VA will recruit for a dedicated Cath Lab Nurse Manager as a part of the re-opening structure plan. The Nurse Manager will report to the Cardiac Cath Lab Medical Director."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"Non-physician staff working within the Cath Lab (nurses, technicians) should all report to the Cath Lab Nurse Manager, who should also report to the Cath Lab Medical Director and to the Chief of Cardiology."	"Upon establishing the opening of the Cardiac Cath Lab, Albany VAMC will recruit for a dedicated Cath Lab Nurse Manager and Cath Lab Medical Director as a part of the re-opening structure plan. An organizational chart will be established delineating that the staff will report to the Cath Lab Nurse Manager, who will then report to the Cath Lab Medical Director and to the Chief of Cardiology."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"Purchase a point of care duplex ultrasound machine and suitable wheeled cart for all femoral and jugular access and difficult radial access procedures."	"An ultrasound machine was purchased in October 2019. Staff were then re-assigned to different care areas and the Cath Lab was closed. Once plans for re-establishing the opening of the Cardiac Cath Lab have begun, the Albany VA will complete the training and policy that is needed to use the ultrasound machine."	"Closed until plans are made to re-open the Cardiac Cath Lab."

"Investigate the need for renovation of the Cath Lab procedural suite including replacement of the fluoroscopy equipment. If subject matter expertise in the renovation and/or construction of the Cath Lab procedure suite is desired."	"The Albany VAMC is currently in the design phase of creating a new Cardiac Cath Lab on the 2nd floor of the medical center as a part of a new ambulatory care area. Albany VA is working actively with Mr. Nagy in our planning for the resumption of Cardiac Cath Lab services."	"Closed until plans are made to re-open the Cardiac Cath Lab."

Source: The recommendation column is from the NCPO report completed on August 2, 2019. The facility response and status columns are from the facility's response to the OIG inquiry on the status of the recommendations.

Note: In this appendix, Cath Lab, Cardiac Cath Lab, and Lab all refer to the CCL (cardiac catheterization lab).

Table C.4. NCPO Review Major Recommendations (September 30, 2019)

The NCPO advised that patient care in the CCL not resume until the following recommendations are addressed.

Recommendation	Facility Response	Status
"Conduct a formal, thorough and complete administrative investigation of the allegations of hostile work environment in the Albany Cath Lab. We defer to VISN 2 regarding how best to conduct this investigation. If serious concerns are identified which might impact patient safety or quality of care, then the facility should address prior to re-opening of the Cath Lab."	"Formal Administrative Investigation (AIB) was conducted. Board letters and staff letters were given on August 15, 2019. The AIB team conducted the AIB from August 21-23, 2019. Final report was received on October 2, 2019."	"Completed."
"PCI [Percutaneous Coronary Interventions] selection should be limited to lesion and patient characteristics discussed in SCAI [Society for Cardiovascular Angiography] /ACC/AHA [American College of Cardiology-American Heart Association] Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without Onsite Surgical Back-up upon resuming Cardiac Catheterization procedures."	"Upon re-establishing opening of the Cardiac Cath Lab, Albany VAMC will reach out to WNY VA [Western NY VA Healthcare System], NYH VA [New York Harbor VA Healthcare System, or our academic partner, Albany Medical Center to establish a case conference structure."	"Closed until plans are made to re-open the Cardiac Cath Lab."

"The facility must develop a formal mechanism for improved decision making particularly in the case of patients with high procedural risk and/or with multivessel coronary artery disease. A heart team approach is recommended in these cases, and this could be done virtually given the lack of onsite cardiac surgery. Virtual consultation with a VA cardiac surgical center within the VISN, and/or with a higher volume PCI center within the VISN for high-risk cases could be employed as an example. A regular case review conference would be the best method to achieve this type of shared decision making, although it could also be done ad hoc."	"Upon re-establishing opening of the Cardiac Cath Lab, Albany VAMC will reach out to WNY VA, NYH VA, or our academic partner, Albany Medical Center to establish a case conference structure."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"[Cardiologist 3] should no longer perform left-sided cardiac catheterization procedures. The review identifies concerns with case selection for procedures, with technical skills, and with low procedural case volume which contributes to increased risk for quality of care concerns."	"[Cardiologist 3] no longer has privileges for left-sided cardiac catheterization procedures."	"Completed."
"Cardiologists 1 and 2 should restrict PCI case selection to the criteria as noted in the SCAI/ACC/AHA Expert Consensus Document on Performance of PCI Without Onsite Surgical Back-Up. Although some technical concerns are identified with each physician, the most common concern regarding their practice is performance of PCI in cases where cardiac surgical consultation should be considered prior to PCI, and performance of high-risk PCI in a low volume Cath Lab without availability of onsite cardiac surgical back-up."	"Upon re-establishing opening of the Cardiac Cath Lab, Albany VAMC will reach out to WNY VA, NYH VA, or our academic partner, Albany Medical Center to establish a case conference structure."	"Closed until plans are made to re-open the Cardiac Cath Lab."

"When Cardiologists 1 and 2 resume practice, they must submit their first 10 consecutive PCI procedures to the CART program office for quality of care review."	"Upon re-opening of the Cardiac Cath Lab, the Albany COS will reach out to National Cardiology Office to ensure that assistance is available to review [Cardiologists 1 and 2's] first 10 consecutive PCI procedures."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"An additional 10 PCI cases will be selected for review by the National Cardiology Office, those cases selected should be submitted to the CART program office for quality of care review each year x 2 years, for both [Cardiologists 1 and 2]. Cases for CART review should be sent to the CART Program Manager."	"Upon re-opening of the Cardiac Cath Lab, the Albany COS will reach out to National Cardiology Office to ensure that assistance is available to review [Cardiologists 1 and 2's] additional 10 PCI cases per year for 2 years."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"The facility may wish to also place [Cardiologists 1 and 2] on a prospective focused professional practice evaluation to evaluate their procedural outcomes once they resume practice, focusing on PCI outcomes."	"FPPE's for [Cardiologists 1 and 2] will be put into place upon their request for Cath Lab privileges once the Cath Lab is re-opened."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"Physicians should not perform radial access catheterization procedures without either completion of an interventional cardiology fellowship, or without formal training in the technique of radial access for cardiac catheterization."	"No radial access catheterizations were performed after Cath Lab operations were suspended after 7/3/19."	"Completed."
"Left ventriculography should not be routinely performed in patients presenting for cardiac catheterization as there are other reliable and non-invasive methods to assess left ventricular function. In situations where left ventriculography is felt to be clinically necessary, it should only be done with Pigtail catheters."	"Prior to re-opening the Cath Lab, an experienced interventional cardiologist will be appointed as Medical Director of the Cath Lab. It will be the responsibility of this individual to ensure that all appropriate non-invasive and invasive options for diagnosis are utilized and that proper techniques for invasive diagnosis are utilized."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"Contrast volumes must be recorded from the amount taken out of the bottle during procedure."	"Documenting contrast volumes was added to the CARDIOLOGY - MANAGEMENT AND CARE OF A PATIENT HAVING A CARDIOVASCULAR PROCEDURE policy in November 2019."	"Completed."

"Reasonable physician orders which are properly documented and communicated to staff must be followed by the staff, unless there are legitimate patient safety or quality of care concerns which would make doing so inappropriate."	"Order sets for cardiology were established in July 2018. Order process is defined in the CARDIOLOGY - MANAGEMENT AND CARE OF A PATIENT HAVING A CARDIOVASCULAR PROCEDURE policy from November 2019."	"Completed."
"The facility must develop a protocol for hydrating Cath Lab procedural patients with renal insufficiency."	"Upon establishing the re-opening of the Cardiac Cath Lab, the Medical Director of the Cath Lab will work with the Associate Chief Nurse of Medicine and Surgery to ensure that there is a procedure for hydration of patients with renal insufficiency."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"The facility must ensure that Cath Lab complications are encoded properly in CART, as per VHA Directive 1158 by physicians, Non-Physician Cath Lab staff should not be making these determinations. Please contact Candice Mueller the CART Program Safety Program Manager if any retraining on how to code complication is required."[19]	"The COS, in collaboration with Quality Manager, Cath Lab Manager, and Medical Director of Cath Lab, will establish a process of entering CART data. This data will be presented to the Invasive Procedure Committee and then to the facility Quality, Safety, and Value Committee."	"Closed until plans are made to re-open the Cardiac Cath Lab."

Source: The recommendation column is from the NCPO report completed on September 30, 2019. The facility response and status columns are from the facility's response to the OIG inquiry on the status of the recommendations.

Note: In this appendix, Cath Lab, Cardiac Cath Lab, and Lab all refer to the CCL (cardiac catheterization lab).

[19] VHA Directive 1158, *CART Program for Invasive Cardiac Procedures*, February 6, 2019.

Table C.5. NCPO Review Minor Recommendations (September 30, 2019)

The NCPO advised that patient care in the CCL could resume pending resolution of the major recommendations above, however these additional minor recommendations should be addressed as soon as possible (five of these are duplicates from the August 2, 2019 report).

Recommendation	Facility Response	Status
"Appoint a physician Medical Director of the Cath Lab. The Medical Director should be a board-certified interventional cardiologist with at least 2 years of experience."	"Upon establishing the re-opening of the Cardiac Cath Lab, the Albany VA will recruit for a dedicated Medical Director of the Cath Lab as a part of the re-opening structure plan. This individual will be a board-certified interventional cardiologist with at least 2 years of experience."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"Appoint a Cath Lab Nurse Manager with Cath Lab nursing experience, who has no additional duties other than management of Cath Lab nursing."	"Upon establishing the re-opening of the Cardiac Cath Lab, the Albany VA will recruit for a dedicated Cath Lab Nurse Manager as a part of the re-opening structure plan. The Nurse Manager will report to the Cardiac Cath Lab Medical Director."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"Non-physician staff working within the Cath Lab (nurses, technicians) should all report to the Cath Lab Nurse Manager, who should also report to the Cath Lab Medical Director and to the Chief of Cardiology."	"Upon establishing the opening of the Cardiac Cath Lab, Albany VAMC will recruit for a dedicated Cath Lab Nurse Manager and Cath Lab Medical Director as a part of the re-opening structure plan. An organizational chart will be established delineating that the staff will report to the Cath Lab Nurse Manager, who will then report to the Cath Lab Medical Director and to the Chief of Cardiology."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"Purchase a point of care duplex ultrasound machine and suitable wheeled cart for all femoral and jugular access and difficult radial access procedures."	"An ultrasound machine was purchased in October 2019. Staff were then re-assigned to different care areas and the Cath Lab was closed. Once plans for re-establishing the opening of the Cardiac Cath Lab have begun, the Albany VA will complete the training and policy that is needed to use the ultrasound machine."	"Closed until plans are made to re-open the Cardiac Cath Lab."
"Develop a protocol for using ultrasound guidance for vascular access for procedures."	"An ultrasound machine was purchased in October 2019. Staff were then re-assigned to different	"Closed until plans are made to re-open the Cardiac Cath Lab."

	care areas and the Cath Lab was closed. Once plans for re-establishing the opening of the Cardiac Cath lab have begun, the Albany VA will complete the training and policy and protocol that is needed to use the ultrasound machine."	
"Investigate the need for renovation of the Cath Lab procedural suite including replacement of the fluoroscopy equipment. If subject matter expertise in the renovation and/or construction of the Cath Lab procedure suite is desired."	"The Albany VAMC is currently in the design phase of creating a new Cardiac Cath Lab on the 2nd floor of the medical center as a part of a new ambulatory care area. Albany VA is working actively with [VHA's architect] in our planning for the resumption of Cardiac Cath Lab services."	"Closed until plans are made to re-open the Cardiac Cath Lab."

Source: The recommendation column is from the NCPO report completed on September 30, 2019. The facility response and status columns are from the facility's response to the OIG inquiry on the status of the recommendations.

Note: In this appendix, Cath Lab, Cardiac Cath Lab, and Lab all refer to the CCL (cardiac catheterization lab).

Table C.6. AIB Recommendations (October 2, 2019)

Recommendation	Facility Response	Status
"Administration of the Cath Lab should be restructured. An administrative officer that is competent in scheduling and time management should be added to the team. Physicians should meet with the administrative officer to triage patients and schedule them fairly and equitably."	"Scheduling and restructuring completed by appropriate administrative staff. Cardioversions, Transesophageal Echocardiography (TEEs), Pacemakers, and AICDs [automatic implantable cardioverter defibrillator] are scheduled through the RN surgical care coordinator."	"Completed"
"Separate [Cardiologist 2 and 3] in as much as it is possible. There should not be any interaction between them as their working relationship is damaged."	"Cardiology clinic structure and schedules have been revamped to ensure that [Cardiologist 2 and 3] have distinct clinic schedules and their patient panels separated."	"Completed"
"Cath Lab staff should receive documented training on behaviors that undermine a culture of safety, team building, ethics, and all other policies and procedures pertaining to patient safety."	"All staff, including MD's, completed 3 mandatory Training Management System courses in May of 2020. Nursing and tech staff completed face to face Just Culture training in February 2020."	"Completed"
"Facility should determine if [Cardiologist 3's] skills, technique and quality of work is appropriate for the CCL. If not appropriate, provide training or recertification."	"[Cardiologist 3's] Privileges were updated on March 7, 2020 and a letter discussed on March 8, 2020. [Cardiologist 3] has been re-assigned to general cardiology duties."	"Completed"
"All Cath Lab staff be offered employee assistance services."	"Nursing and tech staff were offered Employee Assistance Program (EAP) on their re-assignment letters during November and December of 2019. MD staff were offered EAP services via email and verbal meeting in May of 2020."	"Completed"

Source: The recommendation column is from the AIB completed on October 2, 2019. The facility response and status columns are from the facility's response to the OIG inquiry on the status of the recommendations.

Note: In this appendix, Cath Lab, Cardiac Cath Lab, and Lab all refer to the CCL (cardiac catheterization lab).

Glossary

administrative investigations board. A group of people with the knowledge and expertise to sufficiently review the items of concern. Board members must be impartial and objective when applying government requirements and making decisions regarding the matters under review. [20]

cardiologist. "A doctor who specializes in the treating diseases of the heart."[21]

cardiovascular disease. A set of health problems including heart disease, heart attacks, heart failure, strokes, and irregular heart rhythms.[22]

cardioversion. "A way to restore a regular heart rhythm."[23]

case referral. Complaints related to VA operations or quality of care concerns that are received and reviewed by the OIG and referred to VA facilities with specific questions that require a response. [24]

catheter-based diagnostics. "A procedure used to diagnose and treat certain cardiovascular conditions. During cardiac catheterization, a long thin tube called a catheter is inserted in an artery or vein in your groin, neck or arm and threaded through your blood vessels to your heart."[25]

clinical program office. The Office of Patient Care Services is a VHA program office. "The Office of Patient Care Services oversees VHA's clinical programs that support and improve veterans' health care." [26]

clinical restructuring request. A required business plan for proposed restructuring of clinical programs or services that, in the VA system, requires Under Secretary for Health approval.[27]

fact-finding review. Gathering of information including site visits, literature reviews, and a risk assessment regarding events that have potential for harm or disclosure.[28]

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[20] VA Directive 0700; VA Handbook 0700, *Administrative Investigations*, July 31, 2002.

[21] "Cardiologist," Cambridge English Dictionary, accessed June 17, 2020, https://dictionary.cambridge.org/us/dictionary/english/cardiologist.

[22] "What is Cardiovascular Disease?" American Heart Association, accessed June 24, 2020, https://www.heart.org/en/health-topics/consumer-healthcare/what-is-cardiovascular-disease.

[23] "Cardioversion," American Heart Association, accessed June 25, 2010, https://www.heart.org/en/health-topics/arrhythmia/prevention--treatment-of-arrhythmia/cardioversion.

[24] VA Directive 0701.

[25] "Cardiac Catheterization," Mayo Clinic, accessed July 30, 2020, https://www.mayoclinic.org/tests-procedures/cardiac-catheterization/about/pac-20384695.

[26] "VHA Program Offices," VHA, accessed June 25, 2020, https://www.va.gov/health/orgs.asp.

[27] VHA Directive 1043.

[28] VHA Directive 2004-08, *Disclosure of Adverse Events*, October 31, 2018.

focused professional practice evaluation. "A process whereby the facility evaluates the privilege-specific competence of the practitioner who does not have documented evidence of competently performing the requested privileges of the facility."[29]

focused professional practice evaluation for cause. "Is an opportunity for the privileged practitioner to demonstrate competency and improved performance; includes notification to the Practitioner of the areas of weakness."[30]

imaging equipment. Within the context of cardiac catheterization procedures, "this typically has been a combination of fluoroscopic (x-ray) and film system that allowed the cardiologist to see in real time what he was doing inside the body."[31]

interventional cardiologist. A cardiologist with a minimum one-year subspecialty training in an interventional cardiology fellowship, in addition to the training required for the cardiology specialty. Interventional cardiologists treat cardiovascular disease with imaging, catheters and specialized tools.[32]

intra-arterial lines. "A thin, hollow tube that is placed into an artery (blood vessel) in the wrist, groin, or other location to measure blood pressure more accurately than is possible with a blood pressure cuff."[33]

invasive. A medical term used to reference procedures that involve entry into the body.[34]

issue brief. A formal, systematic way for facilities to inform VISN and other VA leadership of problems within the facility. It also supports tracking and follow-up reporting.[35]

MAC-Lab. Software package by GE Healthcare that provides integrated documentation, information collection, and waveform data capture, helping to standardize reporting.

[29] VHA Handbook 1100.19, *Credentialing and Privileging,* October 15, 2012.
[30] *Bylaws and Rules of the Medical Staff of Veterans Health Administration (VHA)*, Albany Stratton VA Medical Center, Albany, New York, April 27, 2017.
[31] "Cardiac Catheterization," Angioplasty.org, accessed June 24, 2020, http://www.ptca.org/imaging/cath.html.
[32] "What is a Cardiac Catheterization Lab?" Interventional Cardiology, American Medical Association, accessed June 9, 2020, https://www.ama-assn.org/specialty/interventional-cardiology.
[33] "Arterial Catheterization," American Thoracic Society, accessed June 25, 2020, https://www.thoracic.org/patients/patient-resources/resources/arterial-catheterization.pdf.
[34] Merriam Webster Dictionary, "Definition of invasive," accessed June 11, 2020, https://www.merriam-webster.com/dictionary/invasive#medicalDictionary.
[35] Deputy Secretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs*, updated version 03-29-18.

management review. A review conducted within the VA for purposes other than confidential quality assurance. These reviews are not protected by 38 U.S.C. 5705 and may be used for administrative investigations.[36]

National Cardiology Program Office. Provides subject matter expertise to VA leaders on policy and strategy development in areas of cardiovascular topics.[37]

ongoing professional practice evaluation. "The ongoing monitoring of privileged providers to confirm the quality of care delivered and ensures patient safety."[38]

pacemaker. An electrical device for stimulating or steadying the heartbeat or re-establishing the rhythm of an arrested heart.[39]

standard of care. The degree of care or competence that one is expected to exercise in a particular circumstance or role.[40]

[36] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.
[37] The NCPO team provide subject matter expertise to VA leaders on policy and strategy development in areas of cardiovascular topics.
[38] VHA Directive 1190.
[39] Meriam-Webster, "Definition of pacemaker," accessed on June 25, 2020, https://www.merriam-webster.com/dictionary/pacemaker.
[40] Meriam-Webster, "Definition of standard of care," accessed June 25, 2020, https://www.merriam-webster.com/legal/standard%20of%20care.

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