DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Facility Leaders' Response to Level 2 and Level 3 Pathology Reading Errors at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas

HEALTHCARE INSPECTION | REPORT #21-01677-259 | SEPTEMBER 21, 2021

In addition to general privacy laws that govern release of medical information, disclosure of certain veteran health or other private information may be prohibited by various federal statutes including, but not limited to, 38 U.S.C. §§ 5701, 5705, and 7332, absent an exemption or other specified circumstances. As mandated by law, the OIG adheres to privacy and confidentiality laws and regulations protecting veteran health or other private information in this report.

Report suspected wrongdoing in VA programs and operations to the VA OIG Hotline:

www.va.gov/oig/hotline

1-800-488-8244

Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess leaders' response to pathology reading errors made by a former facility pathologist, Dr. Robert Levy, at the Veterans Health Care System of the Ozarks (facility) in Fayetteville, Arkansas.[1] The errors resulted in misdiagnoses of slightly more than 3,000 pathological specimens as detailed in a previous OIG report.[2] The severity and magnitude of the concerns addressed in the prior report warranted an OIG follow-up review of facility leader's actions to address the errors.

The inspection was initiated in March 2021 to evaluate facility processes and progress in responding to diagnostic errors categorized as level 2 or level 3 during a 100 percent look-back review that encompassed all cases interpreted by Dr. Levy between September 2005 and October 2017.[3] Specifically, the OIG assessed facility processes for disclosures of pathological errors in diagnosis, the impact on care, and the amendment of electronic health record (EHR) documentation.

Veterans Health Administration (VHA) policy outlines an ethical obligation "to disclose to patients harmful events that have been sustained in the course of their Department of Veterans Affairs (VA) care, including cases where the harm may not be obvious, or where there is a potential for harm to occur in the future."[4]

The OIG determined that facility processes for patient notification, including institutional disclosures and clinical disclosures, met VHA policy requirements. However, opportunities for improvement existed for tracking the completion of clinical disclosures.

Cases categorized by the look-back review team as level 2 or level 3 diagnostic errors were referred to a Clinical Review Team to determine the impact on patient care and the need for

[1] Underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

[2] The number of cases does not represent the total number of individuals as some patients had more than one test or procedure. VA OIG, *Pathology Oversight Failures at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas,* Report No. 18-02496-157, June 2, 2021, https://www.va.gov/oig/pubs/VAOIG-18-02496-157.pdf.

[3] Pathologists performing the look-back review utilized standardized criteria to categorize the results for each case into four levels: 0 No deficiency or diagnostic error; 1 Minor disagreement, practice acceptable, reviewer still comfortable; 2 Disagreement in diagnosis with minimal or no potential negative impact on patient care; 3 Major diagnostic discrepancy with potential for negative impact on patient care/treatment.

[4] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012, was in effect during some of the events discussed in this report; it was rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The two policies contain the same or similar language related to disclosures.

clinical and institutional disclosure.[5] The Clinical Review Team determined if the original pathology reading errors had resulted in harm to patients, and whether those cases warranted a clinical or institutional disclosure.

The Clinical Review Team identified a total of 34 patients requiring institutional disclosure. The facility completed institutional disclosures for 28 of the 34 identified patients between June 2018 and March 2020. While VHA policy did not specify minimum required efforts to complete institutional disclosures, the OIG determined that, though unsuccessful, the facility made reasonable efforts to conduct disclosures in the six identified remaining cases. Additionally, the OIG determined there was no clearly defined process for clinical providers to alert the Clinical Review Team if later changes in a patient's health status during the course of continuing care might indicate reconsideration of the need for institutional disclosure.

The Clinical Review Team recommended clinical disclosures for 520 of the 589 level 3 cases and 41 of the 2,440 level 2 cases. Based on the documentation available, 76.5 percent of the clinical disclosures were completed. The magnitude of the review and need for the facility to respond to the many identified cases introduced greater oversight concerns related to tracking the disclosure process to ensure appropriate actions were taken. While the facility's processes satisfied VHA policy, the inconsistencies in the manner of documenting the clinical disclosures created challenges for tracking and confirming completion of the clinical disclosures.[6]

VHA policy for Pathology and Laboratory Medicine Service (Path and Lab) specifies that when errors are identified in test results that have been released, the report must be corrected in the EHR. Both the original and corrected reports become part of a patient's permanent EHR. Facility policy established guidance for amendment of the record via a modified pathology report in cases when the amendment documents a clinically significant change in diagnosis that would affect a patient's care, and via a supplemental pathology report in cases where the amendment did not change the diagnosis in a way that would affect the patient's treatment.[7]

The look-back review coordinator entered modified pathology reports into the EHR for patients identified with level 3 diagnostic errors. However, the facility subsequently struggled with fully implementing the plan for completion of the supplemental pathology reports for patients

[5] The Clinical Review Team was composed of four core members, including the Veterans Integrated Service Network 16 Chief Medical Officer, a private sector oncologist, the facility's Chief of Staff, and the facility's Chief of Quality, Safety and Value, with ad hoc clinical subject matter experts based on the type of specimen reviewed. For Level 3 cases, subject matter experts were selected from facility clinical staff specialists. For Level 2 cases, clinical subject matter experts were selected from other VHA facilities in Veterans Integrated Service Network 16.

[6] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures,* January 29, 2016.

[7] Veterans Health Care System of the Ozarks, Pathology and Laboratory Medicine Service Procedure 206-A, *Anatomic Pathology Supplemental and Modified Reports*, August 24, 2016. Supplemental pathology reports are issued when there is additional information relevant to a previously signed report which "does not change the diagnosis in a way that would impact the patient's treatment." Supplemental pathology reports do not require notification to the patient's provider, though the provider may be alerted to the supplemental report.

identified with level 2 diagnostic errors. At the time of the OIG site visit, supplemental pathology reports had been entered into patient EHRs for fewer than 5 percent of the level 2 cases. The primary causes for delays in completion of the supplemental pathology reports for level 2 cases included problems encountered during the facility Chief of Pathology's verification process for the supplemental pathology reports, communication lapses that hampered the resolution of some identified concerns, and limited staffing resources to complete the retrospective task while attending to the ongoing demands of the current Path and Lab workload.

The OIG made two recommendations to the Under Secretary for Health related to processes for documentation of clinical disclosures and clinical provider communication to the Clinical Review Team regarding changes in patient health status that may indicate need for institutional disclosure.[8] One recommendation was addressed to the Facility Director related to implementation of a plan for completion of supplemental pathology reports for cases identified with level 2 pathology reading errors.

Comments

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

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

[8] Recommendations addressed to the Under Secretary for Health were submitted to the Deputy to the Deputy Under Secretary for Health, performing the delegable duties of the Under Secretary for Health.

Contents

Abbreviations

2M-2B	2-methyl-2-butanol (2M-2B)
CERT	clinical episode response team
EHR	electronic health record
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess leaders' response to pathology reading errors made by a former facility pathologist, Dr. Robert Levy, at the Veterans Health Care System of the Ozarks (facility) in Fayetteville, Arkansas.[1] The errors resulted in misdiagnoses of slightly more than 3,000 patients' pathological specimens as detailed in a previous OIG report.[2] The severity and magnitude of the concerns addressed in the prior report warranted an OIG follow-up review of facility leader's actions to address the errors.

Background

The facility, part of Veterans Integrated Service Network (VISN) 16, includes a medical center in Fayetteville and seven community-based outpatient clinics located in northwest Arkansas, southwest Missouri, and eastern Oklahoma. VA classifies the facility as level 1c.[3]

Precipitating Events

The following information is sourced from the prior OIG report and provided here as relevant background for the current inspection:

> The VA Office of Inspector General (OIG) received allegations in late 2017 from a confidential complainant concerning issues within the Pathology and Laboratory Medicine Service (Path and Lab) at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas (facility).
>
> The OIG referred the 2017 allegations to Veterans Integrated Service Network (VISN) 16. While waiting for the response to the query, the OIG received additional allegations that the Path and Lab Service Chief, Dr. Robert M. Levy, misdiagnosed patients' pathological specimens, which adversely affected outcomes, and altered quality management documents to conceal his errors.

The report detailed that

[1] Underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

[2] VA OIG, *Pathology Oversight Failures at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas*, Report No. 18-02496-157, June 2, 2021, https://www.va.gov/oig/pubs/VAOIG-18-02496-157.pdf.

[3] The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and 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.

> In spring 2018, when the OIG initiated a healthcare inspection to evaluate facility leaders' actions related to the oversight of Dr. Levy, the OIG team learned that facility leaders had started to take steps to remove Dr. Levy from federal service.
>
> In 2018 a separate division of the OIG, the Office of Investigations, also began a criminal investigation into Dr. Levy's actions. The healthcare inspection was delayed in deference to the criminal investigation. Dr. Levy subsequently admitted to OIG investigators that he had been an alcoholic for 30 years and purchased a substance, 2-methyl-2-butanol (2M-2B), online that could be ingested, was similar to alcohol but more potent, and was not detectable using routine drug and alcohol testing methods.[4]

The report further states

> According to the facility, prior to completing the steps required to remove Dr. Levy in 2018, a review of his cases was initiated. When more diagnostic errors than expected were identified, a facility and a VISN leader contacted a Veterans Health Administration (VHA) official for assistance and a clinical episode review team (CERT) was convened.[5] The CERT determined that a look-back review of all pathology cases that Dr. Levy interpreted during the years he practiced at the facility (September 2005–October 2017) was warranted. The CERT designated a chairperson to coordinate a team of pathologists to complete the look-back review.
>
> Pathologists who conducted the look-back review evaluated almost 34,000 cases interpreted by Dr. Levy and noted slightly more than 3,000 errors, including 589 major diagnostic discrepancies.[6] As results of the look-back review were

[4] Dr. Levy also noted that 2M-2B was a pigment solvent and that he developed symptoms similar to those of a stroke after ingesting it.

[5] VHA Directive 2005-049, *Disclosure of Adverse Events to Patients*, October 27, 2005, rescinded and replaced by VHA Directive 2008-002, *Disclosure of Adverse Events to Patients*, January 18, 2008, rescinded and replaced by VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients,* October 2, 2012, rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The 2005 directive does not discuss large-scale disclosure or CERT. The 2008 directive discusses large-scale disclosure and consultation with a Clinical Risk Assessment Advisory Board. The 2012 handbook does not use the term CERT but describes a subject matter expert panel and a Clinical Review Board. The 2018 directive introduces the term CERT. Although the 2018 directive was not issued until October, VHA and facility interviewees used the 2018 term, CERT, to describe the panel that reportedly convened in May 2018. The OIG also uses the 2018 directive term CERT to describe the convened panel.

[6] The number of cases does not represent the total of number of individual patients as some patients may have received multiple tests or procedures. The look-back team established criteria for the review. Major diagnostic discrepancy is described as a difference in interpretation with potential for negative impact on patient care and treatment.

> received, the CERT tasked a Clinical Review Team to assess if discrepancies adversely affected patient outcomes.[7]

The OIG recognizes the significant efforts of the VHA, VISN, and facility staff; academic affiliates; and contracted community providers whose work ensured a review of Dr. Levy's cases and identification of the patients whose care was affected by diagnostic errors.

Pathology Reading Errors

Pathologists performing the look-back review utilized the following standardized criteria to categorize the results for each case into four levels (reproduced verbatim):

> 0 No deficiency or diagnostic error
>
> 1 Minor disagreement, practice acceptable, reviewer still comfortable
>
> 2 Disagreement in diagnosis with minimal or no potential negative impact on patient care
>
> 3 Major diagnostic discrepancy with potential for negative impact on patient care/treatment

Reviewing pathologists identified 2,440 cases with level 2 errors, and 589 cases with level 3 errors interpreted by Dr. Levy from September 2005 through October 2017.

Impact of Pathology Reading Errors

The OIG's prior review "substantiated that Dr. Levy's misdiagnoses of patients' pathological specimens resulted in numerous adverse clinical outcomes including suboptimal treatment and patient death" and noted

> Diagnostic errors can lead providers to consider and offer incorrect treatment options that fail to address the specific disease process and could negatively affect the patient's prognosis. Healthy patients could receive unnecessary treatment that may carry significant risks.

Concerns

This inspection was initiated in March 2021 to evaluate facility processes and progress in responding to cases categorized as level 2 or level 3 during the look-back review.

Specifically, in this report, the OIG inspection team assessed:

[7] During an interview, the OIG learned that the Clinical Review Team consisted of two VISN 16 facility chiefs of staff and a rotating third member who had subject matter expertise relative to the case under review.

- Facility processes for facilitating disclosures to patients regarding pathological errors in diagnosis and the impact on care, and
- Facility processes for amendment of electronic health record (EHR) documentation of pathological errors in diagnosis.

Scope and Methodology

The OIG initiated the inspection on March 2, 2021, and conducted an unannounced site visit on March 11, 2021.

The OIG interviewed facility staff including the Facility Director; the Chiefs of Quality, Safety and Value and Path and Lab; the Risk Manager; the Laboratory Quality Manager; and Human Resources staff at the facility and VISN. The OIG spoke with key staff involved in the VHA look-back review, including the pathologist who coordinated the look-back review (look-back review coordinator), and the VISN 16 Chief Medical Officer who coordinated the Clinical Review Team. The OIG team also interviewed a pathologist leader from the VHA Path and Lab National Program Office who served as a subject matter expert to the CERT.

The OIG reviewed relevant VHA and facility policies and procedures, documentation related to the look-back review, facility action plans, facility documents tracking disclosures and amendments of EHRs; and a sample of EHRs for patients with diagnostic errors identified through the look-back review. The OIG also reviewed committee minutes and human resources documents related to revocation of clinical privileges and personnel actions for a facility staff member removed from clinical duties.

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1101, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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

Inspection Results

1. Patient Notifications and Disclosures

The OIG determined that facility processes for patient notification, including institutional and clinical disclosures, met VHA policy requirements. However, opportunities existed for improvement related to tracking the completion of clinical disclosures.

VHA policy outlines an ethical obligation "to disclose to patients harmful events that have been sustained in the course of their Department of Veterans Affairs (VA) care, including cases where the harm may not be obvious, or where there is a potential for harm to occur in the future."[8] Depending on the nature of the adverse event, disclosure processes may involve clinical disclosure, institutional disclosure, large-scale disclosure, or more than one type of disclosure.

Concurrent with the initiation of the look-back review in June 2018, the Facility Director sent letters to all known patients whose pathology tests were read by Dr. Levy. The letters alerted them that VHA had initiated a review of Dr. Levy's cases due to concerns of misdiagnoses and that patients would be contacted if an error specific to their test(s) was noted.

Following the categorization and confirmation of modified diagnoses by the look-back review team, cases categorized as level 2 or level 3 diagnostic errors were referred to the Clinical Review Team to determine the impact on patient care and the need for clinical and institutional disclosures.[9] The VISN 16 Chief Medical Officer and clinical subject matter experts within the Clinical Review Team independently reviewed the patients' EHRs. The Clinical Review Team discussed the review findings and an oncologist provided a clinical opinion for level 3 cases involving a malignancy or potential malignancy. Additionally, the VISN 16 Chief Medical Officer explained that in determining harm, the Clinical Review Team considered factors such as delays in care, potential negative impacts related to the delay, the patient's medical status at the time of the evaluation, and whether identification of the correct diagnosis at the time of the original pathology reading would have changed treatment and potentially affected the patient's medical status.[10]

---

[8] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012 was in effect during some of the events discussed in this report; it was rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

[9] The Clinical Review Team was composed of four core members, including the VISN 16 Chief Medical Officer, a private sector oncologist, the facility's Chief of Staff, and the facility's Chief of Quality, Safety and Value, with ad hoc clinical subject matter experts based on the type of specimen reviewed. For Level 3 cases, subject matter experts were selected from facility clinical staff specialists. For Level 2 cases, clinical subject matter experts were selected from other VHA facilities in the VISN.

[10] If the Clinical Review Team determined further information was needed for a determination of the impact, they could take additional steps, such as reaching out to the patient's current provider for input or to recommend additional tests or follow-up to identify if additional care was needed based on the new diagnosis.

The VISN 16 Chief Medical Officer told the OIG that the Clinical Review Team applied criteria for institutional disclosure based on VHA policy, which directs that institutional disclosure is indicated when an adverse event during a patient's care resulted in or was reasonably expected to result in death or serious injury.[11] Institutional disclosure is generally indicated when there is a significant chance the adverse event has caused harm to a patient, which could include permanent disability, prolonged hospitalization, life-sustaining intervention, or intervention to prevent impairment or damage including sentinel events or death.[12] VHA policy indicates that "clinical disclosure is appropriate for all adverse events that cause only minor harm to the patient" and makes exception for "minor harms that are discovered after the patient has completed the associated episode of care and that have no implications for the patient's future health."[13]

The VISN 16 Chief Medical Officer stated if opinions differed among Clinical Review Team members regarding the type of disclosure warranted, the decision was rendered for institutional disclosure. The facility's Quality, Safety and Value service maintained documentation of the Clinical Review Team's determinations and recommendations regarding disclosures. Completion of the identified institutional and clinical disclosures was tasked to facility staff.

Institutional Disclosures

The OIG determined that the facility was compliant with VHA policy on institutional disclosures.

VHA policy assigns VA medical facility directors with responsibility for ensuring the completion and appropriate documentation of institutional disclosures and assigns responsibility for participation in the team conducting institutional disclosures to facility chiefs of staff.[14]

The Clinical Review Team identified a total of 34 patients requiring institutional disclosure. Of the 34 institutional disclosures, 31 stemmed from the 589 level 3 cases with diagnostic discrepancies (as identified by the look-back team) that the Clinical Review Team determined resulted in harm to the patients. Three of the 34 institutional disclosures arose from the 2,440 cases categorized as level 2.

The facility's Risk Manager reported coordinating with the Chief of Staff to conduct institutional disclosures for the 34 patients identified as sustaining harm due to the pathology reading errors. The Risk Manager described that the facility's process involved convening the Chief of Staff, Risk Manager, Chaplain, and clinical subject matter experts, to discuss the diagnostic error,

[11] VHA Handbook 1004.08, 2012; VHA Directive 1004.08, 2018.

[12] The description of events reflecting harm to the patient requiring institutional disclosure were specified by the VISN 16 CMO and consistent with VHA Directive 1004.08, 2018.

[13] VHA Handbook 1004.08, 2012; VHA Directive 1004.08, 2018.

[14] VHA Handbook 1004.08, 2012; VHA Directive 1004.08, 2018.

impact on the patient's care, and related harm with the patient, the family, or personal representative. The facility completed institutional disclosures for 28 of the 34 identified cases from June 2018 through March 2020. Facility leaders attempted to conduct institutional disclosures in the six remaining cases; however, they were unsuccessful due to inability to contact the patient or family, refusal of the meeting by the patient or family, or repeated failure of the patient to attend the scheduled disclosure meeting. While VHA policy does not specify minimum required efforts to complete institutional disclosures, the OIG determined that the facility made reasonable efforts to conduct disclosures in the six identified cases.

Potential for Delayed Identification of Clinical Impact Could Indicate Need for Additional Institutional Disclosures

The VISN 16 Chief Medical Officer leading the Clinical Review Team reported to the OIG that the need to monitor and re-evaluate some patient cases could continue for an indefinite period. The Clinical Review Team reviewed all level 3 cases and made determinations regarding disclosures and the need for additional follow-up care based on the clinical knowledge available at the time of the review. However, the Clinical Review Team could not exclude the possibility that subsequent developments in the patient's health could point to the need for re-review, and additional institutional disclosures.

The VISN 16 Chief Medical Officer indicated that the process for tracking level 3 cases that might require further assessment relied on the facility's Chief of Quality, Safety and Value to alert the Clinical Review Team if a case arose that required additional review. The Chief of Quality, Safety and Value indicated that if the Clinical Review Team had made recommendations for the patient's care in the short term, Quality, Safety and Value staff tracked those cases, and would bring the results of the recommended follow-up care back to the Clinical Review Team for determination as to whether further institutional disclosures were warranted. However, for level 3 cases where the Clinical Review Team did not identify any recommendation for a change in the treatment plan, or where the recommendation was for a shorter, yet still remote follow-up interval, no additional tracking by Quality, Safety and Value staff was planned.[15]

The Chief of Quality, Safety and Value explained that in those cases, the patient's clinical provider would be managing the patient's ongoing care, and if subsequent health developments occurred that the clinical provider determined were relevant to the previous misdiagnosis, the

[15] An example provided would be a case where the Clinical Review Team recommended the patient have a follow-up esophagogastroduodenoscopy in five years instead of 10 years. Johns Hopkins Medicine, *Esophagogastroduodenoscopy (EGD)*, accessed March 29, 2021, https://www.hopkinsmedicine.org/gastroenterology_hepatology/clinical_services/basic_endoscopy/esophagogastroduodenoscopy.html. An EGD is an endoscopic procedure used to evaluate a number of digestive disorders, that allows examination of the esophagus, stomach, and part of the small intestine.

onus would be on the clinical provider to communicate the need for additional review to determine if an institutional disclosure would then be warranted. The OIG determined there was no clearly defined process for clinical providers to alert the Clinical Review Team if later changes in a patient's health status during the course of continuing care might indicate reconsideration of the need for institutional disclosure.

Clinical Disclosures

While the facility had an adequate process in place for completion of clinical disclosures, the OIG determined there was room for improvement in the facility's process for tracking the completion of the clinical disclosures.

VHA policy indicates that, in cases where a secondary or subsequent pathology review identifies a significant change in diagnosis that would affect the patient's treatment, the patient's physician or an appropriate clinical staff provider is notified of the change, and takes action to contact the patient and revise or amend the patient's treatment.[16] VHA policy does not require specific documentation in the EHR for all clinical disclosures, but stipulates the clinical disclosure should be documented when harm is more than minor.[17]

The facility's Chief of Quality, Safety and Value shared that documentation by the clinical providers involved in the notifications for patients varied. While the facility's processes satisfied VHA policy, the inconsistencies in the manner of documenting the clinical disclosures created challenges for the facility's Quality, Safety and Value staff in tracking and confirming completion of the clinical disclosures.

The OIG's analysis of facility documentation indicated the Clinical Review Team recommended clinical disclosures for 520 of the 589 level 3 cases.[18] Additionally, the Clinical Review Team identified 41 of the 2,440 level 2 cases for clinical disclosure. Given the number of patients affected, tracking clinical disclosures to completion presented a unique demand for oversight of the facility's responses to the results of the look-back review.

The facility's Chief of Quality, Safety and Value and the facility's Risk Manager described the process for initiating clinical disclosures:

[16] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016.

[17] VHA Handbook 1004.08, 2012; VHA Directive 1004.08, 2018.

[18] As noted above, institutional disclosures were provided to 31 of the 589 patients with level 3 determinations. Disclosures for the remaining 38 level 3 cases are discussed below.

- The facility's Chief of Quality, Safety and Value placed an administrative note in the patient's EHR, which documented that the Clinical Review Team had reviewed the case and determined that a clinical disclosure was needed.
- The administrative note included the corrected diagnosis from the look-back review master spreadsheet and any notes from the Clinical Review Team meeting regarding additional recommendations for follow-up care.
- The Chief of Quality, Safety and Value designated a provider in the appropriate clinical specialty as a signer to alert the provider to the note and corresponding need for action.

The Chief of Quality, Safety and Value acknowledged that the facility's process did not include tracking the completion of clinical disclosures beyond the step of alerting clinical providers. A more consistent process involving communication from clinical providers back to the Chief of Quality, Safety and Value to verify completion of the clinical disclosures would have assisted the facility in monitoring progress. As noted above, the magnitude of reviews and need for the facility to respond to the many identified cases introduced greater oversight concerns related to tracking the disclosure process to ensure appropriate actions were taken.

The OIG reviewed the facility's documentation of the Clinical Review Team determinations, and found that, while there were some inconsistencies in ability to track completion as noted by the Chief of Quality, Safety and Value, the facility made efforts to confirm completion of the clinical disclosures. Based on the documentation available in the spreadsheet maintained by the facility's Chief of Quality, Safety and Value for the Clinical Review Team meetings, completion of 76.5 percent of the clinical disclosures was confirmed, primarily through direct discussion with the patient or family, though a small percentage were completed via letter or secure messaging. The OIG team reviewed EHRs for documentation of clinical disclosure in a small sample of randomly selected cases marked as completed by the facility. The OIG's review verified the reported completion of a clinical disclosure in each of those cases.

Table 1 provides an overview of the facility's documented progress on completion of the 561 clinical disclosures for level 2 and level 3 cases.

Table 1. Status of Clinical Disclosure Completion

Status of Clinical Disclosure Completion	# Cases (Total=561)	Percentage (%)
Clinical disclosure was completed with patient or family or both	386	68.8
Clinical disclosure information was sent to patient or family or both via letter or secure messaging	43	7.7
Unable to determine status of clinical disclosure completion based on available documentation	76	13.5
Facility was unable to contact the patient or family or both to complete a clinical disclosure	38	6.8
No documentation of clinical disclosure action taken	13	2.3
Other	5	0.9

Source: OIG analysis of facility documentation.

Clinical disclosures are typically performed by a patient's clinician as part of routine clinical care, and occur as soon as reasonably possible, generally within 24 hours of the occurrence.[19] As the look-back review encompassed all of Dr. Levy's cases that he interpreted between September 2005 and October 2017, the errors in question often occurred years prior to the review and subsequent clinical disclosures. This may have presented additional challenges for the facility in completing clinical disclosures, such as patients who were since deceased, and patients or next of kin whose contact information had changed.

Level 3 Cases with No Disclosures Warranted

The OIG's analysis of the facility documentation noted 29 level 3 cases for which neither a clinical nor institutional disclosure was determined to be warranted, and an additional nine level 3 cases for which a determination regarding necessary disclosures was not documented. Rationales documented from the Clinical Review Team for not providing disclosure indicated that clinical review found the errors had resulted in no harm or impact on patient care. Examples included cases in which the diagnostic discrepancy was recognized during prior reviews allowing correction of the diagnosis and discussion with the patient in real time, or cases where the correct diagnosis was identified during the course of a patient's continuing medical care and treatment adjusted as needed prior to an adverse impact. Examples also included cases in which a patient was deceased from causes unrelated to the condition involving the pathology reading error. The Clinical Review Team leader described ethical

[19] VHA Directive 1004.08, 2012; VHA Handbook 1004.08, 2018. A clinical disclosure is "appropriate for all adverse events that cause only minor harm to the patient, except those minor harms that are discovered after the patient has completed the associated episode of care and that have no implications for the patient's future health. A clinical disclosure is also appropriate for more serious adverse events as the appropriate first step in a process that may ultimately require an institutional or large-scale disclosure."

concerns in some cases involving decedents. The team wanted to be transparent but also wished to be sensitive to family's feelings after some families indicated during clinical disclosure notifications that the contact brought up painful feelings related to their loss when the reported error had no impact on the deceased patient's care.

Notification Letters for Level 2 Cases

With the exception of the 44 level 2 cases noted above that were determined to warrant institutional or clinical disclosures, the facility's Risk Manager reported that patients with level 2 pathology reading errors were sent a second letter as a follow-up, advising them of the look-back review findings. The follow-up letter conveyed that the pathology look-back review team had completed a secondary review of the patient's pathology reading and advised that the pathologist performing the secondary review "determined that there was a disagreement in the diagnosis, however, there is no negative clinical impact on [the patient's] care." The letter also offered a contact number in case of further questions.

2. Amendment of EHR Documentation

The OIG determined that the facility had not completed its proposed plan for amending the pathology reports in the EHRs of all patients with diagnostic errors identified during the look-back review. While the look-back review coordinator entered modified pathology reports into the EHR for cases identified with level 3 diagnostic errors, the amendment of EHRs for cases with level 2 diagnostic errors was to be completed by the facility, and was largely unfinished at the time of the OIG inspection.

VHA policy for Path and Lab specifies that when errors are identified in test results that have been released, the report must be corrected in the patient EHR.[20] Both the original and corrected reports become parts of the patient's permanent EHR. Facility policy established guidance for amendment of the record via a modified pathology report in cases when the amendment documents a clinically significant change in diagnosis that would affect the patient's care and via a supplemental pathology report in cases where the amendment did not change the diagnosis in a way that would affect the patient's treatment.[21]

[20] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures,* January 29, 2016.

[21] Veterans Health Care System of the Ozarks, Pathology and Laboratory Medicine Service Procedure 206-A, *Anatomic Pathology Supplemental and Modified Reports*, August 24, 2016. Supplemental pathology reports are issued when there is additional information relevant to a previously signed report which "does not change the diagnosis in a way that would impact the patient's treatment." Supplemental pathology reports do not require notification to the patient's provider, though the provider may be alerted to the supplemental report.

Modified Pathology Reports for Level 3 Pathology Reading Errors

The look-back review coordinator advised the OIG that the amendment of EHR documentation for patients with level 3 diagnostic errors was completed during the look-back review.

Because the scope of the look-back review was too large to be accommodated by a single institution, pathologists from various facilities within VHA and outside of VHA assisted with conducting the look-back reviews for the nearly 34,000 cases. The look-back review coordinator indicated that non-VHA pathologists and pathologists at other VHA sites did not have access to the computerized patient record system at the facility to enter amendments in the EHR for patients at the facility. The look-back review coordinator also noted the intent to minimize administrative duties such as report entry and maximize use of the reviewing pathologists' specialty skill set in reading the pathology specimens. The look-back review coordinator additionally offered that completion of the modified pathology reports for level 3 cases was consolidated to ensure review and concurrence.

The look-back review coordinator indicated that, as the pathologists conducting the look-back reviews confirmed level 3 cases, those cases were sent to the look-back review coordinator, who entered the modified pathology reports in the EHR based on the diagnoses identified by the reviewing pathologists. The look-back review coordinator described documenting the initial review and second confirmation read, noting the pathologists and institutions conducting those reads, and confirming the signatures of the reviewing pathologists.[22] While the look-back review coordinator who entered the modified report in the EHR signed off on the report, the modified report itself specifically mentioned that the signing pathologist was transcribing the report for those pathologists who completed the review of the pathology specimens and established the diagnosis as documented in the modified report.

The pathologist who led the look-back review confirmed that the EHRs had been amended to correct diagnoses for 588 out of 589 level 3 cases. The look-back review coordinator noted that one level 3 case was identified for which a modified pathology report had not been completed because of inability to locate the slide needed for the secondary review to confirm the modified diagnosis. The look-back review coordinator indicated they were trying to locate the slide, and once located, the modified report would be completed, or if unable to locate the slide, a unique modified report would be entered based on the single read and a clinical review.

[22] Verification of signature could utilize a handwritten wet signature, scanned copy of handwritten signature, or electronic signature created by use of the signing provider's personal identity verification card.

Modified Pathology Reports for Select Technically Complicated Level 2 Pathology Reading Errors

While amendment of the EHRs for level 2 cases was outside the scope of the look-back review, the look-back review coordinator noted a small number of level 2 cases that were marked as technically complicated. The look-back review coordinator completed a modified pathology report in the EHR for those cases to ensure the concern was documented for the patients' clinical providers, estimating a total of 20 to 30 such cases.

Supplemental Pathology Reports for Level 2 Pathology Reading Errors

The OIG confirmed that amendment of EHR documentation for patients with level 2 diagnostic errors fell within the facility's purview, and facility documents showed fewer than 5 percent of supplemental pathology reports had been completed for level 2 cases at the time of the OIG inspection. However, during the course of the inspection, the look-back review coordinator and the VISN 16 Chief Medical Officer leading the Clinical Review Team informed the OIG that the completion of amended pathology reports for all level 2 cases was not required under VHA policy and that the facility had been advised accordingly. The OIG team conferred with a leader within the VHA Path and Lab National Program Office who further confirmed those opinions.[23] The OIG noted an apparent misalignment between national program office expectations and wording of VHA policy regarding the need to correct a released patient pathology report in the EHR when errors were identified.[24]

Despite the guidance regarding amended reports noted above, the facility's Chief of Quality, Safety and Value indicated having concerns about the absence of amended pathology reports for the level 2 cases, echoed by the facility's Risk Manager, following the Clinical Review Team's identification of some level 2 cases that required clinical disclosures. The Chief of Quality, Safety and Value described the corresponding need to alert clinical providers to the changes in diagnosis for those patients and recommendations for follow-up care in absence of an amended pathology report, and noted Quality, Safety and Value staff were placed in an awkward position of needing to convey updated diagnostic information that would not be reflected in the EHR.

The Chief of Quality, Safety and Value opined that relying on a process that expected clinical providers to contact Quality, Safety and Value staff about a patient with a level 2 diagnostic error

[23] The VHA Path and Lab National Program Office leader had served as a subject matter expert for the CERT.

[24] The OIG did not offer a recommendation on this issue due to an open recommendation from a prior OIG report that "[T]he Under Secretary for Health evaluates Veterans Health Administration guidance related to amended pathology reports' terminology, use, and entry of such reports into patients' electronic health records, and revises guidance, as appropriate." VA OIG, *Pathology Oversight Failures at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas*, Report No. 18-02496-157, June 2, 2021, https://www.va.gov/oig/pubs/VAOIG-18-02496-157.pdf.

should a future concern arise related to the error "didn't seem like a reasonable process." The lack of an amended report also left the medical record incomplete from a quality perspective. The facility developed a plan to enter supplemental pathology reports for level 2 cases.

The OIG determined that the facility's plan to amend the pathology reports for patients with level 2 errors was in alignment with the wording of VHA policy (to correct released reports that had errors) and the use of supplemental reports for those amendments was consistent with facility policy.

The Chief of Quality, Safety and Value described that when Dr. Levy's successor (Chief of Pathology) was hired, they discussed the look-back review and the concerns regarding amended pathology reports for the level 2 cases. The Chief of Pathology agreed to take on the administrative role of entering supplemental pathology reports for the level 2 cases.

While the facility was advised that completion of amended pathology reports for all level 2 cases was not a policy requirement, the facility committed to this plan of action but subsequently struggled with implementing and completing that plan. At the time of the OIG site visit, the spreadsheets that the facility's Risk Manager used to track the process showed supplemental pathology reports had been entered into EHRs for fewer than 5 percent of the level 2 cases.[25]

Delays Entering Supplemental Pathology Reports into Patient EHRs

The primary causes for delays in completion of the supplemental pathology reports for level 2 cases included problems encountered during the Chief of Pathology's verification process for the supplemental pathology reports, communication lapses that hampered the resolution of some identified concerns, and limited staffing resources to complete the retrospective task while attending to the ongoing demands of the current Path and Lab workload.

Pathologist Verification Process

VHA policy states "[o]nly qualified, licensed, and locally privileged pathologists" may write pathology reports in the EHR.[26] VHA, VISN, and facility level pathologist subject matter experts confirmed that a pathologist must sign the supplemental pathology reports in the EHR. In this case where the signing pathologist is entering the supplemental report, but did not complete the review, signature also indicates verification of the transcription.

The look-back review was conducted by non-facility pathologists who did not have ready access to the EHRs of facility patients. Instead, the non-facility pathologists completed and signed Case

[25] The original look-back review results identified 2,440 cases with level 2 errors. The Risk Manager's binder of spreadsheets for supplemental pathology reports contained 2430 cases with Level 2 errors. The discrepancy in numbers was explained by the exclusion of nine autopsy cases with Level 2 errors, and minor updates to the look-back review master spreadsheets that were not reflected in the printed binders.

[26] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016.

Review and Assessment Forms (review forms) that outlined their findings. For reviews conducted on-site, the hard-copy review forms were stored in binders at the facility. Hard-copy review forms for assessment conducted at other sites were stored elsewhere.

In May 2020, the Chief of Pathology outlined a process for completion of level 2 supplemental pathology reports, which was shared with the Director of Quality, Safety and Value, the Risk Manager, and the Laboratory Quality Manager. The process included review of the original look-back pathologists' signed hard-copy review forms, check of the handwritten comments against the transcribed comments (the master spreadsheet), confirmation of the look-back pathologist's signature, and utilization of the original pathology report in the EHR for the diagnostic section of the supplemental report. The Risk Manager concurred with the Chief of Pathology's proposed process. Once the plan was established, the Chief of Pathology began the process of entering supplemental pathology reports into patients' EHRs using standardized language to indicate the diagnosis was formulated by the look-back pathologist. The Chief of Quality, Safety and Value reported that the Office of General Counsel was consulted due to liability concerns to ensure the language reflected the Chief of Pathology was entering supplemental reports in an administrative capacity only, as the Chief of Pathology had no direct involvement in the look-back review.

As the Chief of Pathology proceeded with the work of entering supplemental pathology reports, concerns arose during the verification process. The Chief of Pathology indicated the pathologist-signed review forms were necessary to verify the transcription and signatures to enter supplemental pathology reports, as detailed in the process described above. The Laboratory Quality Manager further confirmed that review of the look-back pathologists' signatures on their new diagnoses was required for the release of amended reports into the EHR. The Chief of Pathology reported receiving 650 of the look-back pathologists signed review forms. Upon inquiry about the review forms for the rest of the level 2 cases, the Chief of Quality, Safety and Value and the facility Risk Manager, advised that they did not have copies of those original review forms for the approximately 1,800 remaining level 2 cases. The facility only had possession of some of the original look-back pathologists' signed review forms, those completed on-site.

Later, the Risk Manager reported a process change intended to reduce the administrative burden for the Chief of Pathology, however, the modified process failed to address the concern identified by the Chief of Pathology. The Risk Manager described preparing supplemental pathology reports by transcribing information from the look-back review master spreadsheet using the format identified for the supplemental reports. The Risk Manager confirmed the case identifiers, copied and pasted the erroneous pathologist's report content from the original note in the EHR, and transcribed the new modified diagnosis with the name of the pathologist reviewing the case from the look-back review master spreadsheet. The Risk Manager's process did not reference copies of the original signed look-back review pathologists' review forms. The Risk

Manager saved the prepared reports to a shared drive with the plan that the Chief of Pathology could copy and paste those prepared documents to the EHR to reduce the time the process required.

The Risk Manager noted starting this process for the level 2 cases completed by on-site look-back reviewers and available signed review forms. The process was expanded to cases done by off-site reviewers without signed review forms. The Risk Manager thought that the off-site reviewers' signed review forms were not necessary as the look-back review spreadsheet, that the look-back team considered to be the official review document, was available.

The Risk Manager's use of the master spreadsheet to confirm off-site reviewers' findings did not resolve the Chief of Pathology concerns related to the unavailability of the signed review forms. The OIG's review of documentation provided by the Risk Manager tracking completion of the level 2 supplemental reports observed 1,273 cases marked as administratively prepared, but not yet completed by a pathologist.

Communication Deficits

The OIG determined that deficits in communication exacerbated the challenges and contributed to the facility's EHR amendment process stalling when concerns could not be resolved timely. The OIG's discussions with key staff involved in the look-back review and the facility's follow-up efforts highlighted differences in understanding about the quality assurance processes put in place for the original look-back review as well as differences in opinions regarding the requirements for completion of amended pathology reports based on the look-back review.

The following examples reflect deficits in communication affecting the facility's process for completion of the supplemental pathology reports for level 2 cases:

> *Example 1*
>
> *The Chief of Pathology explained that the signature of the pathologist who completed the reading and provided the diagnosis is an essential part of a pathology report, and the signature renders the report an official, legal document. VHA policy requirements for pathology reports also describe that any modification or supplemental addition to a pathology report must clearly indicate the person responsible for the modification.[27] The Chief of Pathology further explained that when a pathologist enters a supplemental report in an administrative capacity for the pathologist who performed the reading, signature on the supplemental report reflects verification of the original pathologist's signature and accurate representation of the original pathologist's review.*

[27] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016.

Verification of signature and transcription from the original look-back pathologists' signed review forms was outlined in the original plan for completion of the supplemental pathology reports offered by the Chief of Pathology to the facility's Chief of Quality, Safety and Value and Risk Manager, and confirmed with the Quality Manager of the Lab. However, during the OIG's review, the Risk Manager confirmed the facility only had possession of the pathologists' original signed review forms for cases that were read on-site at the facility. Cases read at other facilities were stored elsewhere and had never been in the facility's possession. When the Chief of Pathology conveyed concerns about the need for the original review forms, both the facility Chief of Quality, Safety and Value and Risk Manager reported belief that the process could be completed using only the master spreadsheet, since that was understood to be the legal, official record, though it did not contain the signatures for verification. During discussion with the OIG, both the Chief of Quality, Safety and Vale and the Risk Manager indicated uncertainty regarding the Chief of Pathology's verification methods.

During the OIG inspection, the look-back review coordinator indicated that pathologists' signatures were verified during the process of transcription from the review forms into the master spreadsheet, and that with quality assurance processes in place, repeated verification to the original review sheet should not be required. The look-back review coordinator also confirmed that the facility only had the original signed review forms for those cases that were read on-site at the facility by contracted non-VHA pathologists. However, as previously noted, the look-back review did not include a plan for entry of amended pathology reports for level 2 cases. With the facility's decision to complete such reports, the Chief of Pathology, who was not involved in the look-back review or familiar with all the quality assurance processes employed during the look-back review, was asked to perform this function.

The OIG team opined that in this situation and in absence of official legal counsel otherwise, the expectation by the Chief of Pathology, an independently licensed provider, that professional standards as outlined in policy must be observed as a condition of signing off on the supplemental reports is understandable.

Example 2

During the process of confirming the transcription for the supplemental pathology reports against the look-back pathologists signed review forms and checking signatures, the Chief of Pathology noted some transcription errors on the look-back review master spreadsheet. Concerns about transcription errors reinforced the Chief of Pathology's perception that verification of the transcription from signed review forms when another pathologist administratively

enters an amended report was a required step. The OIG interviewed the former VHA Path and Lab National Program Office National Director who agreed with the Chief of Pathology interpretation. Additionally, despite the quality assurance measures used during the look-back review team's compilation of the master spreadsheet, the look-back review coordinator acknowledged transcription errors were possible given the magnitude of the review.

Example 3

The process change noted above, wherein the facility's Risk Manager assumed the administrative tasks associated with preparing the supplemental reports occurred in fall 2020 while the Chief of Pathology was absent. A lack of communication prior to initiating the process change precluded discussion of how the new process would be of limited utility due to failure to address the verification concerns for the off-site pathologists' review forms.

Thus, the OIG concluded that, in light of the processes during the look-back review, discrepancies in understanding and unresolved questions regarding the verification requirements affected the process for completion of supplemental pathology reports, and communication issues hampered resolution of those concerns.

Pathologist Staffing

The facility's Path and Lab experienced significant staff turnover subsequent to the investigation of Dr. Levy's criminal malpractice. The Chief of Pathology described that upon onboarding at the facility and assuming the role of service chief in September 2019, significant work was identified to clean up laboratory processes as a legacy of Dr. Levy's tenure as former Chief. The Chief of Pathology reported discussing with facility leaders the inability to focus on both the look-back and the changes needed internally within the laboratory; however, agreed to enter supplemental pathology reports for the level 2 cases, concurring that should be done to correct the patients' EHRs.

Subsequently, reductions in pathologist staffing resources within Path and Lab were identified as a barrier to completing the supplemental pathology reports, with available staff needing to prioritize the laboratory workload. The Facility Director described efforts to increase pathologist staffing at the facility in the wake of the concerns identified about Dr. Levy. The Facility Director also reported that Path and Lab had approved increased staffing to four full-time pathologists, one of whom served as the chief of the service; however, the service had been operating below the approved target staffing level since January 2020.

The Chief of Pathology reported that concerns about performance issues resulted in one pathologist being summarily suspended from clinical duties in February 2020. At the time of the OIG inspection, that provider remained reassigned to non-clinical duties and no further personnel actions had been taken. Human Resources staff indicated the case was still in process and a

determination was pending.[28] The Chief of Pathology noted that the practical impact of this situation was that one of the pathologist positions allocated to the department had been occupied by a provider without clinical privileges for 13 months, leaving the service short-staffed. Additional staffing challenges occurred in late 2020 to early 2021, when significant health concerns necessitated extended absences for two other pathologists. The cumulative impact was such that a contracted locum tenens pathologist, who had previously retired in summer 2020, came out of retirement and returned to the facility to assist.

Figure 1 displays facility pathologist staff resources for the time frame September 2019 through March 2021.

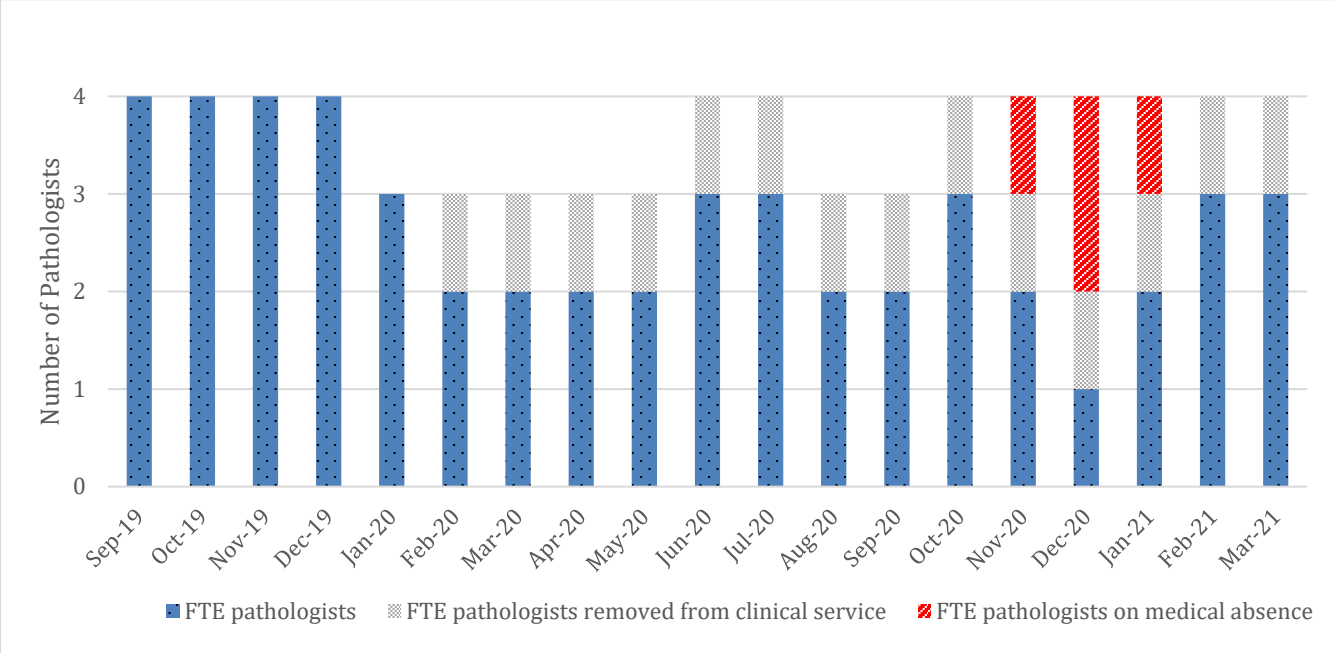

Figure 1. Facility pathologist full-time employee equivalent (FTE) staffing September 2019–March 2021.
Source: VA OIG analysis of data provided by facility Human Resources.

The Facility Director noted that as of March 2021, the facility was in the process of recruiting an additional pathologist, but a date for that provider's onboarding was not yet available as additional information was required to complete credentialing and privileging.

[28] The OIG reviewed Human Resources documents for this case and confirmed that facility leaders acted quickly to remove the provider from clinical duties after concerns regarding performance were identified. The OIG confirmed that the case remained under review as of March 2021 and offers no further comment related to this personnel matter.

Conclusion

The OIG determined that the facility's processes for patient notification, including institutional and clinical disclosures, met VHA policy requirements. However, opportunities existed for improvement related to tracking the completion of clinical disclosures.

From June 2018 through March 2020, the facility completed the necessary institutional disclosures for 28 of the 34 cases identified by the Clinical Review Team. The six remaining cases were not conducted due to inability to contact the patient or family, refusal of the meeting by the patient or family, or repeated failure of the patient to attend the scheduled disclosure meeting. The OIG determined that the facility made reasonable efforts to conduct those disclosures.

The Clinical Review Team recommended clinical disclosures for a total of 561 cases. The OIG's analysis of facility documentation confirmed completion of 76.5 percent of the clinical disclosures. The extended time frame since the events under review may have presented additional challenges for the facility in completing some clinical disclosures, such as patients identified for clinical disclosure who were deceased, and patients or next of kin whose contact information had changed.

VHA policy does not require specific documentation in the EHR for all clinical disclosures. However, the magnitude of the look-back review and need for the facility to respond to the many identified cases introduced greater oversight concerns related to tracking the disclosure process to ensure appropriate actions were taken. Additionally, the OIG found that a more consistent process involving communication from clinical providers back to the Chief of Quality, Safety and Value to verify completion of the clinical disclosures would have assisted the facility in monitoring progress.

The OIG determined that the facility had not completed its proposed plan for amending pathology reports in the EHRs of all patients with diagnostic errors identified during the look-back review. Modified pathology reports were entered into EHRs for cases identified with level 3 diagnostic errors by the look-back review coordinator. The facility was tasked with amendment of EHRs for cases with level 2 diagnostic errors and that process was largely unfinished at the time of this OIG review.

The look-back review coordinator and the VISN 16 Chief Medical Officer leading the Clinical Review Team informed the OIG that the completion of amended pathology reports for every level 2 case was not required under VHA policy, and that the facility had been advised accordingly. The OIG team conferred with a leader within the VHA Path and Lab National Program Office who further confirmed those opinions. The OIG noted an apparent misalignment

between national program office expectations and wording of VHA policy regarding the need to correct a released patient pathology report in the EHR when errors were identified.[29]

Despite the guidance regarding amended reports, the facility initiated a plan to enter supplemental pathology reports for the level 2 cases due to facility staff concerns that updated diagnostic information needed to be available to clinical providers. The OIG determined that the facility's plan to amend the pathology reports for patients with level 2 errors was in alignment with the wording of VHA policy, and the use of supplemental reports for those amendments was consistent with facility policy. Facility documents showed fewer than 5 percent of the supplemental pathology reports had been completed for the 2,440 level 2 cases at the time of the OIG's site visit.

The primary causes for delays in completion of the supplemental pathology reports for level 2 cases included problems encountered during the Chief of Pathology's verification process for the supplemental pathology reports, communication lapses which hampered the resolution of some identified concerns, and limited staffing resources to complete the retrospective task while attending to the ongoing demands of the current Path and Lab workload.

Recommendations 1–3

1. The Under Secretary for Health clarifies the extent and content of documentation that should be included when circumstances require that a clinical disclosure be entered into the electronic health record. [30]
2. The Under Secretary for Health evaluates whether there should be a process for clinical provider(s) to communicate back to the Clinical Review Team when changes in patient health status indicate the need for consideration of institutional disclosures, and takes action as warranted.
3. The Veterans Health Care System of the Ozarks Director implements a plan for completion of amended pathology reports for cases identified with level 2 pathology reading errors that is consistent with VHA Handbook 1106.01.

[29] The OIG did not offer a recommendation on this issue due to an open recommendation from a prior OIG report that "[T]he Under Secretary for Health evaluates Veterans Health Administration guidance related to amended pathology reports' terminology, use, and entry of such reports into patients' electronic health records, and revises guidance, as appropriate." VA OIG, *Pathology Oversight Failures at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas*, Report No. 18-02496-157, June 2, 2021, https://www.va.gov/oig/pubs/VAOIG-18-02496-157.pdf.

[30] Recommendations addressed to the Under Secretary for Health were submitted to the Deputy to the Deputy Under Secretary for Health, performing the delegable duties of the Under Secretary for Health.

Appendix A: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: August 24, 2021

From: Deputy to the Deputy Under Secretary for Health, Performing the Delegable Duties of the Under Secretary for Health, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, Facility Leaders' Response to Level 2 and Level 3 Pathology Reading Errors at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas (VIEWS 5599556)

To: Director, Office of Healthcare Inspections (54HL04)

1. Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) subject draft report. The Veterans Health Administration (VHA) concurs with recommendations 1 and 2 and provides the attached action plan.
2. The Veterans Health Care System of the Ozarks Director provides a response to recommendation 3.
3. VHA takes these recommendations seriously and has committed to improvement opportunities to strengthen internal clinical disclosure procedures and improve communication pathways between physicians and the Clinical Review Team.
4. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at VHA10BGOALACTION@va.gov.

(*Original signed by:*)

Steven L. Lieberman, M.D.

Deputy to the Deputy Under Secretary for Health, Performing the Delegable Duties of the Under Secretary for Health Response

VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan
Facility Leaders' Response to Level 2 and Level 3 Pathology Reading Errors at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas

Recommendation 1. The Under Secretary for Health clarifies the extent and content of documentation that should be included when circumstances require that a clinical disclosure be entered into the electronic health record.

VHA Comments: Concur. The VHA National Center for Ethics in Health Care and the Office of Quality and Patient Safety will distribute a joint memo to reinforce to VHA clinicians the ethical responsibility to share clinical information with the patient, or personal representative, about an adverse event that occurred during clinical care. This clinical information is to be documented in a manner that reflects generally accepted medical record documentation practices and standards. The memo will also remind clinicians about the Talent Management System (TMS) training module available on this topic.

Status: In progress Target Completion Date: September 2021

Recommendation 2. The Under Secretary for Health evaluates whether there should be a process for clinical provider(s) to communicate back to the Clinical Review Team when changes in patient health status indicate the need for consideration of institutional disclosures, and takes action as warranted.

VHA Comments: Concur. The VHA Office of Assistant Under Secretary for Clinical Services under the leadership of its Clinical Episode Review Team (CERT) will establish formal guidance for clinical providers to enable communication back to the CERT Office when changes in patient health status indicate the need for consideration of institutional disclosures. Formal guidance will be disseminated nationally via official memorandum after collaborative evaluation with operational core CERT working partners comprising, but not limited to National Ethics, Diagnostics, and the field working group of Chief Medical Officers, Quality Management Officers, and Chief Nursing Officers.

Status: In progress Target Completion Date: December 2021

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: July 28, 2021

From: Director, South Central VA Health Care Network (10N16)

Subj: Healthcare Inspection—Facility Leaders' Response to Level 2 and Level 3 Pathology Reading Errors at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas

To: Under Secretary for Health (10)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. The South Central VA Health Care Network has reviewed and concurs with the actions submitted by the Veterans Health Care System of the Ozarks, Fayetteville, AR, in response to the facility specific recommendation in the Facility Leaders' Response to Level 2 and Level 3 Pathology Reading Errors Draft Report
2. If you have additional questions or need more information, please call 601-206-6900.

(*Original signed by*:)

Skye McDougall, PhD

Appendix C: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: July 27, 2021

From: Acting Medical Center Director, Veterans Health Care System of the Ozarks (564)

Subj: Healthcare Inspection—Facility Leaders' Response to Level 2 and Level 3 Pathology Reading Errors at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas

To: Director, South Central VA Health Care Network (10N16)

1. I have reviewed the draft report for the Veterans Health Care System of the Ozarks and concur with the report, conclusions rendered, and the recommendations.
2. Please express my thanks to the team for their professionalism and assistance to us in our continuing efforts to improve the care we provide to our Veterans.

(*Original signed by*:)

Stephanie Repasky, PsyD
Acting Medical Center Director

Facility Director Response

Recommendation 3

The Veterans Health Care System of the Ozarks Director implements a plan for completion of amended pathology reports for cases identified with level 2 pathology reading errors which is consistent with VHA Handbook 1106.01.

Concur.

Target date for completion: April 30, 2022

Director Comments

The Veterans Health Care System of the Ozarks will continue amending pathology reports for cases identified with level 2 pathology reading errors in alignment with VHA Handbook 1106.01. To assist with expediting this process, the Medical Center Director will realign additional resources to assist with this until completed.

Glossary

To go back, press "alt" and "left arrow" keys.

adverse event. An untoward diagnostic or therapeutic incident, iatrogenic injury, or other occurrence of harm or potential harm directly associated with care or services delivered by VA providers.[1]

clinical disclosure. A process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the patient's care.[2]

clinical episode review team (CERT). A multidisciplinary group convened by the Deputy Under Secretary for Health for Operations and Management to conduct a "coordinated triage process for review of each potential adverse event that may require large-scale disclosure." The CERT consults with subject matter experts to review and discuss the issues and makes a recommendation regarding disclosure.[3]

institutional disclosure. A formal process by which VA medical facility leader(s), together with clinicians and others as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse.[4]

large-scale disclosure. A formal process by which VHA officials assist with coordinating the notification to multiple patients, or their personal representatives, that they may have been affected by an adverse event resulting from a systems issue.[5]

locum tenens. A medical practitioner who temporarily takes the place of another.[6]

look-back. A type of review. According to VHA policy, "A look-back is an organized process for identifying patients or staff with exposure to potential risk incurred through past clinical activities, with the explicit intent to notify them and offer care and recourse, as appropriate."[7]

---

[1] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

[2] VHA Directive 1004.08, 2018.

[3] VHA Directive 1004.08, 2018; VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2012. The 2012 handbook refers to the CERT team as a Subject Matter Expert panel.

[4] VHA Directive 1004.08, 2018.

[5] VHA Directive 1004.08, 2018.

[6] Merriam-Webster Medical Dictionary, *Medical Definition of locum tenens*, accessed March 31, 2021 https://www.merriam-webster.com/dictionary/locum%20tenens#medicalDictionary.

[7] VHA Directive 1004.08, 2018; VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2012. The handbook and directive contain the same language related to epidemiological investigation and look-back reviews.

major diagnostic discrepancies. Disagreements between pathologists about the interpretation of a specimen. A major diagnostic discrepancy has the potential for negative impact on patient care or treatment.[8]

modified pathology report. A modified pathology report is issued when there is "a clinically significant change in the diagnosis" that requires notification to the patient's provider.[9]

pathologist. A medical healthcare provider who assists other healthcare providers diagnose medical conditions by examining body tissues and performing lab tests.[10]

pathology report. A medical report written by a pathologist about a piece of tissue, blood, or body organ, following analysis of the specimen, which is used by other healthcare providers "to determine a diagnosis or treatment plan for a specific condition or disease."[11]

[8] Fayetteville Pathology and Lab Provider Look-Back Review Action Plan—Standard Quality Review Process and Categories. This is an internal document and not accessible to the public.

[9] Health Care System of the Ozarks, Pathology & Laboratory Medicine, *Supplemental & Modified Reports*, version HT 2016-08, 2016.

[10] Johns Hopkins Medicine, *The Pathologist*, accessed March 25, 2021, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/the-pathologist.

[11] Johns Hopkins Medicine, *The Pathology Report*, accessed March 25, 2021, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/the-pathology-report.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Inspection Team	Clarissa Reynolds, NHA, MBA, Director Jennifer Baptiste, MD Jennifer Broach, PhD Tanya Oberle, LCSW, MSW Andy Waghorn, JD
Other Contributors	Kathy Gudgell, RN, JD Jeanne Martin, PharmD Robyn Stober, JD, MBA April Terenzi, BA, BS

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, South Central VA Health Care Network (10N16)
Director, Veterans Health Care System of the Ozarks (564)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and 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:
  Arkansas: John Boozman, Tom Cotton
  Missouri: Roy Blunt, Josh Hawley
  Oklahoma: Jim Inhofe, James Lankford
U.S. House of Representatives:
  Arkansas: Rick Crawford, French Hill, Bruce Westerman, Steve Womack
  Missouri: Billy Long
  Oklahoma: Markwayne Mullin