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VETERANS HEALTH ADMINISTRATION

Mammography Program Deficiencies and Patient Results Communication at the Washington DC VA Medical Center

HEALTHCARE INSPECTION | REPORT #20-00563-68 | FEBRUARY 25, 2021

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the November 4, 2019, request of Congressman Gerald E. Connolly, Chairman of the U.S. House of Representatives Committee on Oversight and Reform's Subcommittee on Government Operations (Subcommittee), and Subcommittee members Congressman Mark Meadows and Congresswoman Eleanor Holmes Norton. The inspection focused on allegations that patients were not receiving mammography results at the Washington DC VA Medical Center (facility). The members of Congress had learned that the facility was not in compliance with the Veterans Health Administration (VHA) policy on communicating exam results and letters had not been appropriately mailed to patients who had breast imaging studies. Specifically, on August 22, 2019, the facility's lead mammography technologist discovered approximately two "reams" of mammography lay summary letters (a written report summary that uses language clearly understood by a layperson) in a medical support assistant's (MSA) desk drawer.[1] The letters were dated from February 2019 through June 2019 and should have been mailed to patients within 30 days of completing mammography procedures.[2] The letters were mailed to the patients on August 23, 2019. The Subcommittee members requested the OIG evaluate whether the facility had taken the necessary steps to notify patients affected by the communication lapse and whether adequate steps had been taken to prevent a communication lapse in the future.

VHA requires a lay summary letter be conveyed to patients from the facility's Mammography Program (a radiology subspecialty) within 30 days of a procedure. In addition to lay summary letters, VHA requires ordering providers communicate normal mammography results to patients within 14 calendar days of receiving the results, and abnormal results within seven calendar days of receiving the results. Communication of test results to patients must be documented in the electronic health record.[3]

Facility staff informed the OIG that after discovery of the unsent lay summary letters, reviews were conducted of screening and diagnostic breast imaging exams performed from February 1,

[1] The facility used the term "reams" to describe the amount of letters discovered.

[2] VHA Directive 1105.03, Mammography Program Procedures and Standards, May 21, 2018.

[3] VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015. Deputy Under Secretary for Health for Operations and Management (DUSHOM) Guidance Memorandum, *Mammography Results Notification*, February 13, 2019. VHA Directive 1088 and the DUSHOM Guidance Memorandum provide that the ordering provider or a designee must communicate mammography results and document the communication of a patient's test results in the electronic health record. A radiologist is typically not the ordering provider, therefore, should a radiologist communicate test results to the patient and document the communication, the requirement that the ordering provider communicate and document has not been met.

2019, through September 13, 2019.[4] Facility staff outlined that a review of abnormal findings showed all patients with abnormal findings or requiring additional studies were notified of their results, the need for additional testing, or both when appropriate. Facility staff generated another patient list that outlined steps taken to ensure appropriate follow-up care had been scheduled and completed.

The OIG completed an independent review of the patients who received mammography exams at the facility during the same time period and identified nine mammography exams not included in the facility's initial reviews due to errors in diagnostic coding. Facility staff did not consistently enter the Breast Imaging-Reporting and Data System (BI-RADS) code as a primary diagnostic code in the electronic health records as required.[5] After being notified of the nine exams, the facility reviewed them and determined they were not abnormal.

During its review, the facility identified two patients with clinically significant mammography exams (breast cancer). In an independent review, the OIG identified two other patients with breast cancer. While the identified patients may not have received the lay summary letters within the required 30-day period, the OIG determined that all four patients received timely notification of their abnormal results from the ordering provider. However, during its review of other patients, the OIG found that ordering providers did not consistently document patient notification of abnormal mammography results within seven days as required.[6]

In September 2019, the VHA National Radiology Program Office conducted a site visit of the facility's Mammography Program after discovery of the unsent lay summary letters. The National Radiology Program Office issued 20 recommendations. At the time of the OIG review, the facility no longer had a functional facility-based mammography program due to loss of staff and facility managers, and leaders had not taken action on all National Radiology Program Office recommendations.[7] During the program closure since September 20, 2019, patients were receiving mammography services with the care-in-the-community program, and two facility nurses were tracking this care. The facility had plans to reopen the program. A new lead mammography radiologist was hired in February 2020. The new lead mammography radiologist

[4] Data included exams on February 1, 2019, through September 12, 2019.

[5] VHA Directive 1105.03. American Cancer Society, *Understanding Your Mammogram Report,* The Breast Imaging-Reporting and Data System (BI-RADS) is a standard system that sorts mammography results into categories numbered 0 through 6. https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/mammograms/understanding-your-mammogram-report.html. (The website was accessed on April 16, 2020.)

[6] Deputy Under Secretary for Health for Operations and Management Guidance Memorandum; VHA Directive 1088.

[7] VA National Radiology Program, *Radiology,* The National Radiology Program Office provides advice and recommends courses of action to the VA Central Office, Veteran Integrated Service Networks, and facilities in support of effective decision-making and develops draft policies and guidance on multiple radiology programs to include mammography. vaww.va.gov/RADIOLOGY. (The website was accessed on April 5, 2020.) This is an internal VA website and not available to the general public.

was tasked to develop the facility's Mammography Program standard operating protocol as well as meet some National Radiology Program Office recommendations. The proposed timeline to reopen to patients was three months, but this timeline was interrupted by the COVID-19 pandemic and resignation of the new lead mammography radiologist in June 2020.[8] The facility hired another new lead mammography radiologist with a planned start date in December 2020 to continue the efforts toward reopening the Mammography Program.

The OIG noted the National Radiology Program Office did not cite the facility's Mammography Program for lack of a standard operating procedure manual during the 2019 site visit despite a VHA requirement that facilities develop one.

Apart from the National Radiology Program Office recommended changes, the facility initiated procedural changes to its Mammography Program. However, the OIG determined that facility leaders and managers did not fully implement Mammography Program procedural changes and processes that included oversight of the Mammography Program MSA duties and training. The facility's Mammography Program clerical and administrative functions were not defined in a standard operating procedure manual and there was a lack of appropriate oversight and quality controls in delegating the task of mailing patient lay summary letters, one avenue for communicating patient test results. The OIG also found that facility leaders needed to develop a formalized training program for mammography technology staff to ensure monitoring and tracking of patients when experienced staff leave employment at the facility.

The OIG made one recommendation to the National Radiology Program Office related to ensuring mammography programs have a standard operating procedure manual. Six recommendations were made to the Facility Director related to documentation of BI-RADS diagnostic codes in the electronic health record, patient notification of mammography exam results by ordering providers, follow-up of the National Radiology Program Office site visit action plan, development and implementation of a mammography program comprehensive standard operating procedure manual, oversight and training processes for the mammography program MSA, and establishing a formal mammography technology staff training program.

Comments

The Executive in Charge, Office of the Under Secretary for Health, responded to the recommendation addressed to the National Radiology Program Office and Facility Director. The Executive in Charge concurred with the recommendations and provided acceptable action plans (see appendix A). The OIG acknowledges that the facility's Mammography Program is currently

[8] World Health Organization, *Naming the coronavirus disease (COVID-19) and the virus that causes it.* https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it. (The website was accessed on August 24, 2020.) COVID-19 is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

closed and will follow up on the planned actions until they are completed to ensure that they have been effective and sustained upon reopening of the program.

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Abbreviations

BI-RADS	Breast Imaging-Reporting and Data System
COS	Chief of Staff
DUSHOM	Deputy Under Secretary for Health for Operations and Management
MSA	medical support assistant
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of Congressman Gerald E. Connolly, Chairman of the U.S. House of Representatives Committee on Oversight and Reform's Subcommittee on Government Operations and Subcommittee members Congressman Mark Meadows and Congresswoman Eleanor Holmes Norton. The inspection focused on allegations that patients were not receiving mammography results at the Washington DC VA Medical Center (facility).

Background

The facility is part of Veterans Integrated Service Network (VISN) 5 and is classified as a Level 1a (highest complexity) facility.[1] The facility offers comprehensive primary and specialty care in medicine, surgery, neurology, and psychiatry, and provides specialized services including but not limited to women's health, radiology, and a variety of telehealth and virtual services. The facility is also listed as a Veterans Health Administration (VHA) certified mammography site. From October 1, 2018, through September 30, 2019, the facility served 80,750 patients and had several academic affiliations.

VHA Mammography Program

Since the Veterans' Health Care Amendments of 1983 passed, VHA has provided mammography services to veterans. A mammography program is a distinct subspecialty of the department of radiology functioning within a VA medical facility. Complexity may vary from a comprehensive program providing screening, diagnostic mammography, and interventional procedures to programs providing more limited services.[2] According to VHA policy,

[1] 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. Level 3 facilities are the least complex. VHA Office of Productivity, Efficiency and Staffing. http://opes.vssc.med.va.gov/Facility%20Complexity%20Model%20Workgroup%20Library/2.%20FY17%20Facility%20Complexity%20Levels%20List.xlsx. (The website was accessed on November 21, 2019.) This is an internal VA website and not available to the general public.

[2] VHA Directive 1105.03, *Mammography Program Procedures and Standards*, May 21, 2018.

mammography conducted within VA must meet the requirements of the Mammography Quality Standards Act.[3]

National Radiology Program Office and Mammography Program Office

The National Radiology Program Office provides guidance and advises on plans of action to VA Central Office, VISNs, and facilities to aid in successful decision-making with multiple radiology programs including mammography.[4] The Mammography Program Office, within the National Radiology Program Office, verifies whether VA facilities have effectively attained national uniform mammography standards to achieve and maintain VHA mammography certification.[5]

Patient Mammography Reports and Communicating Results

All mammography exam reports, including those performed by non-VA providers, must be entered by the radiologist into the patient electronic health record with a Breast Imaging-Reporting and Data System (BI-RADS) code as the primary diagnostic code per VHA policy.[6]

Breast Imaging-Reporting and Data System

BI-RADS is a standard system that sorts mammography results into categories numbered 0 through 6:

- A BI-RADS score of 0 indicates a mammography study that is incomplete.

[3] VHA Directive 1105.03. The Mammography Quality Standards Act became law on October 27, 1992, and was enacted to "ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages." To be Mammography Quality Standards Act certified, a facility must be accredited by a Food and Drug Administration-approved accreditation body; meet federally developed quality standards for personnel qualifications, equipment, radiation dose, quality assurance programs, record keeping, and reporting; and undergo an annual inspection. https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/about-mammography-program and https://www.fda.gov/radiation-emitting-products/facility-certification-and-inspection-mqsa/facilities-mammography-quality-standards-act-requirements. (The websites were accessed on April 21, 2020.)

[4] VA National Radiology Program, Radiology. vaww.va.gov/RADIOLOGY. (The website was accessed on April 5, 2020.) This is an internal VA website and not available to the general public.

[5] VHA Mammography Office, Mammography. https://vaww.va.gov/RADIOLOGY/Mammography.asp. (The website was accessed on April 5, 2020.) This is an internal VA website and not available to the general public.

[6] VHA Directive 1105.03. BI-RADS is a standard system that sorts mammography results into categories numbered 0 through 6. American Cancer Society, *Understanding Your Mammogram Report,* https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/mammograms/understanding-your-mammogram-report.html. (The website was accessed on April 16, 2020.)

- A BI-RADS score of 1 indicates the mammography study is normal and routine screenings should continue.
- A BI-RADS score of 2 indicates the mammography study is normal with no apparent cancer but other findings (such as cysts) are described in the report and that routine screening should continue as normal.
- A BI-RADS score of 3 means that the mammography study is probably normal but there is an approximately two percent chance of cancer, and a repeat study should be done in six months.
- A BI-RADS score of 4 indicates findings are suspicious and to make a diagnosis, a biopsy should be performed to get a small tissue sample.
- A BI-RADS score of 5 is highly suspicious with a 95 percent chance of breast cancer.
- A BI-RADS score of 6 indicates a diagnosis of breast cancer has already been made and the pathologist has confirmed the diagnosis.[7]

Mammography Lay Summary Letters

VHA requires that a written mammography report summary in language clearly understood by a layperson (lay summary letter) be conveyed to the patient within 30 days of the procedure. This pertains to each patient receiving a mammography study, and the facility must provide an operational communication system for the letters.[8] According to a February 13, 2019, Deputy Under Secretary for Health for Operations and Management (DUSHOM) memorandum, the mammography program is responsible for the lay summary letters.[9] At the facility, the lead mammography radiologist was responsible for overseeing the facility's Mammography Program.[10]

VHA Requirements for Communicating Test Results

In addition to the lay summary letter, the VHA directive also requires providers to communicate test results to patients in a timely manner.[11] Specifically, the ordering provider must communicate normal mammography results within 14 calendar days of receiving the results, and

[7]American Cancer Society, *Understanding Your Mammogram Report*. https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/mammograms/understanding-your-mammogram-report.html. (The website was accessed on April 16, 2020.)

[8] VHA Directive 1105.03.

[9] DUSHOM Guidance Memorandum, *Mammography Results Notification,* February 13, 2019. VHA Directive 1105.03.

[10] The lead mammography radiologist, whose title at the facility was Chief of Breast Imaging, was responsible for overseeing the facility's Mammography Program.

[11] VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.

abnormal results within seven calendar days of receiving the results. The ordering provider must also document the communication of a patient's test results in the electronic health record.[12]

In summary, VHA requires that patients receive exam results via both a lay summary letter from the facility's Mammography Program (a radiology subspecialty) and a separate communication documented in the electronic health record, either by letter, phone call, or secure message, from the ordering provider or appointed designee. On occasion, the radiologist may communicate results directly to the patient and document that communication, but neither the lay summary letter nor the communication from the radiologist substitutes for an ordering provider's communication of mammography exam results to the patient.

Prior OIG Report

Within the last three years, the OIG issued one report with a similar topic. In *Comprehensive Healthcare Inspection Program Review of the Washington DC VA Medical Center*, January 28, 2019, the OIG assessed whether the facility conformed with VHA requirements for reporting mammography results by evaluating relevant documents and interviewing selected employees and managers. The OIG also examined the electronic health records of 48 randomly chosen female veterans who obtained a mammogram from July 1, 2016, through June 30, 2017. The OIG found that the facility generally met the performance measures and made no recommendation.[13]

Request for Review and Concerns

On October 16, 2019, Congressman Connolly sent a letter to the Facility Director requesting specific responses regarding information he received alleging facility staff had uncovered mammography and breast imaging exam results performed at the facility that had not been sent to patients.[14]

On October 29, 2019, the Facility Director responded to the Congressman that the facility was not in compliance with VHA policy on communicating exam results and important letters had not been appropriately mailed to patients who had breast imaging studies.[15] The Facility Director outlined a review of abnormal breast imaging exam findings between February 1, 2019, and

[12] DUSHOM Guidance Memorandum, *Mammography Results Notification,* February 13, 2019. VHA Directive 1088 and DUSHOM Guidance Memorandum provide that the ordering provider or a designee must communicate mammography results and document the communication of a patient's test results in the electronic health record. The mammography radiologist may not act as the ordering provider's designee for the purpose of communicating a patient's test results.

[13] VA OIG, Comprehensive Healthcare Inspection Program Review of the Washington DC VA Medical Center, Report No. 17-01757-50, January 28, 2019.

[14] Congressman Gerald E. Connolly is the Chair of the House Oversight and Reform Subcommittee on Government Operations and represents Virginia's 11th District; some of his constituents are served by the facility.

[15] VHA Directive 1088; DUSHOM Guidance Memorandum.

September 13, 2019; preliminary information on steps the facility had taken to ensure compliance with VHA Mammography Program Procedures and Standards; and follow-up of a September 2019 National Radiology Program Office site visit that occurred after the unsent lay summary letters were discovered.

On November 4, 2019, Subcommittee members Connolly, Meadows, and Norton requested the OIG evaluate whether the facility had taken the necessary steps to notify patients affected by the communication lapse and whether adequate steps had been taken to prevent a communication lapse in the future. The Subcommittee had several concerns with the October 2019 response from the facility and requested that the OIG evaluate whether the facility staff had

- Completed a sufficient clinical review of affected breast imaging patients,
- Implemented the recommendations provided by the National Radiology Program Office, and
- Effected procedural changes to prevent a lapse from happening in the future.[16]

Scope and Methodology

The OIG initiated an inspection on December 5, 2019, and conducted interviews from January 30 through March 26, 2020. The OIG interviewed the Director of the VHA National Radiology Program Office, the Assistant Director of the VHA National Radiology Program Office, and the VHA Deputy Chief Consultant Woman's Health Service. Other interviewees included the following facility leaders and staff: Director; Chief of Staff (COS); Chief of Radiology; Chief of Primary Care; Women's Health Medical Director; Women Veterans Program Manager; Risk Manager; Director of Patient Safety (retired); Quality, Safety and Value Consultant; Radiology Administrative Officer; Medical Support Assistant (MSA) Supervisor; lead mammography technologist; Nurse Navigator (mammography); and an MSA. The OIG also interviewed individuals who are no longer employed at the facility to include the former lead mammography radiologist and an MSA.

[16] VA National Radiology Program, *Radiology,* vaww.va.gov/RADIOLOGY. (The website was accessed on April 5, 2020.) The National Radiology Program Office provides advice and recommends courses of action to VHA Headquarters, VISNs, and facility staff in order to facilitate the provision of timely, cost effective, and highest quality diagnostic care in environments that are safe for patients and caregivers.

The OIG team reviewed relevant VHA and facility policies and procedures related to mammography programs, and mammography program adverse event disclosures.[17] OIG staff evaluated patient electronic health records, mammography staff training records, physician education on communicating mammography exam results, and an issue brief. The OIG team also reviewed facility responses, action plans, and lay summary letter patient reviews, and patient comparison data independently derived from VA's Corporate Data Warehouse.[18]

Facility managers provided data of clinical reviews of the screening and diagnostic mammography exams from February through September 13, 2019. The facility reviewed a list of patients obtained from the Veterans Health Information System Technology Architecture using BI-RADS codes and then conducted a subsequent review of mammography exams using dedicated mammography software.[19] Facility managers used the results of the reviews to ensure patients with abnormal exams received follow-up care and managers reported the results and updates directly to the COS or Facility Director.

For completeness, the OIG team compared the facility's full patient review list with a list of patients obtained from the VA Corporate Data Warehouse who received mammography exams from February through September 13, 2019. The OIG identified nine patients who were not included on the facility list and notified the facility about those nine patients for review and response.

Using the same Corporate Data Warehouse patient list noted above, OIG staff identified 252 patients with abnormal mammography and breast imaging exams and identified 40 patients requiring follow-up. The OIG provided the list of 40 patients to facility leaders and requested an updated status with verification by the COS.[20] To assess delays in patient notification of abnormal mammography exam results, OIG staff reviewed all 252 abnormal mammography exam results for timely patient notification. In specific response to the Subcommittee's request, the OIG team considered a delay in notification as a lack of documentation of patient notification from either the ordering provider or the mammography radiologist within seven days of

[17] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. An adverse event is an occurrence of harm or potential harm directly associated with care or services delivered by VA providers. Institutional disclosure is a formal process of notification to a patient or patient's personal representative an adverse event has happened during the patient's care and that has or is expected to result in serious injury or death. Clinical disclosure, made as part of routine clinical care, of a "harmful or potentially harmful" event is the process in which the patient's provider informs the patient or patient's representative of the adverse event that occurred during their course of care.

[18] "VA Health Services Research and Development," *Corporate Data Warehouse*, The VA Corporate Data Warehouse is the VA's program for the standardization, consolidation and streamlining of clinical data systems. https://www.hsrd.research.va.gov/for_researchers/vinci/cdw.cfm. (The website was accessed on April 8, 2020.)

[19] Veterans Health Information System Technology Architecture is VA's core system for the electronic health record. The facility used a commercial computer software application that tracks and reports on mammography exam reports. Data included exams from February 1, 2019, through September 12, 2019.

[20] The COS verified the patients were reviewed and further indicated that no adverse events had been noted.

receiving abnormal results. Although VHA specifies that the ordering provider notify the patient of their results, for purposes of this review, the OIG team considered documented notification of results by the mammography radiologist within seven days to also be timely notification.

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).

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

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.

Summary of Events

On August 22, 2019, the facility's lead mammography technologist discovered approximately two "reams" of mammography lay summary letters in an MSA's desk drawer.[21] The lead mammography technologist initially secured the letters overnight and subsequently provided them to the Radiology Administrative Officer the next morning. The discovered lay summary letters were mailed to patients on August 23, 2019. The letters were dated from February 28, 2019, through June 22, 2019, and were required to have been mailed to patients within 30 days of completing mammography procedures.[22]

Following discovery of the lay summary letters, facility managers began an evaluation of abnormal mammography exam reports to confirm patients received notification from a provider.

On September 18 and 19, 2019, in response to the lay summary letter discovery, the National Radiology Program Office conducted an on-site review, and provided its findings and recommendations to the Facility Director approximately three weeks later.

[21] The information in the summary of events came from interviews, reports of contact, emails, and facility reviews. The facility used the term "reams" to describe the amount of letters discovered.

[22] VHA Directive 1105.03.

On September 20, 2019, the facility's COS accepted the resignation of the lead mammography radiologist and submitted an issue brief to VISN 5 leaders due to the unplanned closure of the Mammography Program.[23]

In October 2019, the facility received the request for information regarding the unsent lay summary letters from Congressman Connolly as described above. The Facility Director responded that the facility conducted a review of screening and diagnostic breast imaging exams that occurred from February 1, 2019, through September 13, 2019.[24] The Facility Director confirmed the review showed all patients with abnormal findings or those requiring additional studies were notified of their results and the need for additional testing. At the time of the facility's review, staff confirmed that in all cases of diagnosed breast cancer, every patient was notified timely and proper care had been initiated. The Quality, Safety and Value Consultant also generated a list of patients the facility was working on to ensure that appropriate follow-up care had been scheduled or completed.

After the facility's Mammography Program closure, facility staff updated the original Issue Brief to VISN 5 leaders with an action plan containing steps aimed at reopening.[25]

On January 13, 2020, the facility's COS completed an institutional disclosure for one patient identified from the facility's reviews.[26]

On February 3, 2020, a new full-time lead mammography radiologist started. Ten days later, the lead mammography technologist resigned for promotion and career growth.

The MSA left VA employment in early 2020. See figure 1 for a timeline of events.

[23] VA Deputy Under Secretary for Health for Operations and Management, *10N Guide to VHA Issue Briefs,* June 26, 2017. Issue briefs provide specific information to leadership regarding incidents that might impact patient care. Site visits conducted by oversight bodies trigger an issue brief.

[24] Data included exams on February 1 through September 12, 2019.

[25] Actions items included but were not limited to (1) referring all breast imaging to care in the community, as there was no firm date when the facility would return to full operational status; (2) assigning two registered nurses to work with care in the community and the mammography program staff to ensure patients received appropriate follow-up and that results were received at the facility; (3) hiring a new mammography radiologist with a planned start date of February 2020; and (4) developing a mammography program standard operating procedure.

[26] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. Institutional disclosure is a formal process of notification to a patient or patient's personal representative that an adverse event has happened during the patient's care and that has or is expected to result in serious injury or death. The impetus for the institutional disclosure for this patient was not related to the unsent lay summary letters.

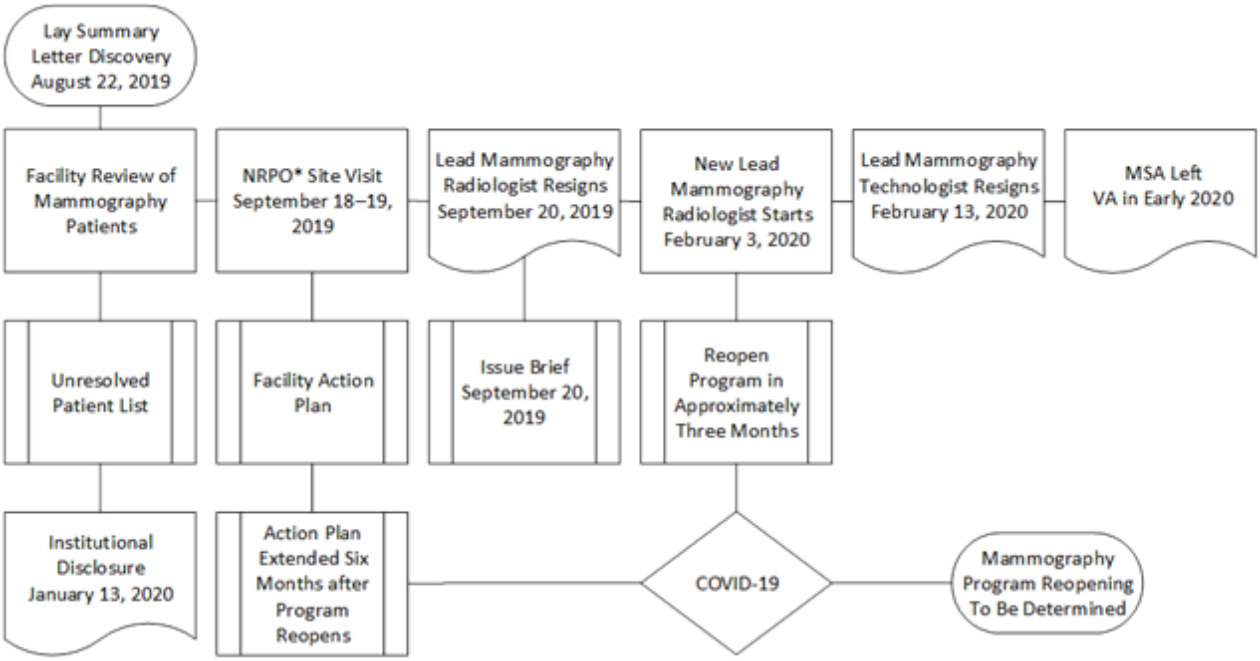

Figure 1. Summary of events and concerns
Source: VA OIG review and analysis
** National Radiology Program Office*

Inspection Results

The OIG reviewed steps taken by the facility after discovery of the unsent lay summary letters, conducted an independent review of the affected patients, and confirmed that patients with abnormal mammography results during the time frame at issue were notified of the results.

1. Review of Mammography Patients

Mammography Exams and Abnormal Findings

The OIG found facility managers completed reviews of screening and diagnostic mammography exams and documented evaluations of abnormal findings. In an independent assessment, the OIG identified nine mammography exams that were not included in the facility's reviews. Facility staff subsequently found these nine exams were not abnormal.

VHA requires that all mammography exam reports be entered in the patient's electronic health record and that the BI-RADS code be listed in the primary diagnostic code field.[27]

Facility managers provided data of clinical reviews of the screening and diagnostic mammography breast imaging exams between February and September 2019. Facility managers

[27] VHA Directive 1105.03.

used the results of these reviews to ensure patients with abnormal exam results received follow-up care. According to the facility Quality, Safety and Value consultant, the results and updates were reported directly to the facility's COS or Director.

The OIG compared the list of patients whose mammography exam results were reviewed by the facility with the Corporate Data Warehouse patient list obtained by the OIG for the same time period. It was noted that nine patients on the OIG's list were not included in the facility's review.[28]

The OIG found that the nine mammography exams did not have the BI-RADS in the primary diagnostic code field of the mammography exam report, which allows notification of clinical reminders and alerts in the patient's electronic health record. BI-RADS diagnostic codes will not be listed in electronic health records if staff do not consistently enter the information as the primary diagnostic code in the mammography exam report.

Facility's Follow-Up on Abnormal Mammography Exams and Findings

Facility leaders and managers assessed patients with potential for clinically significant disease and identified two patients with breast cancer. One of the patients underwent a breast biopsy at the facility and was diagnosed with intraductal carcinoma.[29] The other patient was diagnosed with triple negative carcinoma of the breast from a biopsy that was performed in the community.[30] The OIG found no evidence to support that the delay in receipt of the lay summary letters was linked to the abnormal mammography exams.

The OIG's Independent Review of Abnormal Mammography Exams

The OIG reviewed the patient data provided by facility managers and obtained independent data on abnormal mammography exams from the VA's Corporate Data Warehouse. The OIG conducted an electronic health record review and identified 40 patients who needed follow-up of their abnormal mammography exam results. The OIG provided the list to the facility, and the COS verified the patients were reviewed.[31]

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[28] The OIG team was unable to determine the initial status of the nine mammography exam results because the primary diagnostic code field did not contain a BI-RADS code.

[29] Mayo Clinic. *Ductal carcinoma in situ,* Intraductal Carcinoma (also known as ductal carcinoma *in situ*) is an early form of breast cancer where abnormal cells are found in the milk or breast duct. It is noninvasive meaning it has not spread outside the duct. https://www.mayoclinic.org/diseases-conditions/dcis/symptoms-causes/syc-20371889. (The website was accessed on May 1, 2020.)

[30] Breast Cancer.ORG. *Triple-Negative Breast Cancer*, "Triple-negative breast cancer is cancer that tests negative for estrogen and progesterone receptors," and excess HER2 protein, the common hormones fueling breast cancer growth. https://www.breastcancer.org/symptoms/diagnosis/trip_neg. (The website was accessed on April 18, 2020.)

[31] The COS further indicated that no adverse events had been identified for the 40 patients.

The OIG noted 2 of 40 patients were diagnosed with breast cancer. These two breast cancer patients were in addition to the two patients already identified by facility leaders discussed above. The OIG team determined that the four patients with breast cancer received timely notification of abnormal results from the ordering provider.

Notification of Abnormal Mammography Results

The OIG confirmed that ordering providers did not consistently document mandatory patient notification of abnormal mammography results within seven days of receiving the results.[32]

VHA requires the ordering provider communicate abnormal results within seven calendar days of receiving the results and the communication of the patient's test results must be documented in the electronic health record.[33]

In response to Congressman Connolly, the Facility Director acknowledged the facility did not comply with the February 2019 Acting Deputy Under Secretary for Health for Operations and Management Memorandum that ordering providers (typically a primary care provider) convey results to the patient.

The OIG reviewed the patient data provided by facility managers and the data from VA's Corporate Data Warehouse. Of the 252 electronic health records of patients with abnormal exams reviewed, 161 (64 percent) did not contain documentation of timely patient notification by the ordering provider as required.

Without timely notification of mammography exam results by the ordering provider, coordination of patient care plans may be compromised resulting in the potential for adverse clinical outcomes. The OIG did not identify clinically significant adverse outcomes related to the lack of timely notification.[34]

2. National Radiology Program Office Recommendations

The OIG determined the facility leaders and managers had not fully implemented the National Radiology Program Office recommendations that were issued after the September 2019 site visit. The National Radiology Program Office specifically provides oversight to VHA's Mammography Quality Standards Act program and certifies whether VA facilities have

[32] Deputy Under Secretary for Health for Operations and Management Guidance Memorandum, *Mammography Results Notification,* February 13, 2019. VHA Directive 1088.

[33] Deputy Under Secretary for Health for Operations and Management Guidance Memorandum. VHA Directive 1088.

[34] Within the context of this report, the OIG considered an adverse clinical outcome to be death, a change in diagnosis, a change in the course of treatment, or a significant change in the patient's level of care.

successfully achieved the required mammography standards.[35] In February 2020, the facility employed a new lead mammography radiologist to facilitate implementation of the recommendations but this was delayed by the coronavirus pandemic and subsequent resignation of the new lead mammography radiologist in June 2020. The facility hired another new lead mammography radiologist with an anticipated start date in December 2020 to continue implementation efforts.

After the discovery of the unsent lay summary letters in August 2019, the National Radiology Program Office conducted an on-site review (September 18–19, 2019) of the facility's Mammography Program to evaluate "compliance with the Food and Drug Administration (FDA) Mammography Quality Standards Act (MQSA) regulations, provision of care including mammography patient tracking, access, scheduling and orders management, and quality." Shortly after the visit, the lead mammography radiologist resigned and on the same day, the facility sent an Issue Brief to VISN 5 leaders closing the facility's Mammography Program.[36]

On October 9, 2019, a report with its findings and recommendations was provided to the Facility Director. The National Radiology Program Office issued 20 recommendations.

Dated November 1, 2019, facility leaders compiled a Mammography Action Plan that addressed the National Radiology Program Office recommendations with target dates for the actions ranging from November 2019 to February 2020. The Radiology Chief, lead mammography technologist, Radiology Administrative Officer, and the Office of Quality, Safety and Value had responsibility for the listed action items.

According to the Facility Director, a new lead mammography radiologist started in February 2020 and, along with facility leaders, identified several key items required before reopening the facility's Mammography Program.[37] Staff in the Office of Quality, Safety and Value had originally projected reopening the Mammography Program in three months depending on the acquisition of necessary technology and staff, but stated with the COVID-19 pandemic, the time frame for reopening was unclear.

The Facility Director reported that Quality, Safety and Value staff requested to extend all action items for six months after reopening the facility's Mammography Program to allow for review and oversight of the implemented processes to ensure sustainability.

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[35] VA National Radiology Program, *Radiology,* vaww.va.gov/RADIOLOGY. (The website was accessed on April 5, 2020.) This is an internal VA website and not available to the general public. VHA Mammography Office, *Mammography,* https://vaww.va.gov/RADIOLOGY/Mammography.asp. (The website was accessed on April 5, 2020.) This is an internal VA website and not available to the general public.

[36] 10N Guide to VHA Issue Briefs. Issue briefs provide specific information to leadership regarding incidents that might impact patient care. As noted in the summary of events, the lead mammography technologist for the Mammography Program resigned in February 2020.

[37] One key item identified by the new lead mammography radiologist was a computer software package used to transfer non-VA facility three-dimensional breast images to the VA system.

The new lead mammography radiologist resigned in June 2020. The facility hired another new lead mammography radiologist with a planned start date in December 2020 further delaying reopening of the Mammography Program.

At the time of the OIG review, the facility no longer had a functional facility-based mammography program due to loss of staff, and facility managers and leaders had not taken action on all National Radiology Program Office recommendations.[38]

3. Program Procedural Changes and Processes

Apart from the National Radiology Program Office recommendations, the Facility Director initiated procedural changes to the facility's Mammography Program. The OIG determined facility leaders and managers did not fully implement Mammography Program procedural changes and processes to include having a standard operating procedure manual and providing oversight of the mammography program MSA duties and training. The OIG also found the facility leaders needed to develop a formalized training program for mammography technology staff to ensure appropriate monitoring and tracking of patients when experienced staff leave employment at the facility.

Standard Operating Procedure Manual

The OIG found the facility's Mammography Program did not have a standard operating procedure manual.[39] This finding was not included in the 2019 National Radiology Program Office site visit recommendations.

VHA requires all mammography programs maintain a comprehensive standard operating procedure manual covering critical technical, clerical, and administrative staff functions.[40]

Staff reported standard operating procedures were being drafted; however, at the time of the OIG review, there was no Mammography Program standard operating procedure manual.

Oversight of Mammography Program MSA

The OIG determined there was lack of clear oversight of Mammography Program MSA duties and training.

[38] While the facility's Mammography Program was shutdown, patients were receiving mammography services with the care in the community program. Two nurses were tracking community mammography services.

[39] VHA Directive 1105.03.

[40] VHA Directive 1105.03.

VHA requires all mammography programs maintain a comprehensive standard operating procedure manual covering clerical and administrative functions; as noted above, the facility did not have a standard operating procedure manual.[41]

Staff described that the MSA, who failed to send the lay summary letters at issue, was assigned operationally to the Business Office but worked in the mammography clinic. The MSA Supervisor reported the MSA had been trained to schedule patients but the supervisor was unaware of the mammography clinic MSA's responsibility to mail lay summary letters and acknowledged the MSA had not been trained to do so. The MSA Supervisor further expressed the Radiology Administrative Officer was responsible for providing the MSA's tasks specific to mammography. During an interview, the Radiology Administrative Officer affirmed supervising the assigned MSA's daily administrative needs in coordination with the MSA Supervisor but reported not providing training to the mammography clinic MSA and had no knowledge about the MSA's task to mail lay summary letters.[42]

The lead mammography technologist told the OIG only one technologist was available for the Mammography Program between January and August 2019; prior to January 2019, the lead mammography technologist mailed the lay summary letters. The lead mammography technologist reported the former lead mammography radiologist rearranged duties, and the MSA was then assigned to mail the lay summary letters. The former lead mammography radiologist reported providing training to the MSA on scheduling procedures and mailing lay summary letters, but the processes were not included in a standard operating procedure.

The MSA told the OIG during an interview that "it wasn't like I was purposely not sending out the letters." The MSA reported setting the letters aside in order to get patients scheduled as soon as possible since "I was the only one doing everything." The MSA also reported not receiving training on the lay summary letters. The MSA Supervisor did check in routinely but did not ask if help was needed. The MSA left employment.

Mammography Program clerical and administrative functions were not defined in a standard operating procedure manual and there was a lack of appropriate oversight and quality controls in delegating the task of mailing lay summary letters by staff. These oversights resulted in delays in mailing patient lay summary letters, one avenue for communicating patient test results.

Mammography Technology Staff Training

The OIG determined that facility actions taken to resolve mammography technology staff training deficiencies identified by the National Radiology Program Office in September 2019 were not effective. The facility arranged one-time training to address the identified deficiencies

[41] VHA Directive 1105.03.

[42] The Business Office assigned MSAs to various facility Service Lines including Radiology.

but did not implement an ongoing training program that would be available to new staff should more experienced staff leave.

VHA Directive 1105.03 designates the lead mammography radiologist as responsible for ensuring persons assigned to quality assurance tasks are competent to perform those tasks and their job performances are sufficient.[43] This includes designating a lead mammography technologist who is responsible for quality assurance and quality control tasks not assigned to the lead mammography radiologist or medical physicist. The lead mammography technologist would perform quality control duties as well as patient care.

The VHA National Radiology Program Office site visit in fall 2019 noted the facility's mammography technologists needed more training in managing the facility's breast imaging electronic tracking system after identifying variable monitoring and follow-up of abnormal breast imaging results. The site visit report also stated the lead mammography technologist "lacked expertise" in operating facility radiology information technology systems and the monitoring and follow-up of patients in the breast imaging reporting software. The problem with orders management and radiology scheduling was noted to be a repeat finding that had also been cited in a previous site review.

In accordance with the facility's action plan to address the mammography technologist training deficiencies, a technologist from another VA medical center provided training that included workflow tools, breast imaging codes, mammography templates for documentation, as well as competencies for the mammography technologists.[44] Both mammography technologists at the facility received the training in October; however, the lead mammography technologist then resigned.

The OIG found the action plan did not create a long-term plan for a formalized training program to address mammography technologists' training deficiencies. Without a formal training system for all mammography technology program staff, as staff turn over, the program staff risk failing to properly perform critical functions.

Conclusion

While the facility managers completed reviews of screening and diagnostic mammography exams and documented evaluations of abnormal findings, the OIG found there were nine exams that were not included in the facility's reviews due to errors in diagnostic coding. However, these exams were found not to be abnormal by the facility.

[43] VHA Directive 1105.03 refers to the lead mammography radiologist as the lead interpreting physician. For ease of discussion in this report, the OIG uses the term, lead mammography radiologist.

[44] VHA Directive 1105.03.

Facility leaders and managers followed up with two facility-identified patients who had clinically significant mammography exams (breast cancer). Facility staff also addressed the abnormal mammography exams of the two additional breast cancer patients identified by the OIG. There was no evidence that the four patients' clinically significant disease was linked to a delay in receipt of the lay summary letters. All four breast cancer patients received timely notification by the ordering provider. Facility leaders also reviewed the other patients noted by the OIG who potentially required follow-up and did not identify adverse outcomes.

Similar to the facility's acknowledgment to Congressman Connolly related to patient notification of abnormal test results, the OIG found that ordering providers did not consistently document patient notification of abnormal mammography results within seven days as required.

At the time of the OIG review, the facility no longer had a functional facility-based mammography program due to loss of staff, and patients were receiving mammography services with the care-in-the-community program. The facility had plans to reopen the program. In February 2020, the facility employed a new lead mammography radiologist to facilitate implementation of the recommendations, but this was delayed by the coronavirus pandemic and subsequent resignation of the new lead mammography radiologist in June 2020. The facility hired another new lead mammography radiologist with an anticipated start date in December 2020 to continue implementation efforts. Facility managers and leaders had not taken action on and fully implemented the September 2019 National Radiology Program Office site visit recommendations. The OIG noted the National Radiology Program Office did not cite the facility's Mammography Program for lack of a standard operating procedure manual during the 2019 site visit despite a VHA requirement.

Apart from the National Radiology Program Office recommendations, the Facility Director initiated procedural changes to the facility's Mammography Program. The OIG determined facility leaders and managers did not fully implement Mammography Program procedural changes and processes that included oversight of the Mammography Program MSA duties and training. Mammography Program clerical and administrative functions were not defined in a standard operating procedure manual and there was a lack of appropriate oversight and quality controls in delegating the task of mailing patient lay summary letters, one avenue for communicating patient test results. The OIG also found the facility leaders needed to develop a formalized training program for mammography technology staff when trained staff leave employment at the facility to ensure appropriate monitoring and tracking of patients.

Recommendations 1–7

1. The Washington DC VA Medical Center Director evaluates documentation processes for entering the Breast Imaging-Reporting and Data System as primary diagnostic codes in the electronic health record and takes actions as necessary.

2. The Washington DC VA Medical Center Director evaluates the processes for notification of mammography exam results by ordering providers and takes actions as necessary.

3. The Washington DC VA Medical Center Director fully implements action plans for all issues listed in the September 2019 National Radiology Program Office site visit and monitors to completion.

4. The National Radiology Program Office ensures mammography programs have a comprehensive standard operating procedure manual and confirms compliance.

5. The Washington DC VA Medical Center Director develops and implements a comprehensive standard operating procedure manual covering critical technical, clerical, and administrative functions for the facility's Mammography Program.

6. The Washington DC VA Medical Center Director evaluates the oversight and training processes for the facility's Mammography Program medical support assistant and takes actions as necessary.

7. The Washington DC VA Medical Center Director evaluates mammography technology staff training processes and takes actions to ensure mammography technology staff receive training through a formalized program.

Appendix A: Executive in Charge Memorandum

Department of Veterans Affairs Memorandum

Date: November 30, 2020

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

Subj: OIG Draft Report, Mammography Program Deficiencies and Patient Results Communication at the Washington DC VA Medical Center (Report #2020-00563-HI-0981) (VIEWS: 03831852)

To: Office of Healthcare Inspections (54MC00)

1. Thank you for the opportunity to review and comment on the draft report on mammography at the DC VA Medical Center. The Veterans Health Administration's (VHA) National Radiology Program Office (NRPO) welcomes the OIG's feedback and the opportunity for improvement. VHA concurs with the recommendation to ensure mammography programs have a comprehensive standard operating procedure manual.
2. The Mammography Advisory Committee (MAC) is a group of breast imaging radiologists, mammography technologists, and field-based staff who work collaboratively to provide guidance to NRPO and the VHA imaging community. Recently, the MAC Chair worked with NRPO, the National Surgery Office and the Women's Health Office to issue a consensus statement for VHA breast imaging that medical facilities may use to prioritize breast imaging exams during the Coronavirus (COVID-19) pandemic.
3. Eighty-eight percent of VHA's mammography programs offer state-of-the-art 3-dimensional digital breast tomosynthesis, which has been shown to improve a radiologist's ability to diagnose breast cancer and decrease the number of women called back for additional imaging.
4. For comments related to this memorandum, contact Karen Rasmussen, M.D., Director, GAO OIG Accountability Liaison Office at VHA10BGOALAction@va.gov.

(*Original signed by*:)

Richard A. Stone, M.D.

Executive in Charge Response[53]

VETERANS HEALTH ADMINISTRATION (VHA)
OIG Draft Report DC Medical Center Director Action Plan
Mammography Program Deficiencies and Patient Results Communication at the Washington DC VA Medical Center
OIG (Report #2020-00563-HI-0981)

Recommendation 1. The Washington DC VA Medical Center Director evaluates documentation processes for entering the Breast Imaging-Reporting and Data System as primary diagnostic codes in the electronic health record and take actions as necessary.

VHA Comments: Concur. The Washington DC VA Medical Center has conducted an evaluation of the intricate documentation processes surrounding the Breast Imaging-Reporting and Data System (BI-RADS) capture. The process is automated and is further supported by a three-level system of redundancies. The Medical Center identified that the primary system of capturing the diagnostic code, automatic generation via PowerScribe dictation to the Medical Reporting Software (MRS7), had an integration failure which caused the BI-RADS code to not properly populate. The vendors (PowerScribe and MRS7) have worked to correct the integration and initial validation and communication between the two systems indicates that the problem is resolved. The Radiology Quality Improvement Committee will monitor Mammography reports once the program reopens for instances where BI-RADS is not communicated.

Status: Completed Completion Date: June 30, 2020

OIG Comment

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

Recommendation 2. The Washington DC VA Medical Center Director evaluates the processes for notification of mammography exam results by ordering providers and take actions as necessary.

VHA Comments: Concur. The Washington DC VA Medical Center has evaluated the notification processes for mammography exam results and, in response, implemented registered nurse breast navigators. The breast navigator provides notification for all normal mammography exams as a delegated task by the ordering provider. The breast navigator provides urgent communication to the ordering providers of all abnormal exam results to ensure patients are notified timely. The Medical Center will conduct

[53] Although the recommendations were addressed to the National Radiology Program Office and Washington DC VA Medical Center Director, the Executive in Charge provided responses to all recommendations. The VISN 5 and Washington DC VA Medical Center Directors reviewed and agreed with the Executive in Charge's responses.

randomized chart audits monthly to ensure that the Veterans are being notified of their results timely. The chart audits will consist of a random sampling of 50 patient mammography results monthly and will be audited to ensure all elements of the notification process have been completed in accordance with VHA standards. Evidence of compliance will be a 90% compliance with completing all elements of the notification process for a minimum of two quarters. The chart audits and compliance with this measure will be reported to the Quality, Safety, Value Executive Council.

Status: Ongoing Target Completion Date: June 30, 2021

Recommendation 3. The Washington DC VA Medical Center Director fully implements action plans for all issues listed in the September 2019 National Radiology Program Office site visit and monitors to completion.

VHA Comments: Concur. Between February 2020 and June 2020, under the supervision of the lead interpreting physician (LIP), the Medical Center made some progress in addressing the action items from the National Radiology Program Office site visit. In June 2020, the Medical Center voluntarily closed the Mammography Program with the American Colleges of Radiology after the loss of all LIPs who are credentialed to interpret breast images. In the absence of a full-time LIP, the Medical Center is unable to continue progress to achieve closure of the remaining action items. The new LIP is expected to on-board in the Winter of 2020/2021 and progress will restart on the action plan to ensure closure of the items.

Status: Ongoing Target Completion Date: June 30, 2021

Recommendation 4. The National Radiology Program Office ensures mammography programs have a comprehensive standard operating procedure manual and confirms compliance.

VHA Comments: Concur. The Assistant Under Secretary for Health for Operations in coordination with National Radiology Program Office (NRPO) will direct the Veterans Integrated Service Networks (VISN) Diagnostics Integrated Clinical Communities to provide attestation of compliance that each on-site mammography program within their health care system has a comprehensive standard operating procedure manual as per VHA Directive 1105.03, Mammography Procedures and Standards. For those facilities not demonstrating compliance, an action plan will be developed and submitted to the VISN Diagnostics Integrated Clinical Community.

Status: Ongoing Target Completion Date: July 2021

Recommendation 5. The Washington DC VA Medical Center Director develops and implements a comprehensive standard operating manual covering critical technical, clerical, and administrative functions for the facility's Mammography Program.

VHA Comments: Concur. Between February 2020 and June 2020, under the supervision of the lead interpreting physician (LIP), a standard operating procedure

addressing aspects of the three functional areas (technical, clerical, and administrative) was drafted. Given that the program is currently closed, and a new LIP is in the onboarding process (expected Winter 2020 - 2021), these standard operating procedures will need to be re-evaluated and implemented by the incoming leadership.

Status: Completed Completion Date: June 10, 2020

OIG Comment

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

Recommendation 6. The Washington DC VA Medical Center Director evaluates the oversight and training processes for the facility's Mammography Program medical support assistant and takes actions as necessary.

VHA Comments: Concur. The Washington DC VA Medical Center evaluated the Medical Support Assistant (MSA) role in the organization and found it did not provide the appropriate level of expertise to manage the complex nature of the Mammography program administrative functions. As such, the Medical Center is actively modifying the Radiology Department organizational chart to transition the MSA role to a Program Support Assistant (PSA) role. This PSA will be specifically assigned to the Mammography program. Training at the time of hire will be conducted collaboratively with the National Program Office and other Mammography programs in VA consistent with the American Colleges of Radiology quality requirements for management of a Mammography program. Recruitment for this position will occur when the Medical Center is preparing to reopen the mammography program.

Status: Completed Completion Date: May 30, 2020

OIG Comment

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

Recommendation 7. The Washington DC VA Medical Center Director evaluates mammography technology staff training processes and takes actions to ensure mammography technology staff receive training through a formalized program.

VHA Comments: Concur**.** The Washington DC VA Medical Center acknowledges gaps in mammography technology staff training. In response, the Medical Center has engaged the various vendors responsible for the systems used by the technologist to purchase relevant training resources and provide ongoing training support. This recommendation will be revisited when the Medical Center reopens the mammography program.

Status: Completed Completion Date: May 11, 2020

OIG Comment

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

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