

# Office of Healthcare Inspections

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# Healthcare Inspection Pathology and Laboratory Medicine Services Quality of Care Issues Wilmington VA Medical Center Wilmington, Delaware

May 16, 2017

Washington, DC 20420

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# **Executive Summary**

The VA Office of Inspector General conducted a healthcare inspection in response to complaints received in 2014 concerning Pathology and Laboratory Medicine Services at the Wilmington VA Medical Center (facility), Wilmington, DE.

We reviewed allegations that a facility pathologist:

- Misread oncology test results.
- Did not complete pathology tests timely and the lack of timely tests caused the facility pathologist to send some tests outside the facility on a fee for service basis.
- Altered pathology reports from alternate Veterans Health Administration (VHA) and non-VHA laboratories to make it appear as though he performed the tests at the facility laboratory.

We could not substantiate that the facility pathologist misread oncology tests. Facility quality data did not identify any issues with misread tests or with patient harm associated with misread tests. However, the facility pathologist gathered the data and did not include information for every pathology test conducted; therefore, we attempted to review test data using patient electronic health records. The pathologist was required to document initial diagnoses for tests sent to alternate VHA or non-VHA laboratories for a second review but not for those performed at the facility laboratory. We reviewed tests performed at alternate VHA or non-VHA laboratories; however, the pathologist replaced preliminary pathology results with final results when these became available. Therefore, initial test results were not available for comparison to final test results or to the facility's data. We interviewed oncology staff who could not recall any instances of misread tests or harm to patients related to misread tests.

We substantiated that the pathologist did not always have pathology test results available to ordering providers within required timeframes and had sent specimens to Fee Basis (currently known as the Non-VA Medical Care Program) vendors for processing. However, the pathologist obtained approval from facility leadership to do so in order to eliminate a backlog.

We did not substantiate that the pathologist altered reports of pathology tests performed at alternate VHA and non-VHA laboratories to make them appear as though he performed the tests at the facility laboratory. When the pathologist entered final test results into patient electronic health records, he generally documented that the lab specimens were processed by alternate VHA or non-VHA laboratories. However, we discovered inconsistent documentation identifying non-VHA pathologists on final pathology reports and incomplete documentation for specimens sent to alternate VHA and non-VHA laboratories.

During the inspection, we found that the pathologist, who was also the facility Pathology and Laboratory Medicine Services Director, utilized a non-VHA laboratory to process

pathology tests without a required VHA contractual arrangement for processing pathology tests.

In addition, the pathologist revised a facility laboratory standard operating procedure without confirming that it met current VHA standards or that it reflected requirements set forth by existing facility policy. We also found that Pathology and Laboratory Medicine Service oversight services and committees did not consistently report accurate statistical and performance information to facility leadership, and the oversight service for the facility pathologist did not complete and monitor internal review action plans and ongoing professional performance evaluations using current facility performance data.

We recommended that the Facility Director ensure that:

- Facility Pathology and Laboratory Medicine Service staff establish and use acceptable processing procedures for pathology testing that will ensure established benchmark non-compliance rates for routine pathology test turnaround times, as established by VHA, are met and that facility managers monitor compliance.
- Pathology and Laboratory Medicine Service staff follow facility documentation requirements for non-Veterans Health Administration laboratory pathology reports and that facility managers monitor compliance.
- Facility managers review the pathology tests performed at the unofficial non-Veterans Health Administration laboratory to determine whether quality assurance benchmarks were met, and whether patient harm occurred, and if harm did occur, confer with the Office of Chief Counsel regarding the appropriateness of disclosures to patients and families.
- Facility oversight service and committees for the Pathology and Laboratory Medicine Service review current performance data and follow Veterans Healthcare Administration and facility quality assurance policies and practices concerning reporting data, establishing action plans, and monitoring action plans, and that facility leadership monitor compliance.
- Facility managers monitor and use current performance data, and complete ongoing professional performance evaluations and other internal reviews as required by Veterans Health Administration and facility policies.

### Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 22–26 for the Directors' comments.) Based on information provided to us with the Directors' responses, we consider recommendations 1–5 closed.

JOHN D. DAIGH, JR., M.D. Assistant Inspector General for Healthcare Inspections

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# **Purpose**

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to complaints received in 2014 regarding the Pathology and Laboratory Medicine Service (P&LMS) and a facility pathologist<sup>1</sup> at the Wilmington VA Medical Center (facility), Wilmington, DE.

# **Background**

The facility, a 60-bed acute care facility with a 60-bed Community Living Center, is part of Veterans Integrated Service Network (VISN) 4 and provides a full range of patient care services including medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, geriatrics, and extended care.

At the time of our review in September 2014, pathology staff included three board certified pathologists—two part-time pathologists and the P&LMS Director, who was the only full-time pathologist and the subject of this report. The P&LMS had the one full-time pathologist since 2009, and the part-time pathologists were available in 2013. Organizationally, the P&LMS Director reported to the Surgical Service Chief, who reported to the Medical Executive Board (MEB) and Chief of Staff.<sup>2</sup> The P&LMS processed 2,709 pathology tests between January 1, 2014 and July 31, 2014. The full-time pathologist processed 1,071 of these tests and sent 833 tests to other laboratories for processing. He retired the week of our site visit.

## **Pathology and Laboratory Standards**

Pathology and laboratory medicine is a specialized medical practice area with trained staff who perform tests on samples of body tissue and fluids and foreign objects removed from the body.<sup>3</sup> Providers use the results to assist them with medical diagnoses and treatment. To ensure that providers and patients receive accurate and timely test results, VHA P&LMS programs must meet education and clinical standards, quality protocols, compliance requirements set forth by the Clinical Laboratory Improvement Amendments,<sup>4</sup> and the pathology and laboratory accreditation requirements of The Joint Commission (JC) and the College of American Pathologists.<sup>5</sup>

<sup>&</sup>lt;sup>1</sup> A pathologist is a physician who specializes in the diagnosis and interpretation of disease through various laboratory methods including the assessment of tissue alterations, often microscopically.

<sup>&</sup>lt;sup>2</sup> Wilmington VAMC General Policies Manual, *Pathology and Laboratory Medicine*, March 22, 2013.

<sup>&</sup>lt;sup>3</sup> VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 8, 2008. This VHA Handbook was in effect during the time of the events discussed in this report but has been rescinded and replaced with VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, February 2, 2016. For issues discussed in this report, the 2016 Handbook does not contain substantive changes in requirements.

<sup>&</sup>lt;sup>4</sup> Clinical Laboratory Improvement Amendments (42 CFR 493) are federal regulations that establish quality standards for laboratory testing performed on specimens from humans, such as blood or tissue, for the main purposes of diagnosis, prevention, or treatment of disease.

<sup>&</sup>lt;sup>5</sup> VHA Handbook 1106.01, Pathology and Laboratory Medicine Service Procedures, October 8, 2008.

VHA laboratories can contract to have tests performed at non-VHA laboratories that have a Certificate of Accreditation issued by the U.S. Department of Health and Human Services under the provisions of the Clinical Laboratory Improvement Amendments.<sup>6</sup>

To assess compliance with these and any applicable VHA standards, the VHA Pathology and Laboratory Medicine National Enforcement Program reviews VHA facility P&LMS policies and procedures at least once every 24 months or as needed. The VHA Pathology and Laboratory Medicine National Enforcement Program reviewed the facility laboratory in July 2014 and found that the facility routine turnaround time (TAT) policy was not compliant with the VHA standards.

We contacted the VHA Pathology and Laboratory Medicine National Enforcement Program to determine if the facility laboratory policies and practices had recently been A technologist from the program reviewed the facility laboratory in June 2016. During this visit, the technologist found the P&LMS routine TAT policy compliant with VHA standards.

### **Pathology Testing Elements**

Accurate interpretation, availability, communication, and documentation of pathology test results are critical elements of the testing process that ensure providers have the essential information to diagnose a patient's condition and determine treatment options.8 P&LMS Directors oversee all laboratory functions and are responsible for ensuring sufficient qualified personnel with the appropriate training and expertise are available to meet the laboratory's needs.9

Accurate interpretation of tests depends on properly Test Result Accuracy. functioning equipment and staff expertise. 10 Laboratory staff must regularly test and monitor equipment to maintain  $JC^{11}$  and the College of American Pathologists accreditation, <sup>12</sup> and meet Clinical Laboratory Improvement Amendments standards and certification requirements.<sup>13</sup> In addition, VHA requires facilities to have procedures and monitoring methods in place to prevent inaccurate test results due to equipment malfunction. 14

Laboratory staff must possess expertise in specimen testing procedures and, in some instances, clinical interpretation. The expertise required varies with the complexity of

<sup>&</sup>lt;sup>6</sup> VHA Handbook 1106.01, Pathology and Laboratory Medicine Service Procedures, October 8, 2008.

<sup>&</sup>lt;sup>7</sup> Turnaround time is the time between when a test is brought to the laboratory for testing until the time when the final result is available to the provider who ordered the testing.

<sup>&</sup>lt;sup>8</sup> VHA Handbook 1106.01.

<sup>&</sup>lt;sup>9</sup> VHA Directive 1106, *Pathology and Laboratory Medicine Service*, April 5, 2013.

<sup>&</sup>lt;sup>10</sup> VHA Handbook 1106.01.

<sup>&</sup>lt;sup>11</sup> JC Standard AOP.5.5. Accessed January 20, 2016.

<sup>&</sup>lt;sup>12</sup> College of American Pathology, 2013 Continuing Compliance Master Series, July 17, 2013.

<sup>&</sup>lt;sup>13</sup> Clinical Laboratory Improvement Amendments (42 CFR 493) are federal regulations that establish quality standards for laboratory testing performed on specimens from humans, such as blood or tissue, for the main purposes of diagnosis, prevention, or treatment of disease. <sup>14</sup> VHA Handbook 1106.01.

tests.<sup>15</sup> For example, a laboratory technician may be competent to perform blood sample testing procedures and report results to the provider, but not to interpret the results as they pertain to the patient. In that case, ordering providers interpret results and formulate a diagnosis. Because body tissue and fluid specimens are more complex, a board-certified pathologist is required to examine the specimens and interpret the results before communicating with the ordering provider.<sup>16</sup>

**Timeliness and Documentation.** In addition to accurate interpretation of pathology tests, rapid availability, documentation, and provider notification of results are key elements in the process. VHA requires that the diagnostic provider communicate pathology test results to the ordering provider within a TAT that allows for prompt attention and appropriate action. VHA further requires each facility to develop and implement a written policy regarding communication of test results to ordering providers. <sup>19</sup>

In addition, VHA requires facilities to define acceptable TATs for results that are critical to a patient's immediate needs (STAT<sup>20</sup> or urgent<sup>21</sup>), and JC requires that hospitals define routine, STAT, and urgent TATs, and perform tests within those defined TATs.<sup>22</sup> The VHA Pathology and Laboratory Medicine National Enforcement Program supports a TAT for routine (not STAT or urgent) surgical and non-gynecological pathology tests of within 2 working days. Facility policy should be consistent with this VHA requirement.

VHA requires the pathologist from the facility where a specimen originates to document and authenticate the final pathology test results in the patient's electronic health record (EHR) regardless of where the specimen was tested.<sup>23</sup>

The facility P&LMS had policies that defined pathology TATs and the monitoring of whether TATs were met; P&LMS staff followed specific procedures to track specimen TATs throughout the testing process. The facility used the same initial tracking procedure for all pathology specimens, regardless of where the specimens were ultimately processed. TATs are determined by measuring the amount of time

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<sup>&</sup>lt;sup>15</sup> VHA Handbook 1106.01. *Pathology and Laboratory Medicine Service Procedures*, October 8, 2008. <sup>16</sup>Ibid.

<sup>&</sup>lt;sup>17</sup> VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009. This VHA Directive was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015. The 2015 Directives had no substantive changes in requirements relating to this issue.

<sup>&</sup>lt;sup>18</sup> VHA Directive 1088, Communicating Test Results to Providers and Patients, October 7, 2015.

<sup>&</sup>lt;sup>19</sup> VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009. This VHA Directive was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015. The 2015 Directives had no substantive changes in requirements relating to this issue.

<sup>&</sup>lt;sup>20</sup> STAT is derived from the Latin word statim, meaning immediately.

<sup>&</sup>lt;sup>21</sup> VHA Directive 2009-019.

<sup>&</sup>lt;sup>22</sup> JC, LD.04.01.05

<sup>&</sup>lt;sup>23</sup> VHA Handbook 1106.01.

<sup>&</sup>lt;sup>24</sup> Wilmington VAMC Anatomic Pathology Department Administrative Policies, 2.0 Policy and Procedure for Referrals of Case Material to Outside Agencies, September 2013.

between accession, when the specimen was received in the laboratory, and when the test results were authenticated by the pathologist and available for review by the ordering provider.

According to established procedure, P&LMS staff assigned an accession or identification number to specimens in the order they were received in the laboratory to begin the tracking process.<sup>26</sup> Staff entered the accession number, specimen information, and the date the accession number was assigned into the corresponding EHR<sup>27</sup> and on a tracking log.<sup>28</sup>

- For testing at the facility laboratory, a pathologist prepared and read specimen slides and dictated a final report with test results. The pathologist reviewed the transcribed report for potential errors and electronically signed the report. To complete the tracking process, the pathologist or designee entered the completion date, known as the verification date, into the tracking log.<sup>29</sup>
- When the facility sent specimens to alternate VHA laboratories, the VHA pathologist who processed the specimen was required to make the results available to the facility pathologist, who entered the results into the corresponding EHR, authenticating the entry with a dated electronic signature.<sup>30</sup> The pathologist or designee entered the verification date into the tracking log to complete the tracking process.
- When non-VHA laboratories processed specimens, those laboratories were required to fax, mail, or email results to the facility pathologist or designee who placed a scanned copy of the results in the EHR. The facility pathologist was required to authenticate the results and enter the final result into the laboratory section of the EHR within 2 business days of receiving the information from the non-VHA laboratory.<sup>31</sup> The facility pathologist or designee would then enter the dates of the authentication into the tracking log to complete the tracking process.<sup>32</sup>

<sup>&</sup>lt;sup>25</sup> Wilmington VAMC Pathology and Laboratory Medicine Administrative Policy 4.0, *Reports Returning From Consultation (Send-Out)*, September 2009.

<sup>&</sup>lt;sup>26</sup> Wilmington VAMC Anatomic Pathology Department Administrative Policies, 10.0 General Quality Management Policies, September 2013.

<sup>&</sup>lt;sup>27</sup> Wilmington VAMC General Policies Manual, *Pathology and Laboratory Medicine*, March 22, 2013.

<sup>&</sup>lt;sup>28</sup> Wilmington VAMC Pathology and Laboratory Medicine Administrative Policy 4.0, *Reports Returning From Consultation (Send-Out)*, September 2009.

<sup>&</sup>lt;sup>29</sup> Verification dates are considered the completion or authentication dates.

<sup>&</sup>lt;sup>30</sup> The process of validating the EHR entry is called authentication or verification, and attests that information is from the VHA laboratory or received from another laboratory outside of VHA; VHA Handbook 1907.01, *Health Information Management and Health Records*, April 15, 2004, revised July 22, 2014, and March 19, 2015. For issues discussed in this report, the 2004, 2014 and 2015 Handbooks have no substantive changes in requirements.

<sup>&</sup>lt;sup>31</sup> Wilmington VAMC Anatomic Pathology Department Administrative Policies, 2.0 Policy and Procedure for Referrals of Case Material to Outside Agencies, September 2013.

<sup>&</sup>lt;sup>32</sup> Wilmington VAMC Pathology and Laboratory Medicine Administrative Policy 4.0, *Reports Returning From Consultation (Send-Out)*, September 2009.

In addition to documenting and authenticating results in the EHR, VHA pathologists are required to identify pathologists who perform the tests as well as the alternate VHA or non-VHA laboratory,<sup>33</sup> when applicable, so ordering providers can contact the appropriate pathologist with any questions or concerns. VHA pathologists are required to notify ordering providers when results are available for review.<sup>34</sup>

Additionally, VHA and facility policies require that facilities establish a direct communication procedure, such as a telephone tree, to notify providers if a test result is critical or needs immediate attention. 35,36

### **Quality Assurance Practices**

VHA requires that all P&LMS Directors develop comprehensive quality assurance (QA) programs to monitor and evaluate the services of the facility laboratory as well as non-VHA laboratories.<sup>37</sup> To accomplish this, the P&LMS director must ensure that processes are in place to evaluate the effectiveness of policies and procedures and ensure that laboratory staff communicate accurate, reliable, and timely laboratory test results and pathology reports to ordering providers. P&LMS Directors and laboratory staff must collect and evaluate statistical information based upon VHA requirements and industry and local standards for acceptable performance.<sup>38</sup> QA data must also be collected from contracted non-VHA vendors who supply services to veterans.<sup>39</sup>

VHA also requires all P&LMS Directors, under the direction of facility leadership, to measure performance related to accuracy of test results, timeliness of testing processes, and detrimental patient outcomes. To accomplish this, facilities set benchmarks or triggering thresholds and collect data to compare against the established thresholds. VHA encourages the use of triggering thresholds or compliance/non-compliance rates and comparison data to ensure that facility aggregated data are analyzed and reviewed by QA program managers to monitor for

<sup>39</sup> VA Directive 1663, *Health Care Resources Contracting – Buying*, August 10, 2006.

<sup>&</sup>lt;sup>33</sup> VHA Handbook 1106.01, Pathology and Laboratory Medicine Service Procedures, October 8, 2008.

<sup>&</sup>lt;sup>34</sup> VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009. This VHA Directive was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015 that contains the same or similar language for this issue.

<sup>&</sup>lt;sup>35</sup> VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009. This VHA Directive was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015. The language of "direct communication" is not present in the 2015 policy; it was replaced with communication "as determined by each facility's policies or procedures." VHA has added "direct communication" guidance language similar to the 2009 policy in the Communication of Test Results Toolkit, Updated in October 2015 under Appendix E.

<sup>&</sup>lt;sup>36</sup> Wilmington VAMC Center Memorandum NO. 460-113.04, *Reporting of Critical Laboratory Values*, February 7, 2011. This policy was in effect during the time frame of the events described in this report; it was replaced by Wilmington VAMC Center Memorandum NO 460-113-04, *Reporting of Critical Laboratory Values*, March 30, 2015.

<sup>&</sup>lt;sup>37</sup> VHA Handbook 1106.01.

<sup>38</sup> Ibid.

<sup>&</sup>lt;sup>40</sup> VHA Handbook 1106.01.

<sup>&</sup>lt;sup>41</sup> VHA Directive 1106, *Pathology and Laboratory Medicine Services*, April 5, 2013.

facility system issues.<sup>42</sup> The facility P&LMS staff referred to benchmarks or triggering thresholds as error/non-compliance rates, and exceeding established error rates indicated the program was not meeting its goals.<sup>43</sup>

The full time pathologist and P&LMS Director served as the chair of the Pathology and Laboratory Medicine Quality Assurance (PLMQA) committee, which was established to provide oversight of P&LMS QA activities. 44 Other members included the laboratory quality manager, supervisory medical technologist, hematology/coagulation representative, chemistry and microbiology department representatives, laboratory safety manager, and the blood bank representative. The committee collected and analyzed data relative to accurate test interpretation and TATs and reported the analysis to the Surgical Care Review Council (SRC<sup>45</sup>), who then reported to the Medical Executive Board (MEB). The P&LMS Director also provided QA data to the facility Patient Care Council upon request.

### **Allegations**

In August 2014, the OIG received allegations that a pathologist:

- Misread oncology test results.
- Did not complete pathology tests timely, and the lack of timely tests caused the pathologist to send some tests outside the facility on a fee for service basis.
- Altered pathology reports from alternate VHA and non-VHA laboratories to make it appear as though he performed the tests at the facility laboratory.

# Scope and Methodology

We conducted the inspection from September 12, 2014 through September 12, 2016. Because the pathologist gathered test result data that may have been compromised by inaccurate parameters, we performed our own review of patient test results. We reviewed 1,904 pathology test results entered or scanned into patient EHRs that were performed or verified by the subject pathologist between January 1, 2014 and July 31, 2014. This was the most recent period of time that the subject pathologist worked and provided facility leadership with QA data. The 1,904 test results included tests that were performed as STAT or urgent, and we used the facility's non-compliance rate of 10 percent or less to evaluate the data for compliance with VHA and facility requirements. We also reviewed patient EHRs for 92 of the 1,904 pathology test results and additional 2015 QA data.

We conducted a site visit September 22–23, 2014. We interviewed the subject pathologist (who was planning to retire after our site visit), Chief of Staff, oncology

<sup>&</sup>lt;sup>42</sup> VHA Directive 1026, VHA Enterprise Framework for Quality, Safety, and Value, August 2, 2013.

<sup>&</sup>lt;sup>43</sup> Wilmington VAMC Center Memorandum NO. 460-00.24, *Performance Improvement Plan*, October 5, 2012.

<sup>&</sup>lt;sup>44</sup>VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 8, 2008.

<sup>&</sup>lt;sup>45</sup> SRC is now called the Surgical Work Group.

providers, laboratory manager, and other key staff. We reviewed VHA and facility policies and procedures; accreditation documents, including a review conducted by the VHA Pathology and Laboratory Medicine National Enforcement Program; JC, College of Pathology and Clinical Laboratory Improvement Amendments; meeting minutes; and data reports from the facility from October 1, 2013 through October 6, 2015.

We substantiate allegations when the facts and findings support that the alleged events or actions took place. We do not substantiate allegations when the facts show the allegations are unfounded. We cannot substantiate allegations when there is no conclusive evidence to either sustain or refute the allegation.

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

# **Inspection Results**

### **Issue 1: Accurate Interpretation of Oncology Pathology Tests**

We could not substantiate that the subject pathologist misread oncology test results.

VHA requires facilities to have ongoing mechanisms for monitoring and evaluating potential and actual detrimental patient outcomes resulting from incorrect surgical or cytopathology<sup>46</sup> diagnoses.<sup>47</sup>

To meet VHA requirements, the facility PLMQA committee collected and analyzed initial and second test review data (excluding gynecology tests) to determine whether major discrepancies (inaccurate interpretations of the initial diagnosis) between the two diagnoses occurred and whether treatment based upon an inaccurate initial diagnosis led directly to irrevocable patient harm. The committee presented the collected data to the SRC in the facility Quality Assurance Plan – Anatomic Pathology FY 2014. The established non-compliance rate for this analysis was zero percent, meaning that no patient should experience irrevocable harm due to treatment based upon an inaccurate initial diagnosis.

According to the data collected by the facility laboratory staff during the first 3 quarters of FY 2014, inaccurate interpretations of initial pathology tests did not result in irrevocable patient harm (zero percent non-compliance rate). The review data included 2,749 test results generated by all pathologists that underwent second diagnostic reviews.

Because the facility data did not include every type of pathology test and the subject pathologist assisted in collecting the data, we attempted to independently review test result information. For tests performed or verified by the subject pathologist from January 1, 2014 through July 31, 2014, we attempted to compare preliminary test results to final test results obtained after a secondary review.

When tests were performed at the facility laboratory, pathologists were not required to document preliminary results. However, facility policy required pathologists to document preliminary diagnoses before sending specimens to non-VHA or alternate VHA laboratories for a second review. We reviewed documentation of specimens processed by the subject pathologist that were subsequently sent to non-VHA or alternate VHA laboratories for a secondary review. The only exception to the process of performing an initial review prior to sending specimens to non-VHA laboratories was when the facility sent specimens to the Johns Hopkins Hospital laboratory. Facility

<sup>&</sup>lt;sup>46</sup> Cytopathology is a branch of pathology that deals with the manifestations of disease at the cellular level. <a href="http://www.merriam-webster.com/dictionary/cytopathology">http://www.merriam-webster.com/dictionary/cytopathology</a>. Accessed on September 27, 2016.

<sup>&</sup>lt;sup>47</sup> VHA Handbook 1106.01. *Pathology and Laboratory Medicine Service Procedures*, October 8, 2008.

<sup>&</sup>lt;sup>48</sup> Wilmington VAMC Anatomic Pathology Department Administrative Policies, 2.0 Policy and Procedure for Referrals of Case Material to Outside Agencies, September 2013.

policy required these specimens to be placed in a fixative solution prior to being transported so an initial review could not be performed. In 814 of 1,904 tests sent to alternate VHA or non-VHA laboratories (other than Johns Hopkins) for a secondary review, the subject pathologist re-verified the second review report, and replaced the preliminary test results with the new results from the non-VHA or alternate VHA laboratory. We have no way of knowing if preliminary results of the subject pathologist differed from those of the second reviewer, and could not compare the preliminary results with the final test results. When we interviewed laboratory staff, they told us that the subject pathologist could easily manipulate the EHR test result data and often would verify and re-verify test results thus eliminating previous test result information. The reason the subject pathologist used this method of recording results was unknown; however, laboratory staff told us that other pathologists working in the facility laboratory did not follow this procedure, and the initial test results were recorded and kept in the EHR.

Oncology providers told us they could not recall instances of misread or inaccurate interpretations of oncology tests causing delays in treatment or patient harm. However, they did express that getting reports back in a timely manner was an issue, and that they often compensated by seeing their patients more frequently to ensure that issues were addressed on a timely basis.

We recommended that the Facility Director ensure that P&LMS staff follow facility documentation requirements for non-VHA laboratory pathology reports and that facility managers monitor compliance.

# **Issue 2: Pathology Test Timeliness**

We substantiated that the subject pathologist, who performed the majority of pathology tests, did not always have test results available for patient providers within the required TAT for routine pathology tests.

To establish whether the facility met routine pathology test TAT requirements, we reviewed surgical and non-gynecological pathology routine test result data reported by the PLMQA committee for the first 3 quarters of FY 2014,<sup>50</sup> the period when the heaviest backlog occurred.<sup>51</sup> The P&LMS staff, including the subject pathologist and laboratory manager, collected non-compliance data based on a routine pathology test TAT requirement of 2–3 weeks, created by the subject pathologist, and beyond the VHA and facility requirement of 2 working days. The PLMQA committee assessed the

<sup>&</sup>lt;sup>49</sup> Wilmington VAMC Anatomic Pathology Department Administrative Policies, 2.0 Policy and Procedure for Referrals of Case Material to Outside Agencies, September 2013.

<sup>&</sup>lt;sup>50</sup> We reviewed Patient Care Council minutes to determine whether critical results TATs (1 hour) were met during FY 2014. We found that during FY 2014, critical test results were reported within an hour 97 percent of the time (90 percent compliance rate was the benchmark).

OA Committees are required by VHA to gather specific information, which does not require all routine pathology tests.

collected data against a benchmark non-compliance rate of 10 percent or less utilizing the 2-3 week requirement created by the subject pathologist.

After evaluating the PLMQA data, we determined that, because the subject pathologist assisted in gathering the routine TAT data, facility pathology test TATs would require a more in-depth analysis. We used the VHA and facility requirement of 2 working days, and also compared the data to the higher end of the TAT established by the subject pathologist (P&LMS Director) of 2–3 weeks (3 weeks). To account for weekends and holidays we extended the required definition of 2 working days to 5 calendar days, and to allot time for second reviews at other laboratories, we extended the 2 working days requirement to 7 calendar days. We also applied the non-compliance benchmark utilized by the facility of 10 percent or less. Our review period was from January 1, 2014 through July 31, 2014 and included the 1,904 test results performed or verified by the subject pathologist. Figure 1 on the next page illustrates the percentage of the 1,904 test results that did not meet (non-compliance) the TAT definitions described above.

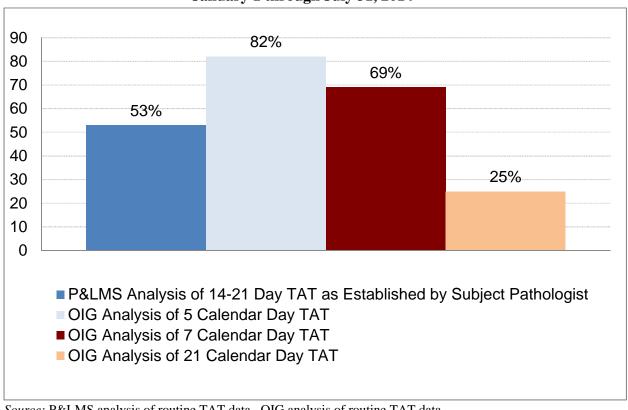


Figure 1. Non-Compliance Rates for Reviewed Routine Test TATs **January 1 through July 31, 2014** 52,53

Source: P&LMS analysis of routine TAT data. OIG analysis of routine TAT data.

Note: P&LMS Analysis is from an average of Routine TAT data for FY 2014 Quarters 1, 2 and 3 OIG Analysis of 5 calendar days – 1,557 of 1,904 test results (82 percent) were available beyond 5<sup>th</sup> calendar day

OIG Analysis of 7 days – 1,320 of 1,904 test results (69 percent) were available beyond 7<sup>th</sup> calendar day

OIG Analysis of 21 days – 479 of 1,904 test results (25 percent) were available beyond the 21st calendar day

Figure 2 on the next page illustrates when tests were available to ordering providers. Of the 1,904 tests, 584 (31 percent) were available within 7 calendar days; and 1,425 (75 percent) test results were available within the subject pathologist's requirement of 21 days. The number of tests completed did not meet the facility non-compliance benchmark of 10 percent or less until day 35.

<sup>&</sup>lt;sup>52</sup> P&LMS routine TAT data for FY 2014 Quarters 1, 2, and 3.

<sup>&</sup>lt;sup>53</sup> OIG routine TAT data from January 1, 2014, through July 31, 2014.

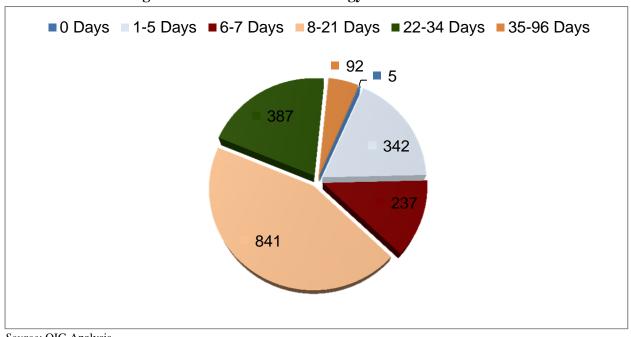


Figure 2. EHR Review: Pathology Test Results TATs<sup>54</sup>

Source: OIG Analysis

Note: 0 days (5), 1-5 days (342), and 6-7 days (237) = 584; 0 days (5), 1-5 days (342), 6-7 days (237), and 8-21 days (841) = 1,425.

**Patient Harm.** To assess whether excessive pathology TATs may have caused delays in treatment and patient harm, we conducted a more in-depth review of those pathology specimens with the longest TATs. Of 1,904 pathology tests performed or verified by the subject pathologist between January 1, 2014 and July 31, 2014, 92 represented the longest elapsed time from accession to verification of results, with TATs ranging from 35 days to 96 days. The subject pathologist performed 66 of these tests, and non-VHA or alternate VHA pathologists performed the remaining 26 tests.

Test specimens included gynecological tissue as well as tissue and other items (not tissue) removed during surgical procedures (inpatient and outpatient). Fourteen of the 92 test results (14 different patients) were positive for carcinoma and required follow-up. We reviewed test results, diagnoses, treatments, and medical conditions for the patients associated with all 92 test results. Patient EHRs reflected no indication that the longer TATs led to patient harm. In addition, oncology staff informed us that they could not recall any delay in reporting results that led to patient harm.

**Contributing Factors.** According to the SRC Summary to the MEB in July 2014, the subject pathologist reported that the P&LMS department needed additional assistance to process pathology tests. He felt this was due to a loss in funds that would have been used to send tests to other laboratories. In addition, he told us that another laboratory no longer processed specimens for the facility and that due to this and his other duties,

<sup>&</sup>lt;sup>54</sup> Routine pathology test results provided to the ordering provider from January 1, 2014, through July 31, 2014.

specimens became backlogged. He also stated that another part-time pathologist helped process pathology tests in addition to sending tests out to alternate VHA and non-VHA laboratories. The test QA data from FY 2013 to FY 2014 indicated that the routine TAT non-compliance rate rose from less than 10 percent to well above 10 percent. However, test data from FY 2013 and FY 2014 also indicated no increases in the number of pathology tests performed by the P&LMS department and no change in staffing except for the addition of 2 part-time pathologists.

We have no additional information that funding was limited; however, the Chief of Staff told us that funding was provided to deal with the backlog in 2014. According to a 2010 study conducted by the Association of Directors of Anatomic and Surgical Pathology, 16 laboratories reported that the number of surgical tests per pathologist full time employee equivalent ranged from 1,291 to 6,087annually with a mean of 2,818.<sup>55</sup>

The TAT testing process can be complicated by several factors such as pathologist productivity, pathologist involvement in teaching or other outside activities, and specimen preparation. During the 7-month period we reviewed, the subject pathologist actually processed 1,071 pathology tests (these tests were not sent to other laboratories). Extrapolated to an annual rate of 1,836 tests, the subject pathologist's productivity would likely be considered in the low middle range for a full-time employee pathologist. Besides his position as a full-time pathologist for the facility laboratory, the subject pathologist acted as the Delaware State Commissioner for the College of American Pathologists and was involved in the education committee and laboratory inspections, though he stated he performed out of country inspections while on leave from the VA. He also relied upon other laboratory personnel to prepare his pathology specimens. Any of these factors could have contributed to delays in the TAT testing process.

Laboratory staff stated that one of the factors that contributed to test TAT delays was that the subject pathologist used an extra step in processing specimens. Generally, laboratory specimens are processed first come first serve, but the subject pathologist would prioritize all pathology specimens to determine which specimens would be processed first. This procedure slowed down specimen processing as staff would need to wait until the pathologist had prioritized the specimens.

**Update.** In July 2014, the SRC reported to the MEB that the prioritization process would be changing, and the MEB approved those changes as well as changes in the TAT for critical and routine laboratory tests. The laboratory manager told us that this process would return to a first come first serve basis. We also obtained updated facility routine (not STAT or urgent) test TAT non-compliance rates for surgical and non-gynecological pathology tests. The rates were based upon a 2-working day TAT. According to data submitted for the first 2 quarters of FY 2015, the non-compliance rate

<sup>&</sup>lt;sup>55</sup> Association of Directors of Anatomic and Surgical Pathology, description of survey pathologist productivity data, <a href="http://www.adasp.org/Surveys/Pathologist-Staffing-Survey.html">http://www.adasp.org/Surveys/Pathologist-Staffing-Survey.html</a> March 2010 data, published 2014. Accessed July 1, 2016.

was 90.53 percent in the 1<sup>st</sup> quarter and 96.17 percent in the 2<sup>nd</sup> quarter, well above the required 10 percent or less. In the July summary for the MEB, the SRC reported in October 2015 that the TAT non-compliance rate for the first month of the 3<sup>rd</sup> quarter of FY 2015 was 88.02 percent.

We recommended that the Facility Director ensure that P&LMS staff establish and use acceptable processing procedures for pathology testing that will ensure established non-compliance rates for routine pathology test turnaround times are met and that facility managers monitor compliance.

### Issue 3: Use of Fee Basis Vendors

We substantiated that the subject pathologist sent specimens to Fee Basis vendors for processing (currently known as the Non-VA Medical Care Program), but did so with approval from facility leadership to alleviate a backlog of unprocessed pathology tests.

The VA Fee Basis Program allowed facilities to purchase medical services for veterans from non-VHA vendors or community health care providers who then billed facilities for services provided. Under this program, veterans were required to meet VHA eligibility requirements, and non-VHA services needed to be provided under a contract between VHA and the vendor or by an individual purchase order authorized by VHA. <sup>56</sup>

According to laboratory managers and the subject pathologist, they reported a backlog of unprocessed pathology specimens to facility leadership in May 2014. At the request of the subject pathologist, facility leadership approved the use of Fee Basis vendors to purchase services from non-VHA laboratories to process some of the backlogged specimens. From May 1, 2014 through July 31, 2014, the facility sent 404 of 783 pathology specimens assigned to the subject pathologist to non-VHA laboratories to assist with the backlog.

# Issue 4: Alteration of Pathology Test Result Reports

Based upon our review of EHRs, we did not substantiate that the subject pathologist altered reports from alternate VHA and non-VHA pathologists to make them appear as though he performed the tests at the facility laboratory. However, we found that some EHRs lacked documentation identifying non-VHA pathologists and that P&LMS staff did not always track the location of pathology specimens that were sent to alternate VHA and non-VHA laboratories.

According to VHA and facility policy, facility pathologists are required to record the name of the alternate VHA or non-VHA laboratory, the names of all contributing VHA or non-VHA pathologists,<sup>57</sup> and the essential elements of the alternate VHA or non-VHA

<sup>&</sup>lt;sup>56</sup> VA Directive 1601, Non-VA Medical Care Program, January 23, 2013.

<sup>&</sup>lt;sup>57</sup> VHA Handbook 1106.01. Pathology and Laboratory Medicine Service Procedures, October 8, 2008.

pathology test results in the laboratory section of the EHR. The entry ensures that the ordering provider understands the test result is from a source outside of the facility.<sup>58</sup>

Of the 1,904 pathology tests we reviewed, alternate VHA or non-VHA laboratories performed 833. Alternate VHA laboratories performed 333 tests, and non-VHA laboratories performed 500 tests.

EHR Documentation of Alternate VHA and Non-VHA Laboratories. We reviewed the 833 pathology results of tests performed at alternate VHA and non-VHA laboratories to determine if test result documentation appeared to have been altered to make it appear as though the facility laboratory, rather than the alternate VHA or non-VHA laboratory, had performed the tests. One (0.12 percent) EHR lacked the required documentation indicating that an alternate VHA or non-VHA laboratory performed the test. The subject pathologist told us that approximately 2 years prior, he did not enter the name of one specific non-VHA laboratory into EHRs because that laboratory's arrangement for testing with the facility was unofficial (the non-VHA facility did not expect payment and did not submit performance data). However, after 2012, he did document the name of the non-VHA laboratory in EHRs. We identified 45 of 500 (9 percent) tests that were performed under this unofficial arrangement, and found that all 45 had the name of the laboratory in the EHR.

EHR Documentation of Non-VHA Pathologists. VHA requires pathology test reports from non-VHA laboratories to include the name of the pathologist at the non-VHA laboratory that is responsible for the evaluation. Ordering VHA providers can access EHRs at alternate VHA facilities to determine the name of the pathologist who performed any tests. However, facility providers do not have access to non-VHA laboratory records unless the non-VHA laboratory provides a report for the facility staff to scan into the EHR or the pathologist entering the final report enters the name of the pathologist. We reviewed the 500 non-VHA laboratory pathology test results to determine if the names of the non-VHA pathologists who performed the tests and provided the final test results, were scanned or recorded in EHRs. We found that 75 of 500 (15 percent) pathology specimens tested by a non-VHA laboratory had no scanned test results available with the non-VHA pathologist's name and no additional information in the EHR identifying the non-VHA pathologist.

**Documentation of Specimen Tracking.** According to laboratory staff, they used a tracking log, called a Send-Out Log,<sup>61</sup> to track specimens sent to alternate VHA or non-VHA laboratories. When we reviewed the tests sent to alternate VHA or non-VHA laboratories between January 1, 2014 and July 31, 2014, we found that 82 of 833 tests (10 percent) had no entry in the log identifying the outside laboratory. According to a

<sup>&</sup>lt;sup>58</sup> Wilmington VAMC Pathology and Laboratory General Policies Manual, *4.0 Reports Returning from Consultation (Send-Out)*, September 2013.

<sup>&</sup>lt;sup>59</sup> VHA Handbook 1106.01. *Pathology and Laboratory Medicine Service Procedures*, October 8, 2008.

<sup>&</sup>lt;sup>60</sup> Providers are able to access test result information in alternate VHA EHRs.

<sup>&</sup>lt;sup>61</sup> Wilmington VAMC Pathology and Laboratory General Policies Manual, *4.0 Reports Returning from Consultation* (*Send-Out*), September 2013.

P&LMS staff member, they used the log to verify the location of specimens, and to compare invoices from non-VHA laboratories, but not as part of the facility QA process. If the non-VHA laboratory is not on the log, staff reviews the patient's EHR to validate the invoice.

The prior unofficial arrangement between the non-VHA laboratory and the subject pathologist could have been a factor in the lack of information identifying the non-VHA laboratory pathologists, as well as the lack of information on the laboratory log.

As noted above, we recommended that the Facility Director ensure that P&LMS staff follow VHA and facility documentation requirements for non-VHA laboratory tracking and pathology reports and that facility managers monitor compliance.

### **Issue 5: Inappropriate Contracting and Policy Actions**

The subject pathologist told us that he used an unofficial arrangement with a non-VHA laboratory to process dermatology pathology specimens. In addition, the subject pathologist changed the routine pathology test TAT making it non-compliant with VHA and local policies.

Unofficial Arrangement With a Non-VHA Laboratory. VHA specifically requires non-VHA vendors, such as non-VHA laboratories, to have contracts with VHA partners when treating or participating in veteran care. The contracting process ensures that terms are negotiated for appropriate services, qualified staff perform those services, and pricing for those services and that all health care resources provided by non-VHA vendors meet VA quality standards of care. VHA contractual quality standards include providing data on the non-VHA services' performance. The subject pathologist told us that he sent pathology specimens to a non-VHA laboratory for testing under an unofficial arrangement with the non-VHA laboratory director for at least 2 years. According to our review, the subject pathologist sent 45 (9 percent of the 500 tests sent to non-VHA laboratories) tests to this non-VHA laboratory between January 1, 2014 and July 31, 2014.

The non-VHA facility had contracts with VHA for dermatology, urology, and oral physician and surgery services but did not contract for pathology services; however, the subject pathologist stated that the arrangement for pathology laboratory services was consultative in nature, and no payment was expected. The non-VHA laboratory, under this unofficial arrangement, did not bill the facility and did not provide aggregated data or information related to service performance; however, it tested the pathology specimens sent to it by the subject pathologist and determined the diagnoses, which the subject pathologist entered into patients' EHRs. Though the other contracts with this facility addressed the qualifications of the non-VHA facility staff, without a contract for

<sup>&</sup>lt;sup>62</sup> VA Directive 1663, *Health Care Resources Contracting – Buying*, August 10, 2006.

<sup>63</sup> Ibid.

pathology testing, the staff performing the pathology testing may not have been qualified.

In a July 2016 interview, the non-VHA Laboratory Director explained that there was an informal arrangement (no contract), arranged by the subject pathologist, for the non-VHA Laboratory to perform pathology tests. He told us that he was a qualified pathologist, and that he performed all tests sent to the non-VHA laboratory, but that, at the time of the interview, there was no contract between the non-VHA laboratory and VHA for pathology testing, and that he no longer performs pathology testing for the facility. The subject pathologist told us that he entered the non-VHA laboratory's name in the EHRs but not the non-VHA pathologist's name.

**Routine Pathology Test TAT Change.** When changing policy elements and definitions, authors should use the most current industry standards, clinical practices, and guidelines. To avoid confusion, policy changes should be reflected in all pertinent policies or combined in one policy. 66

According to a technologist from the VHA Pathology and Laboratory Medicine National Enforcement Program, the subject pathologist changed the facility routine pathology test TAT for surgical and non-gynecological pathology tests to 2–3 weeks, which did not comply with the VHA requirement of 2 working days. Although he used the new TAT of 2–3 weeks to monitor TAT compliance and wrote an appendix for the P&LMS General Policy Manual with the new TAT, he did not change the facility laboratory QA policy TAT definition, which reflected the VHA requirement. We reviewed both the SRC and MEB minutes for 2011, 2012, and 2013 and found that the subject pathologist started using the 2–3 week TAT in December 2012. Therefore, the facility laboratory had two routine pathology TAT definitions, one that complied with VHA policy, and one that did not comply with VHA policy.

**Contributing Factor**. The subject pathologist stated that he changed the routine TAT because he could not meet the TAT of within 2 working days for routine pathology tests. He consulted with different departments and established the new routine TAT for dermatology at 2 weeks, and for gastroenterology, 3 weeks. He also stated that the new TATs were not presented to the MEB for review.

Facility leaders informed us that they had not been aware of the unofficial arrangement with the non-VHA laboratory or the change in the routine TAT policy. There was no documentation to the MEB about the unofficial arrangement but the TAT change was documented in the SRC report to the MEB in 2012, though not documented in the MEB minutes. Since that time, except for October 2013, (data report for first 3 quarters of FY 2013 was embedded and actual report read that all goals were met), the MEB

<sup>&</sup>lt;sup>64</sup> JC Standard LD.04.04.03 EP 4. Accessed January 20, 2016.

<sup>&</sup>lt;sup>65</sup> Anne V. Irving, "Policies and Procedures for Healthcare Organizations: A Risk Management Perspective," *Patient Safety and Quality Healthcare*, (*PSQH*) <a href="http://psqh.com/september-october-2014/policies-and-procedures-for-healthcare-organizations-a-risk-management-perspective">http://psqh.com/september-october-2014/policies-and-procedures-for-healthcare-organizations-a-risk-management-perspective</a> Accessed March 8, 2016.

<sup>66</sup> Ibid.

minutes only reflected a summary from the SRC, which stated that all anatomic pathology goals were met. We were also informed that the subject pathologist planned to retire the week of our site visit.

**Update.** In October 2014, the MEB approved an Anatomic Pathology Turnaround Time policy, which included the routine test TAT definition of "within 2 working days" for surgical and non-gynecological pathology tests. However, the policy regarding a routine TAT of 2-3 weeks existed for at least 2 years during which time the MEB did not acknowledge the change. In addition, MEB minutes now reflect submission of the P&LMS quarterly data.

We recommended that the Facility Director ensure that facility managers review the pathology tests performed at the unofficial non-VHA laboratory to determine whether quality assurance benchmarks were met and whether patient harm occurred, and if harm did occur, confer with the Office of Chief Counsel regarding the appropriateness of disclosures to patients and families.

### **Issue 6: Oversight and QA Practices**

We found that the SRC did not consistently report correct routine TAT non-compliance data and trends to medical and facility leadership. In addition, facility managers did not follow or monitor a 2008 internal review correction plan for similar TAT issues. At the time of our September 22-24, 2014 site visit, the facility Director and Chief of Staff were new to their positions at the facility.

During FY 2013, the non-compliance rates all stayed below 10 percent with the 4<sup>th</sup> quarter at 5.3 percent. In FY 2014, the SRC committee identified non-compliance rates of 23.6 percent in the 1<sup>st</sup> quarter, 47.2 percent in the 2<sup>nd</sup> quarter, and 88.3 percent in the 3<sup>rd</sup> quarter, all well above the 10 percent or less non-compliance rate.

During the first 10 months of FY 2014, the SRC reported summaries of routine TAT data to the MEB on three occasions. Though the SRC reported that this information was provided through the data collection dashboard, no actual data were provided to the MEB during this time. In January 2014, the SRC reported that all TAT goals were met through the 2013 4<sup>th</sup> quarter and year to date. For April 2014, the SRC reported to the MEB that the P&LMS had met non-compliance TAT rates for the 1<sup>st</sup> quarter of 2014 and through 2014 to date. However, according to the SRC committee report, the routine TAT non-compliance rates had consistently increased during the 1<sup>st</sup> quarter of FY 2014 and did not meet the 10 percent non-compliance rate. In the third report to the MEB, at the beginning of the 4<sup>th</sup> quarter, the SRC reported issues with meeting the routine pathology test result TATs during the 1<sup>st</sup> and 2<sup>nd</sup> quarters of 2014, and that plans had been made to change the way specimens were processed and hire another pathologist. We found no additional information on these plans in the ongoing SRC and MEB

<sup>&</sup>lt;sup>67</sup> Wilmington VAMC Pathology and Laboratory Medicine Anatomic Pathology Quality Assurance, *Anatomic Pathology Turnaround Times* October 7, 2014.

minutes, however, the laboratory manager told us that the process for prioritizing laboratory specimens by the subject pathologist had stopped, and pathology specimens were now processed on a first come, first served basis like all other laboratory tests.

We also found that in 2008, facility leadership performed an internal review which identified the inability of the subject pathologist to meet routine pathology test result TATs. The leadership review board approved a plan to correct the issue, but at the time of our review, we found no indication that the assigned supervisor (which would have been the Chief of Surgery at that time) had carried out or monitored the plan. According to the current Chief of Staff, who had been in the position for 2 months, the assigned supervisor had no documentation that the corrective actions from the internal review had been carried out, and did not know why this had not occurred.

We spoke with the current Chief of Staff, who was new to the position, about why the SRC had presented misinformation to leadership in the beginning of the 3<sup>rd</sup> quarter (April), and why the internal review plan was not followed. He explained that during the time period of our review, the subject pathologist was supervised by the Chief of Surgery, who prepared and signed the subject pathologist's ongoing professional practice evaluation (OPPE). The Chief of Surgery also oversaw the SRC, and prepared the laboratory report for the MEB. According to the Chief of Staff, the friendship between certain members of the staff, including the Chief of Surgery, other surgeons, and the subject pathologist, may have contributed to the misinformation and lack of follow through with the internal review by the Chief of Surgery. The Chief of Staff also added that pathologists' OPPEs were based upon data collected on testing processes, including routine TATs. Although issues were identified by the laboratory routine TAT data in 2011, before the routine TAT change from 2 working days to 2-3 weeks, the subject pathologist's OPPEs reflected a satisfactory rating by the supervising Chief of Surgery for routine TAT performance. The Chief of Surgery did not complete an OPPE during the period covering the 2008 internal review.

During our September 22–24, 2014 site visit, facility leadership told us that they had taken steps to improve supervision by changing P&LMS oversight to another department. The QM Director stated that the P&LMS would now report directly to the Chief of Staff. However, at the time of our site visit, other than informing us that the P&LMS Director would be leaving employment, the facility leadership did not provide a clear indication of how the facility planned to ensure compliance with VHA and facility QA policies, including what actions leadership would take if routine test TAT issues persisted.

**Update.** We reviewed SRC and MEB minutes for the first two quarters and one month of the third quarter of FY 2015. At that time, data from the P&LMS dashboard on routine TATs and other benchmarks/goals were reported from the SRC to the MEB and that data were recorded in the minutes of the MEB; however, routine TAT data non-compliance rates were not being met.

We recommended that the Facility Director ensure that facility oversight services and committees for the P&LMS review current performance data and follow VHA and facility

quality assurance policies and practices concerning reporting data, establishing action plans, and monitoring action plans, and that facility leadership monitor compliance.

We recommended that the Facility Director ensure that facility managers monitor and use current performance data, follow up on actions from other internal reviews, and complete OPPEs as required by VHA and facility policies.

# **Conclusions**

We could not substantiate that the pathologist misread oncology tests. Facility data reflected no issues with misread tests or patient harm associated with any misread tests. However, because the data were gathered by the subject pathologist and did not cover every test result, we tried to review data from patient records. We found that because the subject pathologist re-verified and modified test result information, the initial test result no longer existed, and we had no means to recapture this information, and compare it to the final pathology test result or to verify the facility's data. We interviewed oncology staff who could not recall any instances of misread tests or harm to patients related to misread tests.

We substantiated that the subject pathologist, who performed the majority of pathology tests, did not always have pathology test results available for ordering providers within the required timeframe. We also substantiated that the pathologist sent tests to Fee Basis vendors but did so with approval from facility leadership to alleviate a backlog of unprocessed pathology tests.

We did not substantiate that the pathologist altered pathology tests results from alternate VHA and non-VHA laboratories to make them appear as though he performed the tests at the facility laboratory; however, we found inconsistent documentation identifying non-VHA pathologists in EHRs, and inconsistent tracking and documentation methods when sending pathology specimens to alternate VHA and non-VHA laboratories.

The subject pathologist had an unofficial arrangement with a non-VHA laboratory to process pathology tests, and did not ensure that a facility policy was consistent with VHA and facility policies.

In addition, we found that the SRC did not consistently report TAT non-compliance rates and trends for routine pathology test results to medical and facility leadership. Furthermore, facility managers did not follow or monitor a 2008 internal review correction plan for similar TAT issues involving the subject pathologist.

We made five recommendations.

# Recommendations

- 1. We recommended that the Facility Director ensure that Pathology and Laboratory Medicine Service staff establish and use acceptable processing procedures for pathology testing that will ensure established benchmark non-compliance rates for routine pathology test turnaround times, as established by VHA, are met and that facility managers monitor compliance.
- **2.** We recommended that the Facility Director ensure that Pathology and Laboratory Medicine Service staff follow facility documentation requirements for non-VHA laboratory pathology reports and that facility managers monitor compliance.
- **3.** We recommended that the Facility Director ensure that facility managers review the pathology tests performed at the unofficial non-VHA laboratory to determine whether quality assurance benchmarks were met and whether patient harm occurred, and if harm did occur, confer with the Office of Chief Counsel regarding the appropriateness of disclosures to patients and families.
- **4.** We recommended that the Facility Director ensure that facility oversight services and committees for the Pathology and Laboratory Medicine Service review current performance data and follow Veterans Healthcare Administration and facility quality assurance policies and practices concerning reporting data, establishing action plans, and monitoring action plans, and that facility leadership monitor compliance.
- **5.** We recommended that the Facility Director ensure that facility managers monitor and use current performance data, and complete ongoing professional performance evaluations and other internal reviews as required by Veterans Health Administration and facility policies.

# **VISN Director Comments**

# **Department of Veterans Affairs**

# **Memorandum**

- Date: March 15, 2017
- From: Network Director, VA Healthcare VISN 4 (10N4)
- Healthcare Inspection—Pathology and Laboratory Medicine Services
  Quality of Care Issues, Wilmington VA Medical Center, Wilmington,
  Delaware
- Acting Director, Bedford Office Healthcare Inspections (54BN)
  Director, Management Review Service (VHA 10E1D MRS Action)
  - 1. I have reviewed the responses provided by the Wilmington VAMC and I am submitting to your office as requested. I concur with their responses.
  - 2. If you have any questions or require additional information, please contact Moira Hughes, VISN 4 Quality Management Officer, at 412-822-3294.

Michael D. Adelman, M.D.

Michael D. Adulman, mo.

# **Interim Facility Director Comments**

# **Department of Veterans Affairs**

# **Memorandum**

Date: March 13, 2017

From: Interim Director, Wilmington VA Medical Center (460/00)

Healthcare Inspection— Pathology and Laboratory Medicine Services
Quality of Care Issues, Wilmington VA Medical Center, Wilmington,
Delaware

Network Director, VA Healthcare - VISN 4 (10N4)

- I have reviewed and concur with the recommendations made during the Office of Inspector General's (OIG) Healthcare Inspection of Pathology and Laboratory Medicine Services Quality of Care Issues in September 2014. Resolution actions have been accomplished on 5 of 5 recommendations. A plan of action was developed, implemented, monitored, and successfully completed.
- 2. I would like to thank the OIG Survey team for providing a thorough report which provided an opportunity for the medical center to strengthen processes and further improve the care we provide to our Veterans.
- 3. If you have any questions or require additional information, please contact Christine Micek, Director of Quality Management, at (302) 994-2511 ext. 4564.

Robert W. Callahan Interim Director

# **Comments to OIG's Report**

The following Director's comments are submitted in response to the recommendations in the OIG report:

### **OIG Recommendations**

**Recommendation 1.** We recommended that the Facility Director ensure that Pathology and Laboratory Medicine Service staff establish and use acceptable processing procedures for pathology testing that will ensure established benchmark non-compliance rates for routine pathology test turnaround times, as established by VHA, are met and that facility managers monitor compliance.

### Concur

Target date for completion: September 30, 2015

Facility response: Facility Pathology and Laboratory Medicine Service established benchmarks and tracking/monitoring devices for turnaround times, which are compliant with VHA Directives, laboratory accreditation standards and industry best practices, on October 1, 2014. In review of supplemental documentation, incremental and sustained improvement in compliance with turnaround times was achieved by the close of FY15.

**OIG Comment:** Based on information received from the facility, we consider this recommendation closed.

**Recommendation 2.** We recommended that the Facility Director ensure that Pathology and Laboratory Medicine Service staff follow facility documentation requirements for non-VHA laboratory pathology reports and that facility managers monitor compliance.

### Concur

Target date for completion: March 31, 2015

Facility response: Supplemental documentation of non-VHA laboratory processing was completed in compliance with VHA directive and industry standards on October 1, 2015, and reviewed for completeness for a period of 6 months. No compliance issues were identified.

**OIG Comment**: Based on information received from the facility, we consider this recommendation closed.

**Recommendation 3.** We recommended that the Facility Director ensure that facility managers review the pathology tests performed at the unofficial non-VHA laboratory to determine whether quality assurance benchmarks were met and whether patient harm

occurred, and if harm did occur, confer with the Office of Chief Counsel regarding the appropriateness of disclosures to patients and families.

### Concur

Target date for completion: March 10, 2017

Facility response: The Pathology and Laboratory Medicine Service completed a 100% (n=45) review of patient cases identified to have testing performed at the unofficial non-VHA laboratory on March 10, 2017 (case review list received by medical center on March 7, 2017). No discrepancies noted between the initially reported results and the third party review. No cases of patient harm identified.

**OIG Comment**: Based on information received from the facility, we consider this recommendation closed.

**Recommendation 4.** We recommended that the Facility Director ensure that facility oversight services and committees for the Pathology and Laboratory Medicine Service review current performance data and follow Veterans Healthcare Administration and facility quality assurance policies and practices concerning reporting data, establishing action plans, and monitoring action plans and that facility leadership monitor compliance.

### Concur

Target date for completion: September 30, 2015

Facility response: We recommended that the Facility Director ensure that facility oversight services and committees for the Pathology and Laboratory Medicine Service review current performance data and follow Veterans Healthcare Administration and facility quality assurance policies and practices concerning reporting data, establishing action plans, and monitoring action plans and that facility leadership monitor compliance.

**OIG Comment**: Based on information received from the facility, we consider this recommendation closed.

**Recommendation 5.** We recommended that the Facility Director ensure that facility managers monitor and use current performance data, and complete ongoing professional performance evaluations and other internal reviews as required by VHA and facility policies.

### Concur

Target date for completion: December 9, 2014

Facility response: Pathology and Laboratory Medicine Service adhere to the established minimum 10% case review as described in VHA handbook 1106.01. Casework

reviewed is representative of work performed. Clinically significant discrepancies are reported as part of the pathologists' Initial and Ongoing Professional Practice Evaluation. Ongoing Professional Practice Evaluation (OPPE) will be conducted at a minimum of twice a year to assess competence related to the existing privileges and/or to revise/revoke existing privileges for pathologists practicing at the Wilmington VAMC. The reviews will be specific to the performance and care quality of the individual pathologist. This process was updated and approved by facility leadership in the facility 2015 Quality Assurance Plan, dated December 9, 2014.

**OIG Comment**: Based on information received from the facility, we consider this recommendation closed.

# Appendix C

# **OIG Contact and Staff Acknowledgments**

| Contact      | For more information about this report, please contact the OIG at (202) 461-4720.     |
|--------------|---|
| Contributors | Elaine Kahigian, RN,JD, Team Leader<br>Thomas Jamieson, MD<br>Valerie Zaleski, RN,BSN |

Appendix D

# **Report Distribution**

### **VA Distribution**

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Network Director, VA Healthcare - VISN 4 (10N4)
Interim Director, Wilmington VA Medical Center name (460/00)

### **Non-VA Distribution**

House Committee on Veterans' Affairs

House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies

House Committee on Oversight and Government Reform

Senate Committee on Veterans' Affairs

Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies

Senate Committee on Homeland Security and Governmental Affairs

National Veterans Service Organizations

Government Accountability Office

Office of Management and Budget

U.S. Senate: Thomas R. Carper, Christopher A. Coons

U.S. House of Representatives: Lisa Blunt Rochester

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