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OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Pathology Processing Delays at the Memphis VA Medical Center

Tennessee

HEALTHCARE INSPECTION | REPORT #18-02988-198 | AUGUST 27, 2019

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a complainant's allegations regarding surgical pathology specimen processing delays in the Pathology and Laboratory Medicine Service (P&LMS) at the Memphis VA Medical Center (facility), Tennessee.

The complainant alleged that a prior Chief of P&LMS was responsible for delays in surgical specimen processing that resulted in multiple patients' harm and possibly death.

The OIG reviewed the electronic health records of 136 patients who had delayed pathology reports and found no adverse clinical outcomes related to the delays.

The OIG requested that facility leaders review the allegation, and they provided a response. The OIG determined that further review was required to evaluate the status of

1. Surgical pathology specimen processing delays,
2. P&LMS staffing issues,
3. P&LMS Quality Management program,
4. P&LMS staff's competency and training, and
5. Whether facility leaders concealed P&LMS deficiencies.

Facility leaders developed action plans to address surgical pathology specimen processing delays. They initiated an administrative investigation board review, removed a P&LMS chief, and contracted for an additional pathologist.[1] The OIG team reviewed facility data and determined that P&LMS staff improved turnaround times for surgical pathology specimens processed onsite. The OIG was unable to determine if off-site pathology turnaround times improved because of incomplete evidence. However, facility staff told the OIG team that they generated reports daily and weekly to review incomplete results.

In 2018, approximately 39 percent of P&LMS positions were vacant. Recruitment incentives were available for hard to hire positions but were not being used for critical staff vacancies in P&LMS. The OIG team found that Veterans Integrated Service Network (VISN) and national P&LMS leaders were aware of the facility's staffing shortages but did not intervene due to their

[1] VA Directive 0700, *Administrative Investigations*, March 25, 2002. An administrative investigation board (AIB) is a standard VA procedure used to collect and analyze evidence, ascertain facts, and document complete and accurate information regarding matters of interest to VA.

belief that they merely had consultative roles. The pathologists' shortage contributed to inconsistent surgical pathology quality assurance and prolonged specimen turnaround times.[2]

Facility leaders improved their Quality Management program by hiring a specialist for P&LMS. The facility had plans in place to ensure compliance with Quality Management program requirements; however, the plans were not fully implemented at the time of the OIG visit.

The OIG determined that facility leaders did not conduct a formal quality review, such as a root cause analysis or a healthcare failure mode effect analysis, to systematically determine the causes that contributed to the delays.[3] The OIG found that facility leaders conducted an administrative investigation board in September 2017 regarding complaints about surgical pathology specimen processing delays that impacted patient care.

During review of 40 P&LMS technologists' and technicians' records, the OIG identified deficiencies in initial training and annual competency documentation. P&LMS supervisors should have provided general and job specific training and documented consistently, for historical records, in the event of supervisor turnover. The OIG found that due to inconsistent P&LMS leadership, there was no accountability to ensure training was completed on a consistent basis. Without these measures, facility leaders were unable to ensure staff readiness to provide quality services for patients.

The OIG did not find that facility leaders attempted to conceal deficiencies discovered in P&LMS. During an interview with the VISN Chief Medical Officer, the OIG was told that leaders were aware of the surgical pathology specimen processing delays. However, facility leaders submitted an issue brief to the VISN dated approximately two months after their discovery of the delayed surgical pathology specimens. The issue brief listed problems in P&LMS related to environment of care and staffing but did not report delays in processing surgical pathology specimens. The OIG had concerns about Veterans Health Administration (VHA) senior leaders' awareness regarding oversight of processes to manage patients who had delays and evaluation of the need for a large-scale disclosure.

The OIG made one recommendation to the VISN 9 Director related to the development of staffing improvement strategies for P&LMS.

The OIG made seven recommendations to the Facility Director related to formalizing an ongoing process to track specimens, the use of quality processes to systematically identify areas of future

[2] For purposes of this report, quality management refers to a framework to help hospitals organize for, communicate about, monitor, and continuously improve all aspects of care delivery. Quality assurance refers to a process to determine if a product or service meets specific standards or requirements.

[3] Root cause analysis is used to improve and redesign systems and processes. During a root cause analysis, a multidisciplinary team investigate an actual or potential adverse clinical outcome to determine what happened, why it happened, and what can be done to prevent it from happening again. Healthcare failure mode effect analysis is a proactive, systematic, engineering-based approach use to identify system vulnerabilities and failure areas in an effort to correct them before they occur.

risk, the P&LMS Quality Management program, staff competency and training, and the issue brief process.

Comments

The VISN and Facility Directors concurred with the findings and recommendations and provided acceptable action plans. (See appendixes A and B, pages 24–31, for the Directors' comments.) The OIG will follow up on the planned actions until they are completed.

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Contents

Abbreviations

AIB	administrative investigation board
CAP	College of American Pathologists
CLIA	Clinical Laboratory Improvement Amendment
COS	Chief of Staff
EHR	electronic health record
OIG	Office of Inspector General
P&LMS	Pathology and Laboratory Medicine Service
QA	quality assurance
QM	quality management
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a complainant's allegations regarding pathology processing delays in the Pathology and Laboratory Medicine Service (P&LMS) at the Memphis VA Medical Center (facility), Tennessee. The OIG team focused on facility leaders' actions after their discovery of pathology delays and if corrective actions had been taken to prevent reoccurrence.

Background

The facility is part of Veterans Integrated Service Network (VISN) 9 and provides acute medical, surgical and intermediate care, and a full range of primary, specialty, and subspecialty care.[4] The facility has two off-site VA-staffed primary care clinics in the Memphis area, as well as four community based outpatient clinics in Arkansas, Mississippi, and Tennessee. The facility is classified as level 1a-high complexity.[5] In fiscal year 2017, the facility served 66,612 patients and had a total of 260 hospital operating beds, including 234 inpatient and 26 domiciliary beds. The facility's primary affiliation is with the University of Tennessee, Memphis, Colleges of Medicine, Dentistry, Nursing, Pharmacy, and Allied Health, with additional affiliations for associated health professions with colleges and universities throughout the country.

Pathology

Pathology covers a wide range of laboratory functions and supports the diagnosis of disease using laboratory testing of blood and other body fluids, tissues, and microscopic evaluation of individual cells. A pathologist looks at blood, urine, and other body fluid specimens under a microscope to make a diagnosis.[6] Pathologists may specialize in a specific branch of pathology, including surgical pathology and cytopathology.[7]

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[4] Specialty and sub-specialty care provided includes: psychiatry, neurology, spinal cord injury, rehabilitation, oncology, dentistry, and special services designated for women's care.

[5] The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex.

[6] Johns Hopkins Medicine Health Library, *Clinical Pathology Overview*, https://www.hopkinsmedicine.org/healthlibrary/conditions/pathology/clinical_pathology_overview_85,P00955. (The website was accessed on January 16, 2019.)

[7] Surgical pathology is a branch of anatomic pathology used as the basis for diagnosis during or after surgery. Pathologists performing surgical pathology advise surgeons on the correct diagnosis, therapy, and prognosis based off the specimen evaluated; cytopathology is the study and treatment of disease by examination of cells from various body sites.

Ordering providers depend on timely and accurate results of pathology testing to provide effective care.[8] Veterans Health Administration (VHA) requires that the diagnostic provider communicates pathology test results to the ordering provider within a timeframe that allows for prompt attention and appropriate action.[9] VHA guidelines require each facility to establish and monitor the expected turnaround time for surgical pathology.[10] The ordering provider must then communicate results requiring follow-up action within seven calendar days. For results not requiring action, the ordering provider or designee has 14 calendar days to inform the patient.[11]

Pathology and Laboratory Medicine Service

P&LMS functions as the primary source of medical diagnostic laboratory testing and transfusion functions in all VA medical facilities.[12] Testing may be conducted at sites within the facility or at ancillary sites that fall within the administration of the main clinical laboratory, such as community based outpatient clinic testing sites and satellite or specialty laboratories.[13] A laboratory test is an examination, diagnostic, or monitoring procedure on a specimen removed from the body to determine specific information for diagnosis, treatment, or prevention of disease, and to detect the impairment of health status, or assess the health of human beings.[14]

Duties of the Chief of P&LMS

The Chief of P&LMS provides oversight for all laboratory testing conducted at a facility, as well as community based outpatient clinic laboratories ancillary testing sites, and specialty or research laboratories operating under the facility's accreditation umbrella.[15] Although chiefs of P&LMS may delegate certain responsibilities to qualified medical or technical laboratory personnel, the primary management of the laboratory and delivery of patient care remains their responsibility.[16] The Chief of P&LMS is also responsible for implementing and evaluating the laboratory's

[8] An ordering provider is a provider authorized to enter and sign orders for diagnostic tests; Robert C. Hawkins, "Laboratory Turnaround Time," *The Clinical Biochemist Review* 28, no. 4 (November 2007): 179-94.

[9] A diagnostic provider performs or supervises the performance and interpretation of diagnostic tests; VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.

[10] Turnaround time is calculated from the day the specimen is submitted to the lab to the day the final report is signed by the pathologist. Only business days are counted. VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016.

[11] VHA Directive 1088.

[12] VHA Handbook 1106.01.

[13] VHA Handbook 1106.01.

[14] VHA Handbook 1106.01.

[15] VHA Handbook 1106.01.

[16] VHA Handbook 1106.01.

Quality Management (QM) program, as well as ensuring compliance with regulatory standards and VHA policies.[17]

P&LMS Staffing

VHA policy and Clinical Laboratory Improvement Amendment (CLIA) regulations identify the types and qualifications of personnel necessary to operate laboratories based on the complexity level of the facility.[18] Leaders are responsible for taking actions to ensure that staffing is adequate in P&LMS for the workload of the facility.[19] The laboratory must have staff who meet CLIA qualifications for the complexity of tests performed.[20]

P&LMS QM Program

VHA requires that VA medical centers provide an ongoing, comprehensive P&LMS QM program under the direction of the Chief of P&LMS.[21] The P&LMS leader must ensure the availability of accurate, reliable, and timely test results, and reports to the ordering provider. All QM activities must be defined in a written plan that includes elements to be monitored for all sections of the laboratory; in addition, activities must be documented.[22] The QM program must have a system in place to ensure that complaints and problems reported to the laboratory are documented, investigated, and corrective action instituted.[23] A system to provide ongoing assessment of the competency of the individuals performing patient testing is also required.[24]

As a part of the QM program, VHA requires surgical pathology cases undergo a random second-level review on a quarterly basis for quality assurance (QA).[25] During this QA review, a second pathologist evaluates the original pathologist's interpretation of the pathology specimens.

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[17] VHA Handbook 1106.01.

[18] Clinical Laboratory Improvement Amendments (42 CFR 493) are federal regulations that establish standards for laboratory testing performed on specimens from humans for the main purposes of diagnosis, prevention, or treatment of disease; VHA Handbook 1106.01.

[19] VHA Directive 1064, *Pathology and Laboratory Medicine Services Productivity and Staffing*, September 17, 2018.

[20] College of American Pathologists, CAP Personnel Requirements by Testing Complexity, https://documents.cap.org/documents/2016-07-18-personnel-evaluation-roster-personnel-requirements-test-complexity.pdf. (The website was accessed on January 16, 2018.)

[21] VHA Handbook 1106.01.

[22] VHA Handbook 1106.01.

[23] VHA Handbook 1106.01.

[24] VHA Handbook 1106.01.

[25] For purposes of this report, QM refers to a framework to help hospitals organize for, communicate about, monitor, and continuously improve all aspects of care delivery, and QA refers to a process to determine if a product or service meets specific standards or requirements; VHA Handbook 1106.01.

Facilities are required to maintain documentation of these reviews in accordance with VHA records control guidelines.[26]

VHA Oversight of P&LMS

Oversight of all VHA facility P&LMS programs is the responsibility of the P&LMS National Enforcement Office, led by the National Director for P&LMS and the National Enforcement Officer.[27] The National Enforcement Office includes 10 Regional Commissioner's Offices and the CLIA Proficiency Testing/Accreditation office. Responsibilities of the regional offices include key functions of regulatory and accreditation oversight, corrective action review, and onsite inspections and reviews.[28]

Oversight at the VISN level is done by VISN program managers. The VISN 9 P&LMS Program Manager works with the facility Chief of Staff (COS) and Chief of P&LMS to ensure programs are operating appropriately and comply with all federal and regulatory requirements. VISN program managers report findings of their program evaluations to VISN and facility leaders. Facility leaders are required to develop action plans based on the deficiencies found in these reports for any P&LMS requirements that are not met.

Regulatory Oversight of P&LMS

VHA P&LMS programs must meet standards, quality protocols, and compliance requirements set forth by CLIA and the College of American Pathologists (CAP). CLIA establishes standards for all U.S. facilities that conduct testing on human laboratory specimens.[29] Laboratories that receive a CLIA certificate undergo an initial inspection and a biennial recertification inspection.[30] Accreditation organizations, such as CAP and The Joint Commission, are approved to conduct initial and biennial certification inspections to determine compliance with CLIA.[31]

[26] VHA Handbook 1106.01.

[27] VHA Handbook 1106.01.

[28] VHA P&LMS National Enforcement Office, http://vaww.lab.med.va.gov/components/National_Enforcement_Office_Contact_P.asp. (The website was accessed on January 24, 2019.)

[29] Centers for Disease Control and Prevention, *About CLIA,* https://wwwn.cdc.gov/clia/About.aspx. (The website was accessed on October 9, 2018.)

[30] American Academy of Family Physicians, *CLIA Inspections,* https://www.aafp.org/practice-management/regulatory/clia/inspections.html. (The website was accessed on October 9, 2018.)

[31] Accreditation is defined as a hospital or other medical center committed to providing high-quality health care and a demonstrated commitment to meeting high patient-safety standards.

These organizations have proven requirements that meet or exceed the conditions of participation set forth in CLIA.[32] Facilities have the choice of CAP or The Joint Commission surveys.[33]

Accreditation was granted to the facility for survey years 2015 and 2017. For the 2017 survey, accreditation was contingent on the facility meeting certain requirements, including the quarterly CAP submission of the surgical pathology QA review.

Facility and P&LMS Leadership Changes

The Director, COS, Chief of P&LMS, and laboratory manager positions have been variously staffed with permanent, interim, or acting staff at different periods over, at least, the last five years. Many of the events in this report occurred during the tenure of former facility and P&LMS leaders, making some historical information difficult to access. Key leadership changes during this review are detailed in figure 1.

[32] Center for Medicare and Medicaid Services, *Policy and Requirements for an Application for Approval of an Accreditation Program*, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/applicationrequirements.pdf. (The website was accessed on October 9, 2018.)

[33] The Joint Commission, Clarification: Approved Laboratory Services in a Joint Commission-Accredited Primary Program, Joint Commission Perspectives 32, no. 4 (April 2012).

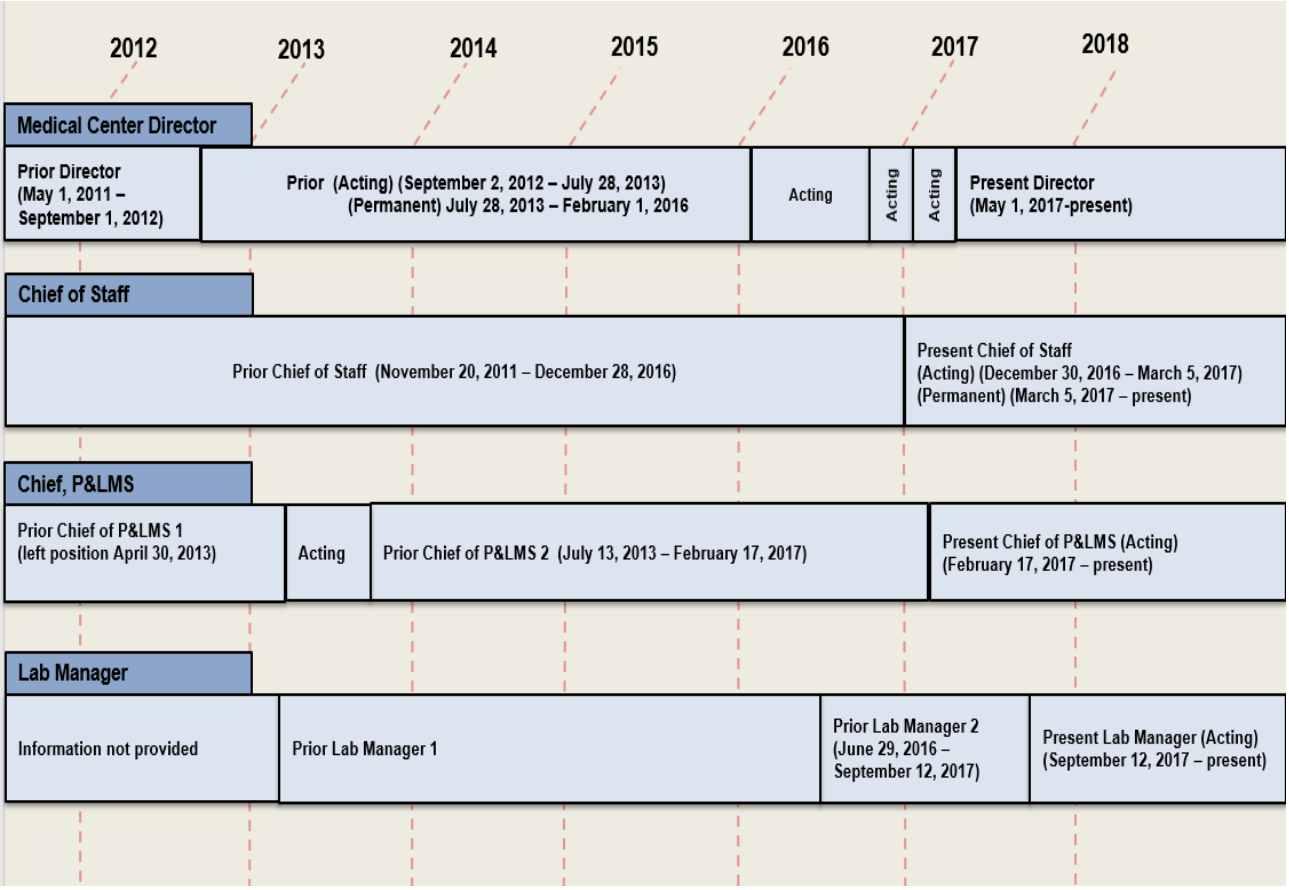

Figure 1. Relevant facility and P&LMS leaders from May 2012 through October 2018
Source: OIG analysis of facility documentation

Allegations and Related Concerns

On March 1, 2018, the OIG received an anonymous complaint alleging that a prior Chief of P&LMS was responsible for delays in laboratory specimen processing that resulted in patient harm and possibly death due to delayed reporting of pathology results.

The OIG referred the allegations to facility leaders on March 13 and received a response on May 9. In their response, facility leaders stated that 123 case reports were not available to ordering providers in patients' electronic health records (EHRs), and there was an insufficient tracking system for specimens sent out of the facility.

The OIG reviewed the facility leaders' response, including results of an administrative investigation board (AIB).[34] The response indicated that clinical reviews of the patients affected were completed with no evidence of adverse clinical outcomes from the processing delays. The OIG determined further review was warranted to evaluate whether increased risk and/or adverse clinical outcomes had occurred to patients, and whether corrective actions had been taken to prevent these issues from recurring. The OIG identified specific concerns for further review including

- Surgical pathology specimen processing delays,
- P&LMS staffing issues,
- P&LMS QM program,
- P&LMS staff's competency and training, and
- Whether Facility leaders concealed P&LMS deficiencies.

[34] VA Directive 0700, *Administrative Investigations*, March 25, 2002. An AIB is a standard VA procedure used to collect and analyze evidence, ascertain facts, and document complete and accurate information regarding matters of interest to VA.

Scope and Methodology

The OIG team initiated the inspection on July 24, 2018, and conducted a site visit from October 30 through November 1, 2018.

The OIG team interviewed the facility COS, acting Chief of P&LMS, and acting P&LMS laboratory manager. Facility staff interviews included medical technologists, pathologists, staff providers, the facility's patient safety manager, risk manager, a QM specialist, the administrative officer, and human resource representatives for P&LMS. Interviews with former P&LMS staff included the former P&LMS laboratory manager, a former P&LMS program support assistant, and the former secretary to the COS. Additionally, the OIG team interviewed the Region 5 Technologist from the National Enforcement Office Regional Commissioner Program, the VISN 9 Chief Medical Officer and P&LMS Program Manager, a specialist in P&LMS programs requested by the VISN to conduct a facility assessment, and residents from the University of Tennessee pathology program. The OIG team reviewed the results of the following external site visits conducted at the facility:

- February 2016: VISN 9 P&LMS Program Manager Site Visit
- March 2016: Regional Technologist/Region 5, P&LMS Regional Commissioner Program
- May 2016: VHA P&LMS Consultant Independent Assessment
- February 2017: Regional Technologist/Region 5, P&LMS Regional Commissioner Program

The OIG team reviewed relevant AIB documents, VHA and facility policies and procedures, directives, handbooks, guidelines, and requirements. The OIG team also reviewed CAP accreditation documents, QA data reports, and employee competency and training files. The OIG team reviewed the EHRs of 136 patients identified from documents provided by the facility as having delayed pathology specimens for the period October 1–December 31, 2016. On October 31, 2018, the OIG team conducted two unannounced observational inspections of the P&LMS area.

Within the context of this report, the OIG team considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level of care associated with care or services delivered by VA providers. The OIG team recognizes that in addition to the potential for adverse clinical outcomes, avoidable delays associated with the deficiencies discussed in this report may impact the quality of care received. This report focuses on patient harm in terms of adverse clinical outcomes.

For purposes of this report, and to review P&LMS timeliness issues, the OIG team defined a processing delay as any routine surgical pathology result completed inside the facility with a

turnaround time of more than two working days.[35] The OIG team defined risk as a delay in patients' care that could result in an adverse clinical outcome. The risk associated with specimen processing delays is a clinical judgment based on many factors including the severity of the patient's condition and the magnitude of the delay. Risk may or may not result in an actual adverse clinical outcome.

In the absence of current VA or VHA policy, the OIG team 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.

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

[35] Facility P&LMS Policy, *Surgical Pathology Quality Assurance Policy*, August 8, 2015.

Inspection Results

1. Surgical Pathology Specimen Delays

The OIG team reviewed surgical pathology reports and substantiated that specimens collected between October through December 2016 were delayed up to 120 days.[36]

During interviews, the COS related becoming aware of potential surgical pathology specimen delays in January 2017 after the Chief of Medicine received a letter of concern from facility providers. This prompted the COS to meet with a prior Chief of P&LMS, who generated a Veterans Health Information Systems and Technology Architecture (VistA) report listing all surgical pathology specimens that were currently in an incomplete status. P&LMS leaders determined that 123 surgical pathology specimens were not available for the ordering provider to view in VistA, and five were unprocessed.[37] The facility goal for turnaround time of surgical pathology is two days. VHA requires that reports are entered into the VistA laboratory module. Delays in uploading and verifying results in VistA were attributed to a transcription software issue that was corrected by facility staff. The COS ensured providers were notified of completed results once the transcription software issue was corrected. Facility staff also determined there was an insufficient tracking system for specimens sent out of the facility for processing in the community.

In February 2017, the COS found surgical pathology specimens in the processing area that appeared to be waiting to be prepared for processing and shipping to community laboratories.[38] According to a prior laboratory manager, these cases were delayed due to a reliance on University of Tennessee pathology residents for initial processing of specimens, who had not been at the facility for several days, and pathologists did not have time to do the initial processing of these specimens. Facility leaders allocated additional internal resources, and approved contract laboratories and other VISN 9 facilities to complete the processing of these surgical pathology specimens.

P&LMS Surgical Pathology Turnaround Times

The OIG team determined that P&LMS staff improved turnaround times for surgical pathology cases processed onsite. VHA guidelines require each facility to establish and monitor the

[36] At the time of this event, the COS had been in an acting status from December 2016 until taking over the position permanently in March 2017. The previous COS retired in late 2016.

[37] VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015. The process of validating is called authentication or verification, and attests that information is from the VA laboratory or received from another laboratory outside of VHA and is available for the ordering provider; VHA Handbook 1106.01.

[38] The processing area is a section of the laboratory where the pathology assistants and residents would prepare specimens for evaluation.

expected turnaround times for routine onsite surgical pathology specimen case processing.[39] The facility's P&LMS Surgical Pathology QA policy establishes a two-working day goal for completion and verification of processed surgical pathology specimen cases.[40] The OIG team reviewed surgical pathology QA documents for January 2017–September 2018 to determine timeliness of specimen turnaround times and found that the facility had demonstrated a steady decrease in turnaround times over a 21-month period (see figure 2).

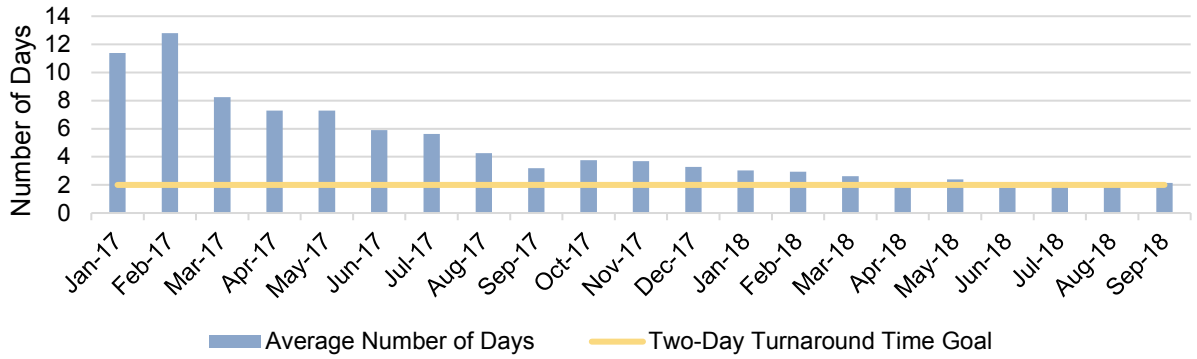

Figure 2. Surgical Pathology Turnaround Times
Source: Facility data on surgical pathology turnaround times for January 2017–September 2018

The OIG team was unable to determine if turnaround times for specimens sent into the community for processing had improved. The OIG team requested turnaround time data for specimens that were sent out of the facility to contract or reference laboratories for processing. However, the acting Chief of P&LMS told the OIG team that facility P&LMS staff did not track turnaround times for specimens sent into the community.

P&LMS staff told the OIG team that reports for specimens are generated daily and weekly to review incomplete results and prevent surgical pathology specimen processing delays from recurring. This task is assigned to a P&LMS medical technologist and reviewed by the laboratory manager. Facility leaders were unable to produce evidence that this practice had been incorporated into standard operating procedures. These measures were identical to actions taken by the former Chief of P&LMS when delays were discovered in December 2015 and were ineffective in preventing these most recent delays. The OIG determined that this process needs to be incorporated into the ongoing quality processes to ensure they are closely followed with analysis and actions when not done.

[39] Although VHA guidelines recommend that each facility develop their own turnaround times, they recommend a two-day benchmark when routine testing is performed onsite; VHA Handbook 1106.01.
[40] Facility P&LMS Policy.

Clinical Impact of Surgical Pathology Processing Delays

Of the patients reviewed who had pathology processing delays, the OIG team did not identify any patients who experienced an adverse clinical outcome from the delays.

Facility leaders reported that as of January 2017, there were 123 unique surgical pathology cases with results pending 120 days or greater.[41] During the site visit, the OIG team requested the list of 123 patients, but did not receive a complete list totaling 123 patients. The COS told the OIG team of conducting an internal review of the patients identified to determine if delayed surgical pathology specimen results harmed patients or if ordering providers knew the results and had provided required patient follow-up. The COS stated that based on this review, patients suffered no adverse clinical outcomes due to the delays.

The COS could not supply a list of the unprocessed specimens from February 2017 but reported that the surgical pathology specimens in question were included on the VistA report provided to the OIG team. The COS reported that the list provided to the OIG team was the list the COS reviewed. The first list provided to the OIG team was a copy of the VistA report generated in January 2017. While the stated total of records on the bottom of the report added up to 123, the report only contained the names of 110 patients with surgical pathology specimen results pending 120 days or greater.

In addition to the VistA report, a second document was provided to the OIG, a supplemental list created by the former P&LMS laboratory manager that contained the names of 26 patients.[42] During interviews, facility staff could not explain why these lists did not total 123 names nor could they verify how patients were identified for the supplemental list. These two sources combined identified a total of 136 cases possibly affected by surgical pathology specimen result delays. The OIG team lacked confidence that facility leaders completed a comprehensive assessment of the processing delays and impact on affected patients due to their inability to verify the methodology used to accurately identify patients.

The OIG team conducted EHR reviews for the 136 patients identified in the two documents provided to determine whether there was evidence of adverse clinical outcomes, such as significant interruptions in care, or change in treatment plans due to surgical pathology specimen processing delays.[43] OIG inspectors referred 19 patients for in-depth review by the OIG medical consultant. Of the 136 patients reviewed, the team did not identify any patients who experienced an adverse clinical outcome from the delays.

[41] The facility did not provide a list of patients affected by the delays in pathology processing at that time.

[42] The supplemental list contained the names of 32 patients; however, six patient names were duplicates of names found on the VistA report.

[43] The OIG defined "adverse clinical outcome" as death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level care.

Facility Response to Surgical Pathology Processing Delays

The OIG team found that facility leaders were unable to provide documentation identifying completion of a formal quality review to systematically determine root causes that contributed to processing delays of surgical pathology specimens.

In evaluating the time frame and facility leaders' response to the delays, the OIG team reviewed AIB documents and a strengths, weaknesses, opportunities and threats analysis related to surgical pathology specimen processing delays.[44] However, facility leaders were unable to provide documentation showing completion of a formal quality review, such as a root cause analysis or healthcare failure mode effect analysis, to systematically determine root causes that contributed to delays and provide information needed for performance improvement plans.[45] Due to a failure to conduct a systematic analysis, causes identified may be assumptions made based on perception rather than actual analysis.

The OIG team determined that facility leaders reported surgical pathology specimen processing delays discovered in January 2017 to VISN 9 leaders. The OIG team found that facility leaders conducted an AIB in September 2017, investigating complaints about surgical pathology specimen processing delays that impacted patient care identified as early as March 2016. The AIB concluded that the implemented corrective action plans, based on these complaints, were unsuccessful in preventing recurrences of surgical pathology specimen processing delays.

During two days in January 2017, facility and P&LMS leaders, along with staff members from engineering, logistics, environmental services, and P&LMS, worked to correct P&LMS environment of care deficiencies, resolve inoperable equipment and maintenance issues, and update operational documents.[46] In February, facility leaders completed the strengths, weaknesses, opportunities, and threats analysis to identify gaps affecting the efficiency and quality of the P&LMS including staffing, equipment, operating procedures, and the relationship with the local medical school. Facility leaders created a document to track progress and implemented weekly meetings to discuss and update the status of each of the items identified in January and during the strengths, weaknesses, opportunities, and threats analysis.

[44] A strengths, weaknesses, opportunities, and threats analysis is a tool used for strategic analysis that identifies internal and external factors affecting an organization.

[45] Root cause analysis is used to improve and redesign systems and processes. During a root cause analysis, a multidisciplinary team investigates an actual or potential adverse clinical outcome to determine what happened, why it happened, and what can be done to prevent it from happening again; healthcare failure mode effect analysis is proactive, systematic, engineering-based approach used to identify system vulnerabilities and failure areas in an effort to correct them before they occur.

[46] The two-day review was ordered by the VISN 9 Director to validate the accuracy of laboratory equipment. During this two-day period, pathology specimens were sent out to other laboratories for processing.

The OIG team reviewed and found that the weekly meetings tracked

- Priority vacancies for P&LMS staff,
- Equipment and supply purchases, updates, and repair,
- Assessment of staff competencies and educational requirements,
- Assessment of space requirements and needs,
- Policy and communication updates, and
- CAP accreditation.

2. P&LMS Staffing

The OIG team found that inadequate staffing affected the ability of P&LMS staff to manage surgical pathology specimens delivered for processing in a timely manner.

VHA requires that facility laboratories have sufficient qualified staff to perform the complexity of needed tests.[47] The OIG team reviewed current and past facility P&LMS staffing to determine if staffing requirements had been met. The review included current P&LMS vacancies, positions remaining unfilled over time, and effects of staffing shortages in P&LMS.

Vacancies

P&LMS leaders provided the OIG team with documents related to unfilled P&LMS positions. At the time of the OIG team visit in November 2018, 79.8 full time employee equivalents were approved for P&LMS with 29.8 full time positions vacant. The COS stated that P&LMS leaders were utilizing contract employees to address vacancies in frontline staff, including medical technicians and histopathologists. Ongoing recruitment efforts were underway for P&LMS positions (see table 1).

[47] VHA Handbook 1106.01.

Table 1. November 2018 P&LMS Vacancies

Position Title	Number of Vacancies
Staff Pathologist	1.8
Pathologist Specialist	1
Program Assistant	1
Laboratory Information Manager	1
Transcription Program Assistant	2
Medical Technologist	8
Supervisory Medical Technician	1
Lead Medical Technician	2
Medical Technicians	10
Supervisory Histopathology Technicians	1
Histopathology Technician	1

Source: OIG analysis of P&LMS organizational data provided by facility leaders in October 2018

Positions Remaining Unfilled Over Time

The facility provided vacancies for P&LMS from fiscal year 2014 through fiscal year 2018. P&LMS vacancies are listed in table 2.

Table 2. 2014–2018 P&LMS Vacancies

Fiscal Year	Approved Full Time Positions	Positions Under Recruitment
2014	83.8	18
2015	83.8	18
2016	75.6	27
2017	81.6	41.8
2018	79.8	30.8

Source: Facility data on P&LMS vacancy rates for fiscal year 2014–2018

The OIG team found through interviews and reviews of external reports that facility and VISN 9 leaders, as well as the Region 5 Commissioner's office, were aware of P&LMS staffing shortages as early as February 2016.[48] Reports to facility and P&LMS leaders consistently contained findings related to staffing.

[48] Additionally, the Program Manager told the OIG team in an interview that results from visits are always briefed to the Chief of P&LMS, COS, and the Facility Director.

The OIG team learned through interviews that the VISN and national P&LMS leaders believed that their roles were consultative in nature, and their responsibility was limited to creating awareness of staffing concerns and making recommendations for improvements to P&LMS leaders. Ultimately, facility and P&LMS leaders had the direct responsibility of ensuring that staffing was adequate for workload of P&LMS.[49] The AIB identified that the service was given approval to hire needed staff; however, staffing levels remained at "critical levels" during that time period. Although facility leaders were monitoring vacancies weekly at the time of our site visit, facility leaders continued to have challenges adequately staffing P&LMS.

The OIG team identified barriers that negatively impacted the ability of facility leaders to consistently staff P&LMS. Facility leaders cited that a lengthy hiring process and lower pay led to the loss of qualified applicants to other area hospitals. The COS told the OIG team that limited promotional opportunities for P&LMS medical technologists and technicians led them to leave the department for other higher paying positions within the facility.[50] Turnover for human resource specialists handling personnel actions for P&LMS contributed to delays in processing hiring actions. Recruitment and retention incentives such as the Education Debt Reduction Program were available for hard to fill positions. However, none of the individuals interviewed could validate the program was being used. To further understand and evaluate recruitment options, the OIG team contacted the National Healthcare Recruitment Service in VHA and learned that the service is available as a resource to facility human resource staffing specialists and can assist with developing strategies to improve outcomes in recruiting.

Effects of Staffing Shortages

The OIG team found that inadequate staffing affected the ability of the P&LMS to manage specimens delivered for processing in a timely manner. The OIG team noted that the shortage of pathologists directly contributed to gaps in surgical pathology QA prolonged turnaround times. The residency program with the University of Tennessee was also adversely affected by a lack of pathologists, as pathology residents did not receive adequate training and mentorship from pathologists on staff, who were unable to find time for teaching. The AIB identified that pathology residents were allowed to work without appropriate levels of supervision. To correct these issues, facility leaders developed an affiliation agreement with the University of Tennessee to address pathologist shortages and provide contract pathologist coverage for P&LMS.

Through OIG team interviews, several facility staff expressed a strained relationship between P&LMS leaders and staff. P&LMS leaders and staff were aware that the P&LMS service lacked a cohesive environment and acknowledged that problems had been difficult to resolve. A lack of

[49] VHA Directive 1064.

[50] The medical technologist position is one of the top five occupations with the largest staffing shortages across VHA.

collaboration within the service had the potential to put patients at risk for adverse clinical outcomes.[51]

3. Lapses in the P&LMS QM Program

At the time of the OIG site visit in November 2018, the facility had action plans in place to ensure compliance with the QM program. However, the OIG team was unable to find evidence of an ongoing, comprehensive P&LMS QM program that ensured the availability of accurate, reliable, and timely test results and reports to the ordering providers.

The OIG team found deficiencies in the facility's required quarterly surgical pathology QA reviews and required quality committee processes, including failure to document monthly QA meetings for reporting of data to facility leaders, and demonstration of analysis of results with defined actions. As a result, the OIG team could not confirm a consistent process was previously in place for oversight by facility leaders of quality for P&LMS. However, the OIG team found that current facility leaders were working to address previous lapses in the program.

Surgical Pathology QA

The OIG team found no documentation that the required surgical pathology QA reviews occurred between October 2015 and December 2016; however, facility staff/pathologists completed reviews monthly since January 2017. VHA requires a sample of all surgical pathology cases be reviewed at least quarterly by a peer.[52] Because pathology specimens are used to diagnose and determine treatment, the accuracy of the pathology diagnosis is critical for patient care and is an important indicator of quality.[53] The OIG team determined that facility and P&LMS leaders could not ensure the accuracy of pathology diagnosis without completion of surgical pathology QA reviews.

A November 2016 CAP Self-Inspection report, and reports from 2016 and 2017 National Enforcement Office Regional Commissioner Program visits, documented that the surgical pathology QA review was incomplete.[54] In January 2017, deficiencies in surgical pathology QA were first addressed by the newly acting P&LMS leaders. The acting Chief of P&LMS and a staff pathologist attributed the surgical pathology QA gaps to pathologist shortages. The COS told the OIG team that lapses occurred due to the extended vacancy of the P&LMS QM position and failure of a prior Chief P&LMS to ensure that QA was completed as required.

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[51] Michelle O'Daniel and Alan Rosenstein, "Professional Communication and Team Collaboration," *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. (Agency for Healthcare Research and Quality, 2008).

[52] VHA Handbook 1106.01.

[53] R.E. Nakhleh, "What is quality in surgical pathology?" *The Journal of Clinical Pathology* 59, no. 7 (July 2006): 669–672.

[54] Laboratories accredited by CAP are required to complete a self-inspection evaluation in the interim year between the scheduled biennial CAP inspection.

That same month, the acting Chief of P&LMS took steps to correct the deficiencies in surgical pathology QA by decreasing surgical pathology workload and allowing facility pathologists to address incomplete QA. In September, the acting Chief of P&LMS hired two temporary contract pathologists to assist with QA.

The inability of facility P&LMS staff to document consistent QA reviews led to a non-conformance finding during the 2017 CAP survey.[55] The OIG team reviewed the 2017 CAP report, which stated that accreditation was granted provided additional requirements were met, including submission of the surgical pathology QA reviews. In April 2018, facility leaders began submitting documentation of QA reviews on a quarterly basis to fulfill CAP accreditation requirements.

QA/Quality Improvement Committee Processes and Data

The OIG team found that facility P&LMS staff did not consistently document monthly QA meetings or report P&LMS QA data to facility leaders. As a result, the OIG team could not confirm a consistent process by facility leaders for oversight of quality for P&LMS.

VHA requires facilities to develop an ongoing, comprehensive P&LMS QM program to evaluate the effectiveness of laboratory procedures in providing accurate, reliable, and timely test and pathology results.[56] Program objectives must be defined in a written Quality Plan that encompasses all areas of P&LMS.[57]

According to the facility P&LMS QM plan, the P&LMS quality manager is responsible for reviewing QA performance indicators and reporting monthly to the Chief of P&LMS.[58] The P&LMS QA/Quality Improvement Committee, led by the Chief of P&LMS, laboratory manager, and quality manager, is responsible for planning, implementing, and reporting oversight of P&LMS performance improvement activities. The COS told the OIG team that prior to the facility's discovery of processing delays in January 2017, there was a lack of accountability for how P&LMS QA data was reported through the facility committee structure. The OIG team found that before hiring the P&LMS quality manager in August 2018, a member of the facility QM Department assisted with the collection of QA data. QM staff provided the OIG team with P&LMS QA data for FY 2016 and FY 2017, but were unable to produce any record of QA/Quality Improvement Committee meeting minutes that would indicate discussion, analysis, or actions of QA data.

The lack of documentation of committee minutes indicates that although facility staff collected quality data, they may not have discussed, analyzed, or taken actions needed as outlined in the P&LMS plan. The OIG team found that during the site visit, the COS received briefings on

[55] "Non-conformance" is defined as a problem that has occurred and needs to be corrected.

[56] VHA Handbook 1106.01.

[57] Areas of P&LMS include clinical pathology, anatomic pathology, and ancillary testing.

[58] The P&LMS Quality Manager position had been vacant until August 2018.

P&LMS QA data from the new P&LMS quality manager during the weekly multidisciplinary team meetings. The OIG team was told in interviews that plans were in place to conduct and record required monthly QA/Quality Improvement Committee meetings, and that P&LMS staff were working to convert the QA data collection process to an electronic format for reporting and trending of corrective actions.

4. P&LMS Staff Competency and Training

The OIG team found training and competency documentation for P&LMS staff was missing.

VHA requires annual competency assessment for all P&LMS laboratory testing personnel. The OIG team identified previous external reports that noted missing training and competency documentation for P&LMS staff. The OIG team requested initial orientation and annual competency documentation for 40 medical technologists and technicians who performed patient testing in P&LMS. The OIG team identified multiple documentation deficiencies:

- Sixteen of 40 (40 percent) P&LMS staff were missing 2017 annual competency documentation.
- Fourteen of 40 (35 percent) P&LMS staff were missing 2018 annual competency documentation.
- Ten of 16 (62.5 percent) P&LMS staff hired between 2016 and 2018 were missing initial orientation documentation.
- Twelve of 16 (75 percent) P&LMS staff hired between 2016 and 2018 were missing required six-month competency assessments.

The OIG team reviewed and found evidence of employee training on newly purchased and implemented equipment while touring the laboratory during the site visit. P&LMS supervisors should have provided general and job specific training and documented consistently, for historical records, in the event of supervisor turnover. Without these measures, facility leaders were unable to ensure staff readiness to provide quality services for patients.[59]

5. Alleged Concealment by Facility Leaders of P&LMS Deficiencies

The OIG team was unable to determine if previous facility leaders concealed deficiencies in P&LMS because of insufficient evidence from the former COS. The OIG team learned through interviews that the former COS lost emails and other files prior to retiring in December 2016. The current COS and the former secretary to the COS confirmed the missing files included provider performance appraisal documents but could not confirm if files related to P&LMS were included in the missing data.

[59] Neeraj Kak, Bart Burkhalter and Merri-Ann Cooper, Measuring the competence of healthcare providers, *Operations Research Issue Paper* 2, no. 1 (2001).

Issue Brief

The OIG team determined during an interview that the VISN 9 Chief Medical Officer was aware of the 123 surgical pathology specimens with processing delays found in January 2017 and that facility leaders submitted an issue brief to the VISN. However, the OIG team was concerned with issue brief details concerning events that occurred in P&LMS and the timeliness of this reporting.

An issue brief provides clear, concise, and factual information about unusual incidents, deaths, disasters, or anything else that might generate media interest or impact patient care. The issue brief that facility leaders submitted to the VISN addressed P&LMS staffing issues but failed to mention the 123 delayed surgical pathology specimens resulting from the staffing issues.

The issue brief was submitted in March 6, 2017, approximately six weeks after delays were discovered and approximately four weeks after the facility's two-day review that was ordered by the VISN 9 Network Director. During this two-day period, pathology specimens were sent out to other laboratories for processing.

The VA medical facility director, VISN director, or program officer, as appropriate, must submit an issue brief within 24 hours of discovery of an event if possible large-scale disclosures may be needed. Large-scale disclosures may be needed if multiple patients may have been affected by an adverse clinical outcome involving actual or potential harm. [60] The VISN 9 Chief Medical Officer did not reach out, as required, to VA Central Office for guidance in evaluation of the extent and impact of processing delays, or to determine whether a large-scale disclosure was needed.

Facility and VISN leaders are required to submit an issue brief within 24 hours for curtailment of services, as a result of staffing vacancies, describing the clinical service(s) affected, the impact on patient care, specifics about the cause of the curtailment, the circumstances that led to the curtailment of service(s), full analysis of all alternatives considered, and a comprehensive plan for returning to full operational status including a timeline, and the use of interim solutions including, if applicable, locum tenens, VISN-wide resources, and telehealth.[61]

It is unknown if submitting the issue brief with all the details of the delayed surgical pathology specimens would have warranted a large-scale disclosure, but it is an important process that was not followed, and full support and oversight by VHA senior officials was not utilized to make these determinations.

[60] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients,* October 31, 2018. Large- scale disclosure is sometimes referred to as notification, is a formal process by which the VHA officials assist with coordinating the notification to multiple patients that they may have been affected by an adverse clinical outcome resulting from a systems issue (problems that might require system improvement at one or more facilities).

[61] Curtailment of facility operations can be temporary and affect clinical care and are due to a variety of conditions including renovations and staffing vacancies.

Conclusion

Of the patients reviewed who had pathology processing delays, the OIG team did not identify any patients who experienced an adverse clinical outcome from the delays. In January and February 2017, surgical pathology processing delays were attributed to a transcription software issue, shortages of facility pathologists, and a reliance on University of Tennessee residents for initial processing of specimens. P&LMS staff improved turnaround time for surgical pathology specimens processed onsite. Facility leaders were unable to produce evidence that processes to prevent delays had been incorporated into a P&LMS policy.

P&LMS staffing was deficient and inadequate technologist staffing affected the ability of P&LMS leaders to manage specimens for processing in a timely manner. Although recruitment incentives were available for critical vacancies, they were not used. A shortage of pathologists contributed to gaps in surgical pathology QA and prolonged pathology specimen turnaround times. Facility leaders developed an affiliation agreement with the University of Tennessee that addressed pathologist shortages and provided contract pathologist coverage for P&LMS.

Prior facility leaders failed to effectively address problems with the P&LMS service, resulting in the removal of a P&LMS chief. New facility leaders implemented corrective actions to address surgical pathology specimen processing delays. However, facility leaders did not conduct a formal systematic quality review investigation to determine root causes that may have contributed to delays.

Because the OIG team could not verify the methodology used to identify patients affected by surgical pathology processing delays, the OIG was unable to determine if facility leaders completed a comprehensive assessment of the processing delays and any impact on affected patients. The OIG reviewed the EHRs of 136 patients identified on documents provided by facility leaders and confirmed that none of the patients experienced adverse clinical outcomes or delays in care due to delayed pathology reports.

There were deficiencies in the P&LMS QM program, including required surgical pathology QA reviews, monthly QA meetings, and failure to document QA data analysis or actions to improve. As a result, the OIG team could not confirm a consistent process was previously in place for oversight by facility leaders of quality for P&LMS. P&LMS surgical pathology QA reviews were up-to-date at the time of the site visit, and plans were in place to conduct and record required monthly QA/Quality Improvement meetings and improve the QA data collection process.

The OIG team reviewed current employee training and competency files and found documentation was missing for initial orientation, six-month competency assessments, and annual competency assessments. Without these documents, P&LMS leaders were unable to ensure staff readiness to provide quality services for patients.

The OIG team was unable to determine if previous facility leaders concealed deficiencies in P&LMS. An issue brief submitted to VISN leaders six weeks after the delayed surgical pathology specimens were identified and addressed P&LMS staffing issues without mention of the delays in surgical specimens. The VISN 9 Chief Medical Officer did not reach out to VA Central Office for guidance or to determine whether a large-scale disclosure was needed. It is unknown if timely submission of the issue brief or consultation with VA Central Office would have changed actions taken by the facility; however, failure to follow guidance on issue briefs may have limited the support and oversight provided by VHA senior officials.

Recommendations 1–8

1. The Veterans Integrated Service Network Director ensures that Memphis VA Medical Center leaders assess staffing needs, to include factors impacting the ability to recruit and retain staff, develop plans to improve staffing, and assist in hiring to staff Pathology and Laboratory Medicine Service as required by the Clinical Laboratory Improvement Amendment and Veterans Health Administration.

2. The Memphis VA Medical Center Director verifies the development and implementation of a formal process to track surgical pathology specimens sent out of the Memphis VA Medical Center for processing and monitors compliance.

3. The Memphis VA Medical Center Director ensures a comprehensive assessment of the Pathology and Laboratory Medicine Service to identify specific root causes of surgical pathology specimen delays and takes steps to prevent risk of future occurrences.

4. The Memphis VA Medical Center Director ensures that Pathology and Laboratory Medicine Service leaders provide an ongoing, comprehensive Quality Management program that identifies the availability of accurate, reliable, and timely test results and reports to the ordering providers.

5. The Memphis VA Medical Center Director ensures compliance with required surgical pathology Quality Assurance policies and practices, and that Memphis VA Medical Center leaders monitor compliance.

6. The Memphis VA Medical Center Director ensures that an ongoing process is developed and implemented for Memphis VA Medical Center oversight of Pathology and Laboratory Medicine Service quality data, that includes documentation of the discussion of quality assurance and analysis of the data and the development of action plans as needed.

7. The Memphis VA Medical Center Director verifies that all Pathology and Laboratory Medicine Service employees that perform patient testing have updated competencies and documented training on their assigned duties.

8. The Memphis VA Medical Center Director ensures that Memphis VA Medical Center leaders understand the importance of the issue brief process and comply with the Deputy Under Secretary for Health and Operations Guidance.

Appendix A: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: July 19, 2019

From: Director, VA Midsouth Health Care Network (10N9)

Subj: Healthcare Inspection—Pathology Processing Delays at the Memphis VA Medical Center, Tennessee

To: Director, Office of Healthcare Inspections (54HL06)
Director, GAO/OIG Accountability Liaison (GOAL) Office (VHA 10EG GOAL Action)

1. Attached please find the Director of VA Midsouth Health Care Network (10N9) and the Memphis VA Medical Center facility response to the Office of Inspector General Unpublished Report regarding Pathology and Laboratory Medicine Services processing delay.
2. If you have any questions regarding the information provided, please contact Dr. David Massaro, VISN 9 Deputy Chief Medical Officer at 615-695-2199 and Mickie McClain, VISN 9 Pathology and Laboratory Medicine Service Program Manager at (423) 926-1171, Ext. 4421.

(*Original signed by:*)

Cynthia Breyfogle, FACHE

Network Director
VA MidSouth Healthcare Network

Comments to OIG's Report

Recommendation 1

The Veterans Integrated Service Network Director ensures that Memphis VA Medical Center leaders assess staffing needs, to include factors impacting the ability to recruit and retain staff, develop plans to improve staffing and assist in hiring to staff Pathology and Laboratory Medicine Service as required by the Clinical Laboratory Improvement Amendment and Veterans Health Administration.

Concur.

Target date for completion: September 27, 2019

Director Comments

a. The VISN 9 Pathology and Laboratory Medicine Service Program Manager has been working with the Health Systems Specialist for the Chief of Staff to have the Memphis Pathology and Laboratory Medicine Service staff upgraded to equivalent grades as the other VISN 9 facilities. The Memphis VAMC is currently working on getting the Supervisory Medical Technologist (Series 0644) upgraded from GS-11 to GS-12. Once the Memphis Human Resources Service completes the Salary Survey and is eligible for Special Salary Rates the Histopathology Technician will be upgraded appropriately.

b. The VISN 9 Pathology and Laboratory Medicine Service Program Manager has been working with the VISN 9 Human Resources Service, the local Human Resources Service and Pathology and Laboratory Medicine Service to request a Salary Survey for Medical Technologist (Series 0644). The Memphis VAMC has been provided the form to complete to determine if they are eligible for a Salary Survey for Medical Technologists (Series 0644). The Health Systems Specialist for the Chief of Staff is waiting on the Laboratory Manager, Assistant Laboratory Manager and the Administrative Officer at the Memphis VAMC to populate the form to determine eligibility for a Salary Survey for Medical Technologists (Series 0644). Once the form is completed and the eligibility verified, a Salary Survey will be conducted by the local Human Resources Service for the Memphis VAMC. During the Salary Survey, the Memphis VAMC Medical Technologist salaries will be compared to the salary structure for comparable positions in the Memphis metropolitan area. If the Salary Survey reveals a gap in the salaries at the Memphis VAMC, a Special Salary Rate will be established for Medical Technologist (Series 0644). The Medical Center Director will approve the Special Salary Rate for implementation.

c. The form has already been completed and the Memphis Histopathology Technicians are eligible for a Salary Survey to be conducted by the local Human Resources Service. Once

completed, if eligible for a Special Salary Rate, the Medical Center Director at the Memphis VAMC will approve.

d. If other hard to fill positions in Pathology and Laboratory Medicine Service are identified at the Memphis VAMC, the process will be completed for possible eligible Salary Survey and possible eligible Special Pay Rates.

e. Between 2017 and 2019 Pathology and Laboratory Medicine Service increased staffing by 20%. This includes VA Staff members and All-Pro Staffing contractors. The Memphis VAMC also has a contract with the University of Tennessee to provide employees to supplement their workforce. Several key positions in Pathology and Laboratory Medicine Service have been filled: Service Chief; Laboratory Manager; Assistant Laboratory Manager; Quality Manager and Chemistry Supervisory Medical Technologist.

f. Pathology and Laboratory Medicine Service maintains ongoing announcements for the following positions: Medical Technologist-Generalist, Medical Technician-Phlebotomy and Histopathology Technicians. Recruitment/Relocation incentives may be authorized for a well-qualified candidate that meets the requirements.

g. Monitoring: VISN 9 Pathology and Laboratory Medicine Service vacancies are reported to the Healthcare Delivery Board quarterly. Memphis Human Resources Service and Pathology and Laboratory Medicine Service meet every Wednesday to discuss employee recruitment and sustainment initiatives. These discussions include recruitment incentives and active position management. The status of the Salary Survey and Special Pay Rates will be reported to the Memphis Medical Center Director, Chief of Staff, Health Systems Specialists for Chief of Staff, Pathology and Laboratory Medicine Service Chief; Pathology and Laboratory Medicine Service Laboratory Manager and VISN 9 Pathology and Laboratory Medicine Service Program Manager by the local Human Resources Service.

Appendix B: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: July 17, 2019

From: Director, Memphis VA Health Care System (614/00)

Subj: Healthcare Inspection—Pathology Processing Delays at the Memphis VA Medical Center, Tennessee

To: Director, VA Midsouth Health Care Network (10N9)

1. Attached please find the Memphis VA Medical Center facility response to the Office of Inspector General Unpublished Report regarding Pathology and Laboratory Medicine Services processing delay.
2. If you have any questions regarding the information provided, please contact Sharon O'Mearns, Risk Manager, Quality Management and Performance Improvement. Mrs. O'Mearns can be reached at (901) 577-7379, menu choice #3.

(*Original signed by:*)

Thomas Ferguson, M.D.

Acting Medical Center Director

Comments to OIG's Report

Recommendation 2

The Memphis VA Medical Center Director verifies the development and implementation of a formal process to track surgical pathology specimens sent out of the Memphis VA Medical Center for processing and monitors compliance.

Concur.

Target date for completion: January 31, 2020

Director Comments

a. Pathology and Laboratory Medicine actively maintains records regarding "sent out" specimens and their return. The development of an electronic SharePoint manifest is currently in the evaluation phase. The prototype will be evaluated against other commercially available systems offered by companies such as Primera and Thermal Fisher. Pathology and Laboratory is actively soliciting quotes from the above vendors. https://www.primera.com/healthcare-and-laboratory-printers.

b. Monitoring the progress of the implementation of the system will be recorded monthly in the Pathology and Laboratory Medicine Services Committee meetings and reported to the Medical Executive Committee, and further reported to the Executive Leadership Committee.

Recommendation 3

The Memphis VA Medical Center Director ensures a comprehensive assessment of the Pathology and Laboratory Medicine Service to identify specific root causes of surgical pathology specimen delays and ensure steps are taken to prevent risk of future occurrences.

Concur.

Target date for completion: September 27, 2019

Director Comments

a. An assessment of the surgical specimens delayed greater than 72 hours will be monitored daily by the Pathology Staff. Any delays greater than 72 hours will be reported through the Joint Patient Safety Reporting System. The Patient Safety Managers work directly with Pathology and Laboratory to confirm closure of all Pathology Safety Events and any possible Root Cause Analysis needed. The Pathology Staff will work with the Patient Safety Manager to analyze and evaluate any trends regarding delays. The Patient Safety Manager will score the patient safety events utilizing the National Center for Patient

Safety SAC scoring system to determine the level of risk and if an RCA [root cause analysis] is needed.

b. Monitoring: The Patient Safety Events related to surgical specimen delays with be reported to the monthly QSVB [Quality, Safety, and Value Board] meetings and then to the Executive Leadership Committee.

Recommendation 4

The Memphis VA Medical Center Director ensures that Pathology and Laboratory Medicine Service leaders provide an ongoing, comprehensive Quality Management program that identifies the availability of accurate, reliable, and timely test results, and reports to the ordering providers.

Concur.

Target date for completion: September 27, 2019

Director Comments

a. Quality Metrics are reported from each lab section supervisor to the Pathology Quality Manager monthly and presented at the monthly Laboratory Committee.

b. Monitoring: Quality metrics will be recorded monthly in the Pathology and Laboratory Committee meetings and reported to the Medical Executive Committee, and further reported to the Executive Leadership Committee.

Recommendation 5

The Memphis VA Medical Center Director ensures compliance with required surgical pathology Quality Assurance policies and practices, and that Memphis VA Medical Center leaders monitor compliance.

Concur.

Target date for completion: September 27, 2019

Director Comments

a. Memphis VA Pathology and Laboratory Medicine is fully accredited by the College of American Pathology (CAP). All Pathology and Lab departments actively participate in the CAP proficiency testing program that assists in maintaining our commitment to quality and regulatory compliance. Proficiency performance is monitored by each section's supervisor, general management, and Department of Veterans Affairs regional commissioner. Utilize the CAP QA checklist for each of section of pathology and laboratory to confirm all QA policies and practices are being followed.

b. Monitoring: Compliance with Quality Assurance policies through use of the CAP checklist will be monitored monthly through the Pathology and Laboratory. The monthly Pathology and Laboratory Committee will report to the Medical Executive Committee, and further reported to the Executive Leadership Committee.

Recommendation 6

The Memphis VA Medical Center Director ensures that an ongoing process is developed and implemented for Memphis VA Medical Center oversight of Pathology and Laboratory Medicine Service quality data, that includes documentation of the discussion of quality assurance and analysis of the data and the development of action plans as needed.

Concur.

Target date for completion: September 27, 2019

Director Comments

a. The Pathology and Laboratory Committee will review all quality data and utilize Patient Safety as well as Laboratory QM to analyze and develop necessary action plans for any quality concerns. The assessment, analysis and development of action plans will be recorded in the Pathology and Laboratory Committee minutes.

b. Monitoring: The monthly Pathology and Laboratory Committee will report to the Medical Executive Committee, and further reported to the Executive Leadership Committee.

Recommendation 7

The Memphis VA Medical Center Director verifies that all Pathology and Laboratory Medicine Service employees that perform patient testing have updated competencies and documented training on their assigned duties.

Concur.

Target date for completion: November 29, 2019

Director Comments

a. Documented competencies and training are verified by CAP inspection bi-annually. The documentation is kept in the employee's permanent file.

b. Monitoring**:** Reinspection by CAP should occur prior to November 18, 2019 to maintain accreditation.

Recommendation 8

The Memphis VA Medical Center Director ensures that Memphis VA Medical Center leaders understand the importance of the issue brief process and comply with the Deputy Under Secretary for Health and Operations Guidance.

Concur.

Target date for completion: August 30, 2019

Director Comments

a. The 10N IB Guidance has been distributed to all Memphis VA Medical Center leaders. There will be follow up discussion by the Medical Center Director at the August 2019 Executive Leadership Committee.

OIG Contact and Staff Acknowledgments

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