

DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Radiology Concerns at the VA Illiana Health Care
System

Danville, Illinois



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of Senator Tammy Duckworth in June 2018 on behalf of a constituent to assess concerns regarding the appropriateness of facility leaders' response to incorrectly interpreted imaging studies (radiologic errors) by a staff radiologist (radiologist) at the VA Illiana Health Care System (facility), Danville, Illinois. The names of four patients were included as evidence of radiologic errors that resulted in treatment delays, sentinel events, and failure by facility leaders to appropriately disclose. The OIG reviewed the four patients' electronic health records, determined there were no concerns with the care of one patient, and submitted the remaining three patient names to the facility for review on July 19, 2018. Based on the OIG's interpretation of Veterans Health Administration policy, one of the three patients met criteria for institutional disclosure. Specifically, a radiologic error contributed to a five-month delay in cancer diagnosis. The patient subsequently died while undergoing cancer treatment.

As a result of the OIG inquiry, facility leaders were alerted to the radiologist's potential interpretation errors and conducted a review, with Veterans Integrated Service Network (VISN) and National Teleradiology Program (NTP) assistance, of 198 exams read by the radiologist.⁴ The radiologist's reading error rate was 16.7 percent (33 of 198 exams), which exceeded the nationally accepted five percent error rate.⁵ None of the 33 patients' cases met Veterans Health Administration criteria for required institutional disclosure. An expanded review of the radiologist's 3,484 exams ensued, was completed on September 29, 2019, and identified a

¹ Radiologic errors refer to instances where a reviewer determines that a radiologist made a mistake, such as an interpretive error, diagnostic error, documentation error, or inappropriate recommendations.

² VHA defines a sentinel event as a specific type of adverse event that causes death or disability and leads to prolonged hospitalization. In this report, the OIG uses the term adverse event to describe radiologic errors.

³ In addition to the radiologic error, the patient was examined four times by three providers, including two examinations by an Ear, Nose, and Throat physician over a five-month period. These providers failed to associate the patient's signs and symptoms with the cancer diagnosis which contributed to the delay in diagnosis and treatment.

⁴ In consultation with the Acting NTP Director, the facility selected 100 CT and 100 MRI imaging studies from April 1 through September 30, 2018, for review. Two of the randomly selected imaging studies were removed from the study because they did not meet criteria for evaluation.

⁵ VA NTP offers secure, remote radiology procedure interpretations in VA facilities where sufficient radiology coverage is unavailable. The National Guidelines for Radiology Professional Competency state that five percent or less may be deemed an acceptable error rate depending on the seriousness of the error. If a specific pattern of errors or particularly egregious errors are detected, the service chief may elect to initiate a Focused Professional Practice Evaluation for cause. Itri, Jason, Tappouri, Rafel, McEachern, Rachel, Pesch, Arthur, Patel Sohil. "Fundamentals of Diagnostic Error in Imaging," *Radiographics*, 2018; 38:1845–1865. The worldwide radiologic error rate averages from three to five percent.

12.94 percent radiological error rate. As of December 5, 2019, facility leaders conducted four institutional disclosures, with two additional cases pending further review by facility clinicians to determine if institutional disclosure is warranted.

Given that radiological error rates exceeded the national level, the OIG determined that facility leaders, in consultation with VISN leaders and the NTP director, should evaluate additional steps required, including large-scale disclosure and reporting to outside agencies, as indicated.⁶

During its inspection, the OIG team determined that the Radiology Service lacked an effective early detection and identification process for radiologic errors. However, once errors were identified in the NTP review, VISN and facility leaders took appropriate actions.

The former Chief of Radiology did not have a Radiology Service quality monitoring or reporting process. The ongoing professional practice evaluation (OPPE) process was also flawed as the evaluations completed by the former Chief of Radiology did not identify concerns affecting the radiologist's reprivileging. Prior to 2017, facility policy required service chiefs to complete semi-annual OPPE provider reviews but did not define the sample size of imaging studies required for review. The radiologist interpreted (read) an average of 8,122 exams in a six-month period, with an average of 44 exams (0.5 percent) reviewed for OPPE. The former Chief of Radiology rated the radiologist's overall OPPEs as satisfactory from October 2015 through December 2017. Although the OPPE sample size was compliant with facility policy, it was insufficient to adequately assess the radiologist's performance.⁷

In October 2017, the National Radiology Program Office (NRPO) developed guidelines for facility leaders to assess radiologists' clinical competence. These guidelines include

- A minimum of two percent of a radiologist's exams are reviewed for a semi-annual OPPE;
- The reviewed radiologist's exams reflect a random sample of all modalities the radiologist interprets; and
- A review is conducted, by external reviewers if needed, to ensure objectivity.

The NRPO guidelines recommend a larger review sample size than facility policy and an external reviewer; however, the guidelines do not consider the different modalities and complexities of exams reviewed. Since radiologic exams vary in complexity and risk to patients,

⁶ Facility leaders informed the OIG, while on-site, that NTP-assisted reviews were also completed on the former Chief of Radiology that resulted in error rates lower than the nationally accepted level.

⁷ The radiologist was employed at the facility from January 25, 2015, until January 21, 2019. The former Chief of Radiology was employed from October 4, 2015, until December 28, 2017, and served as the radiologist's supervisor the entire time. As of July 2018, facility policy recommended a minimum of 10 patient charts reviewed in a six-month OPPE review period.

a risk stratification methodology of radiologic exams is necessary to further and better inform the OPPE process. ⁸

The OIG team reviewed the November 2016 to November 2018 Professional Standards Board minutes and found no documented concerns at the time of reprivileging related to the radiologist. The radiologist was reprivileged on November 1, 2018, summarily suspended on November 26, 2018, due to the 16.7 percent error rate, and then terminated from the facility.⁹

The OIG made six recommendations with one recommendation to the Under Secretary for Health regarding guidelines to better inform radiologists' professional practice evaluations, and one recommendation to the VISN Director regarding continued oversight of the facility's response to NTP findings. Four recommendations were made to the Facility Director related to appropriate patient follow-up including completion of disclosures to the patients or families as warranted; development of a Radiology Service quality assurance and performance plan; consideration for radiologist competency reviews based on VA's National Guidelines for Radiology Professional Competency; and evaluation of the National Teleradiology Program final findings to determine what additional steps are required.¹⁰

⁸ Risk stratification is a process of assigning a risk status to and dividing patient cases into groups of similar complexity levels. http://www.nachc.org/wp-content/uploads/2019/03/Risk-Stratification-Action-Guide-Mar-2019.pdf. (The website was accessed on February 6, 2020.) Without a risk-based random sampling of cases reviewed by an expert opinion, it's unreasonable to expect the OPPE process to provide comprehensive evaluation of radiologists.

⁹ A provider's privileges may be summarily suspended, pending comprehensive review and due process, when the failure to take such action could result in imminent danger to the health of any individual. Facility leaders reported the radiologist to the appropriate State Licensing Boards.

¹⁰ The recommendation directed to the Under Secretary for Health was submitted to the Executive in Charge who has the authority to perform the functions and duties of the Under Secretary for Health.

Comments

The Under Secretary for Health and the Veterans Integrated Service Network and Facility Directors concurred with the recommendations (see appendixes B, C, and D). The OIG considers all recommendations open and will follow up on the planned and recently implemented actions to ensure that they have been effective and sustained.¹¹

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¹¹ Given VA's need to focus on the COVID-19 response, the OIG developed interim measures for the release of oversight reports. Accordingly, this report's release was delayed. At the time this report was scheduled for release, the OIG was generally disseminating only those reports that were relevant to the COVID-19 pandemic, statutorily required, or that involved compelling circumstances related to the welfare of veterans, the safety of patients and VA personnel, or significant risk to VA resources.

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Abbreviations

CT computed tomography

EHR electronic health record

MRI magnetic resonance imaging

NRPO National Radiology Program Office

NTP National Teleradiology Program

OIG Office of Inspector General

OPPE ongoing professional practice evaluation

VHA Veterans Health Administration

VISN Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of Senator Tammy Duckworth in June 2018 on behalf of a constituent. The OIG assessed concerns regarding the appropriateness of facility leaders' response to incorrectly interpreted imaging studies (radiologic errors) by a staff radiologist (radiologist) at the VA Illiana Health Care System (facility), Danville, Illinois.¹

Background

The facility is part of Veterans Integrated Service Network (VISN) 12 and is designated as a Complexity Model Level 3, with services available to more than 150,000 veterans from a 34-county area in central Illinois.² The facility's imaging service provides <u>computed tomography</u> (CT) and <u>magnetic resonance imaging</u> (MRI). A total of 28,278 imaging studies were performed in fiscal year 2018. <u>The imaging service</u> (radiology) is authorized three full-time radiologists; however, at the time of the OIG site visit, there was only one full-time staff radiologist supplemented by two part-time contracted radiologists.³ The <u>National Teleradiology Program</u> (NTP) also provided the facility with remote radiology procedure interpretations.

Request for Review

The request from Senator Duckworth included the names of four patients as evidence of incorrect interpretations (radiologic errors) by the radiologist that resulted in treatment delays, sentinel events, and failure to appropriately disclose by facility leaders.⁴ The OIG reviewed the

¹ For this report, the term, imaging studies, refers to exams performed to produce pictures of the inside of a patient's body. Healthcare providers use the results of imaging studies to treat illness or injuries. https://www.myhealth.va.gov/mhv-portal-web/my-healthevet-va-radiology. (The website was accessed on May 30, 2019). Radiologic errors refer to instances where a reviewer determines that a radiologist made a mistake, such as an interpretive error, diagnostic error, documentation error, or inappropriate recommendations. *The Concept of Error and Malpractice in Radiology*, Semin Ultrasound CT MRI 33 (2012): 275–279.

² The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity levels include 1–3, with level 1a facilities being the most complex and level 3 facilities being the least complex.

³ The facility's current Chief of Radiology assumed the position in February 2018. The former Chief of Radiology was employed with the facility from October 4, 2015, through December 28, 2017. Under 38 U.S.C. § 7405(a)(2), the VHA employs medical and non-medical consultants on a contract to provide services within a VHA medical facility. https://www.govinfo.gov/app/details/USCODE-2010-title38/USCODE-2010-title38-partV-chap74-subchapI-sec7405. (The website was accessed on December 2, 2019).

⁴ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. This handbook was in effect during the timeframe discussed in this report. This handbook 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 and define a sentinel event as a specific type of adverse event that causes death or disability and leads to prolonged hospitalization. In this report, the OIG uses the term adverse event to describe radiologic errors.

electronic health records (EHRs) of the four patients and determined that for one patient, the imaging results/interpretations error was not likely a factor in the patient's death that occurred several months after the imaging study at issue and other intervening events. The names of the other three patients were sent to the facility for review. Facility leaders did not identify radiologic errors and took no further action in one of the three cases. Additionally, facility leaders stated they were unaware of two of the three cases and thus had not reviewed for possible facility-level action. Since the OIG identified the possibility of a radiologic error in all three patient cases, facility leaders were prompted to conduct an external review of these additional two cases. In all three patient cases, an external review was either completed previously or after OIG contact.

The OIG corresponded with facility leaders over the next eight months. The facility identified concerns and expanded its review of the radiologist's interpretations.

On February 21, 2019, the OIG opened a hotline inspection to evaluate the following concerns:

- Facility leaders' responses including the three patients' case reviews and the expanded NTP reviews.
- Radiology Service oversight including quality monitoring processes.

Scope and Methodology

The OIG team initiated the inspection on February 21, 2019, and conducted a site visit the week of April 8, 2019.

The OIG team interviewed the current and former facility radiology staff and managers including the radiologist and former Chief of Radiology, Risk Manager, Patient Safety Manager, and other staff knowledgeable about the concerns under review; current and former facility and VISN leaders; and the Acting Director of the NTP.

The OIG reviewed Veterans Health Administration (VHA) and facility policies and procedures, EHRs, quality management documents, pertinent committee meeting minutes, and other relevant documents. The OIG also reviewed the facility's two expanded reviews of the radiologist's imaging studies. Additionally, electronic communications exchanged among facility leaders, quality management, and radiology staff during the review period were evaluated to gain insight into concerns that VISN and facility leaders were aware and did not respond to the radiologist's incorrect interpretations of imaging studies.⁵

⁵ During the site visit, facility leaders informed the OIG that NTP-assisted reviews were also completed on the former Chief of Radiology. The OIG expanded the scope of this inspection to include these additional reviews and concluded that the former Chief of Radiology's error rates were within acceptable standards.

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

The OIG 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. Facility Leaders' Response

The OIG determined that once the concerns regarding the possible radiologic errors were identified, facility leaders took appropriate actions in reviewing the three patients' cases. However, the OIG review identified a radiologic error from one of these cases that met VHA criteria for <u>institutional disclosure</u> that facility leaders had not disclosed.⁶ The OIG inquiry prompted VISN and facility leaders to contact the NTP that resulted in the initiation of a review of 198 of the radiologist's interpretations and subsequently, an expanded NTP review of over 3.400 cases.⁷

According to VHA policy, facility leaders may take actions including management reviews or peer reviews for quality management purposes. Management and peer reviews are to evaluate the performance of professionals in the healthcare setting. VHA policy recommends the use of outside/external peer reviews when an appropriate peer reviewer is not available at the facility. 10

VHA policy requires that if, during any of these reviews, an <u>adverse event</u> was harmful or potentially harmful and meets the criteria for disclosure, that facility leaders are required to

⁶ VHA Handbook 1004.08. VHA Directive 1004.08.

⁷ In consultation with the Acting NTP Director, the facility selected 100 CT and 100 MRI imaging studies from April 1 through September 30, 2018, for review. Two of the randomly selected imaging studies were eliminated because they did not meet criteria for evaluation.

⁸ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. This directive was in effect during the timeframe of the reviews in this report; it was rescinded and replaced by VHA Directive 1190, *Peer Review for Quality Management*, *November 21*, 2018. The 2010 and the 2018 directives contain the same or similar language to define management and peer reviews. Facility leaders referred to management reviews as administrative reviews. Within the context of the report, the OIG considers the two terms synonymous.

⁹ VHA Directive 2010-025. VHA Directive 1190.

¹⁰ VHA Directive 2010-025. VHA Directive 1190.

ensure the patient's clinical care needs are met and inform the patient of the error as appropriate through disclosure.¹¹

Three Patient Cases

The OIG submitted the three patient cases with concerns for radiologic errors to the facility for review. The facility identified a radiologic error in one of the three cases.

The OIG determined that facility leaders appropriately reviewed the three patients' cases; however, the OIG disagreed with facility leaders' determination that an institutional disclosure was not needed for one of the three patients. Based on the OIG's interpretation of VHA policy, one of the three patients met criteria for institutional disclosure due to a radiologic error that contributed to a five-month delay in treatment. The patient subsequently died with metastatic cancer. As of January 2, 2020, the OIG confirmed that the patient's EHR does not contain evidence of completion of an institutional disclosure.

NTP Review

In October 2017, the VA NRPO released guidelines indicating that if the total number of significant errors is equal to or greater than five percent of reviewed cases, a review of a larger sample of the physician's work should be considered. In instances where a radiologist's error rate exceeds five percent, facility leaders should consider a focused review. The review should include recent imaging studies and expand incrementally until discrepancies and performance are within acceptable standards, or less than five percent.¹³ After initial imaging studies are complete, and if a radiologic error is found, patient notification must be completed when clinically indicated, and subsequent clinical actions must be documented in the EHR.¹⁴

VISN and facility leaders requested an NTP-assisted initial review of the radiologist on October 24, 2018. To avoid patient safety issues, the radiologist was summarily suspended pending the review. In consultation with the Acting NTP Director, the facility selected 100 CT and 100 MRI imaging studies from April 1 through September 30, 2018, for review. NTP radiologists completed the review of 198 imaging studies and the results were forwarded to the facility on December 6. Review findings identified 33 of the 198 imaging studies (16.7 percent)

¹¹ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This handbook expired in March 2016 and has not been recertified or replaced. VHA Handbook 1004.08. Adverse events are defined as "untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered."

¹² See appendix A for this patient's case summary.

¹³ National Guidelines for Radiology Professional Competency.

¹⁴ VHA National Radiology Program Office, *Radiology Online Guide*. A dictated radiology report is considered acceptable for "routine communication" of imaging results to ordering providers.

¹⁵ Two of the randomly selected imaging studies were eliminated because they did not meet criteria for evaluation.

were radiologic errors. Facility staff developed a monitoring tool which captured findings from the NTP review and tracked actions taken for the radiologic errors. The Chief of Staff reviewed and updated the 33 patient EHRs with an addendum that noted the radiologic errors. The patient cases were referred to two designated facility primary care providers to determine if a patient required additional follow-up with the assigned primary care provider. The primary care providers evaluated all assigned patients to identify outstanding clinical needs and take action as indicated. The OIG confirmed facility actions were taken to include documentation of the radiologic error in patient EHRs and follow-up was established with the assigned primary care provider, when necessary. None of the 33 patients with radiologic errors identified by the NTP review met criteria for institutional disclosure.

NTP Expanded Review

As a result of the 16.7 percent radiologic error rate, VISN and facility leaders, in consultation with the Acting NTP Director, further expanded the review of the radiologist's imaging studies to include readings performed from April 1 through November 30, 2018, yielding 3,484 additional CT and MRI imaging studies.

A primary care provider and a physician's assistant reviewed each NTP-completed patient case and updated the EHR with an addendum noting identified radiologic errors with the comments provided by the NTP. The reviewers used the same process as the first NTP-assisted review and completed the task in September 2019. As of December 5, 2019, facility leaders conducted four institutional disclosures, with two additional cases pending further review by facility clinicians to determine whether an institutional disclosure is warranted.

The NTP expanded review revealed a calculated radiological error rate of 12.94 percent. As this radiological error rate also exceeded the national level, the OIG determined that the facility, in consultation with VISN leaders and the NTP director, should evaluate what additional steps are required, including large-scale disclosure and reporting to outside agencies, as indicated.¹⁶

2. Radiology Service Oversight

The OIG found that the former Chief of Radiology did not have a Radiology Service quality monitoring process and the <u>ongoing professional practice evaluations</u> (OPPE) completed by the former Chief of Radiology was not aware and did not identify concerns affecting the radiologist's <u>reprivileging</u>.¹⁷

¹⁶ Outside agencies would include state licensing boards and the National Practitioner Data Bank.

¹⁷ The review, conducted by NTP, identified errors that were not identified by the Chief of Radiology's OPPE process.

According to facility policy, Radiology Service was responsible for the development and implementation of a quality assurance and performance plan to establish performance improvement goals and to provide an opportunity for processes improvement and identification of clinical issues. ¹⁸ VHA policy requires that providers be evaluated through OPPE processes to assess proficiency in several areas of general competency including patient care, procedural skills, and medical/clinical knowledge. ¹⁹ Facility policy stated that the <u>Professional Standards</u> <u>Board</u> members review privileging and OPPE documents to make decisions regarding provider reprivileging. ²⁰

The OIG found that Radiology Service managers had not developed or implemented the required quality assurance and performance plan to establish Radiology Service performance improvement goals. The plan would have set performance improvement goals, and an opportunity for improvement of processes that could have identified clinical issues, such as radiologic errors, during the period under review. The former Chief of Radiology stated that as a new employee to VHA with competing demands, his attention was focused primarily on supervisory issues.

The OIG also found that the former Chief of Radiology rated the radiologist's overall OPPEs as satisfactory from October 2015 through December 2017.²¹ Prior to 2017, facility policy required service chiefs to complete semi-annual OPPE provider reviews but did not define the sample size of imaging studies required for review. The radiologist read an average of 8,122 exams in a six-month period, with an average of 44 exams (0.5 percent) reviewed for OPPE. Although the OPPE sample size was compliant with facility policy, it was insufficient to adequately assess the radiologist's performance.

In October 2017, the NRPO developed guidelines for facility leaders to assess radiologists' clinical competence and better inform the professional practice evaluation. These guidelines include

¹⁸ Facility Memorandum 00-03, Organizational Performance/Quality Management Program, September 2016.

¹⁹ VHA Directive 2010.025, *Peer Review for Quality Management*, June 03, 2010, was in effect during part of the time frame of the events discussed in this report; it was rescinded and replaced by VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. The two policies contain the same or similar language related to OPPE.

²⁰ Facility Memorandum 11-20, *Executive Committee for the Medical Staff*, February 2013. The 2013 memorandum was replaced by Facility Memorandum 11-20, *Professional Standards Board*, June 2016. The two policies contain the same or similar language related to provider reprivileging and covered the timeframe of the radiologist's employment at the facility.

²¹ The radiologist was employed at the facility from January 25, 2015, until January 21, 2019. The former Chief of Radiology was employed from October 4, 2015, until December 28, 2017, and served as the radiologist's supervisor the entire time.

- A minimum of two percent of the radiologist's exams are reviewed for a semi-annual OPPE;
- The reviewed radiologist's exams reflect a random sample of all modalities the radiologist interprets; and
- A review is conducted, by external reviewers if needed, to ensure objectivity.

The NRPO guidelines recommend a larger review sample size than facility policy and an external reviewer; however, the guidelines do not consider the different modalities and complexities of exams reviewed. Since radiologic exams vary in complexity and risk to patients, a <u>risk stratification</u> methodology of radiologic exams is necessary to further and better inform the OPPE process.²²

During an interview with the former Chief of Radiology, the OIG team discussed the radiologist's OPPE results to clarify why clinical concerns were not documented on the overall summary. The former Chief stated that leaders were aware of past significant clinical concerns related to the radiologist; however, was unable to provide documentation to support this statement. When interviewed, the radiologist stated he was overtasked and struggling to manage his workload; he reported his concerns to facility leaders but was unable to provide evidence to support this claim.

The OIG team reviewed Professional Standards Board November 2016 to November 2018 minutes and found no documented concerns at the time of reprivileging related to the radiologist. On November 1, 2018, the radiologist had been reprivileged, summarily suspended on November 26, and then terminated.²³ The supervisory oversight through the OPPE process did not identify concerns involving radiologic errors that was not consistent with the NTP review reflecting a high radiologic error rate.

Conclusion

The OIG determined that there were no concerns with the care of one out of four patients received with Senator Duckworth's request for review and submitted the remaining three names to the facility for review. Based on the OIG's interpretation of VHA policy, one of the three patients met criteria for institutional disclosure due to a radiologic error that contributed to a five-month delay in cancer treatment. Facility leaders were alerted to the radiologist's potential interpretation errors by the OIG and conducted a review, with VISN and NTP assistance, of 198 exams read by the radiologist. The radiologist's reading error rate was 16.7 percent (33 of

²² As of July 2018, facility policy recommended a minimum of 10 patient charts reviewed in a six-month OPPE review period. Without a risk-based random sampling of cases reviewed by an expert opinion, it's unreasonable to expect the OPPE process to provide comprehensive evaluation of radiologists.

²³ Facility leaders reported the radiologist to the appropriate State Licensing Boards.

198 exams) exceeding the nationally accepted five percent error rate. None of the 33 patients' cases met VHA criteria for required institutional disclosure.

An expanded review of the radiologist's 3,484 exams ensued, was completed on September 29, 2019, and identified a 12.94 percent radiological error rate. As of December 5, 2019, facility leaders conducted four institutional disclosures, with two additional cases pending further review by facility clinicians to determine if an institutional disclosure is warranted. As a result of the radiological error rates that exceeded the national level, the OIG determined that facility leaders, in consultation with VISN leaders and the NTP director, should evaluate what additional steps are required, including large-scale disclosure and reporting to outside agencies, as indicated.

The OIG concluded that Radiology Service lacked an effective early detection and identification process for radiologic errors. However, once radiologic errors were identified in the NTP review, VISN and facility leaders took appropriate actions.

The former Chief of Radiology did not have a Radiology Service quality monitoring or reporting process. The OPPE process was flawed as the evaluations completed by the former Chief of Radiology did not identify concerns affecting the radiologist's reprivileging. The sample size of exams reviewed by the former Chief of Radiology for the OPPE process was insufficient to adequately assess the radiologist's performance; and the sample size did not consider the different modalities and complexities of exams reviewed. In October 2017, the NRPO developed guidelines for facility leaders to assess radiologists' clinical competence and better inform the professional practice evaluation. These guidelines include a minimum of two percent of the radiologist's exams are reviewed for a semi-annual OPPE; the reviewed radiologist's exams reflect a random sample of all modalities the radiologist interprets; and a review is conducted, by external reviewers if needed, to ensure objectivity. Since radiologic exams vary in complexity and risk to patients, a risk stratification methodology is necessary to further and better inform the OPPE process.

The former Chief of Radiology rated the radiologist's overall OPPEs as satisfactory from October 2015 through December 2017. The OIG team reviewed the November 2016 to November 2018 Professional Standards Board minutes and found no documented concerns at the time of reprivileging related to the radiologist. The radiologist had been reprivileged on November 1, 2018, summarily suspended on November 26, 2018, due to the 16.7 percent error rate, and then terminated from the facility.

Recommendations 1–6

- 1. The Under Secretary for Health adopts the National Radiology Program Office established guidelines and confers with the National Radiology Program Office to develop and incorporate a risk stratification methodology of the random sample of imaging modalities reviewed, to better inform radiologists' professional practice evaluations.²⁴
- 2. The Veterans Integrated Service Network Director provides continued oversight of the National Teleradiology Program expanded review results, ensures an appropriate response from VA Illiana Health Care System, and takes actions, as indicated.
- 3. The VA Illiana Health Care System Director verifies that appropriate patient follow-up occurs, disclosures are conducted for events that meet disclosure criteria, and compliance with Veterans Health Administration policy is monitored.
- 4. The VA Illiana Health Care System Director ensures the Radiology Service follows VA Illiana Health Care System policy to develop and implement a quality assurance and performance plan and monitors for compliance.
- 5. The VA Illiana Health Care System Director considers following the National Guidelines for Radiology Professional Competency for radiologist competency reviews.
- 6. The VA Illiana Health Care System Director evaluates the final findings of the National Teleradiology Program review to determine what additional steps are required, including large-scale disclosure and reporting to outside agencies.

²⁴ The recommendation directed to the Under Secretary for Health was submitted to the Executive in Charge who has the authority to perform the functions and duties of the Under Secretary for Health.

Appendix A: Patient Case Summary

The patient was a 54-year-old man with throat pain. He had a medical history significant for chronic obstructive pulmonary disease, smoking, and chronic abdominal scar tissue pain requiring treatment with narcotic analgesics.²⁵

The patient first reported throat pain in fall 2015. A VA primary care physician ordered bacterial pharyngitis testing that was negative.²⁶ The patient was treated symptomatically and given instructions to call or return to clinic if experiencing persistent or worsening symptoms.

In early 2016, the patient returned to the primary care clinic with complaints of one to two weeks of throat pain and left-sided neck swelling and tenderness. On examination, the primary care physician noted swelling in the patient's left jaw. The patient was prescribed an oral antibiotic.

Later that month, the patient returned to see the primary care physician with complaints of no improvement in the throat pain. On examination, the primary care physician documented left-sided lymph node swelling in the neck. The primary care physician ordered a CT scan of the neck and sinuses. At the patient's request, a medication to treat gastroesophageal reflux disease was ordered as a trial for the throat pain.²⁷

Two days later, a CT scan of the neck and sinuses was performed. The radiologist reported the results:

There are no abnormal enhancing masses.

Impression:

Mild left mastoiditis.

No significant lymphadenopathy.²⁸

The primary care clinic nurse notified the patient of the CT scan results the same day. The primary care physician ordered a different antibiotic and entered a consult to the VA Ear, Nose, and Throat (ENT) service for further evaluation.

²⁵ Chronic obstructive pulmonary disease is a disease of the lungs that causes chronic non-reversible airway obstruction when exhaling air. This interferes with normal breathing.

²⁶ Bacterial pharyngitis is throat inflammation caused by bacterial infection.

²⁷ Gastroesophageal reflux disease refers to stomach acid flowing backwards, or "refluxing," into the tube connecting the mouth and stomach (esophagus). This backflow, or acid reflux, may irritate the lining of the esophagus.

²⁸ This is an excerpt of the 2016 computed tomography scan report. It was shortened to include the critical sections that are directly quoted from the report. Mastoiditis is inflammation and infection in the mastoid bone that is located behind the ear. Lymphadenopathy is an enlargement of lymph nodes.

The next month, an ENT physician evaluated the patient for complaints of left ear pain and sore throat. Despite taking the gastroesophageal reflux disease medication, the patient also complained of pain with swallowing, difficulty swallowing, and a seven-pound weight loss. On physical examination, the ENT physician documented normal ears, neck, and throat with no enlarged lymph nodes. There was tenderness over the left neck and jaw (temporomandibular) joint. A fiberoptic scope examination was performed in the clinic and showed redness and edema (swelling) in the patient's throat. The ENT physician diagnosed the patient with laryngeal pharyngeal reflux/gastroesophageal reflux disease and referred left ear pain.²⁹ The physician recommended an increase in the patient's anti-reflux medication, prescribed ibuprofen, and recommended lifestyle changes.

Two months later at an ENT clinic follow-up appointment, the ENT physician noted the patient's left ear pain was improved, but the patient had continued gastroesophageal reflux disease. The ENT physician recorded a normal examination and entered a consult to the gastroenterology service for evaluation of the patient's gastroesophageal reflux disease. The non-VA gastroenterology consult evaluation took place approximately six weeks later, with a recommendation for a procedure to better evaluate the gastroesophageal reflux disease.

Almost a month later, the patient arrived at the primary care clinic with worsening throat pain over the previous month. He also complained of lumps on both sides of the neck. The primary care physician ordered a repeat CT scan of the neck that was completed four days later. The CT scan showed the following:

Technique: ...compared with previous neck CT examination from [early] 2016.

Report: Since the previous exam, lymphadenopathy has progressed extensively with bilateral necrotizing lymph nodes...³⁰

Impression:

Extensive necrotizing lymphadenopathy in both sides of the neck, left greater than right with extensive infiltrative appearing changes in the epiglottic and aryepiglottic regions with significant airway compromise possibly present.³¹ Findings are concerning for malignant process,

²⁹ Laryngeal pharyngeal reflux is caused by stomach acid traveling up the esophagus and into the throat. This causes irritation of the throat and larynx (voice box). http://uthscsa.edu/oto/lpr.asp. (The website was accessed on April 30, 2019.) Referred pain is a pain that is subjectively felt in one area of the body due to irritation in another area. https://www.merriam-webster.com/medical/referred%20pain. (The website was accessed on May 23, 2019.)

³⁰ Bilateral means both sides. Necrotizing is the process of localized death of cells or tissue. https://www.merriam-webster.com/dictionary/necrosis#medicalDictionary. (The website was accessed on April 30, 2019.)

³¹ The epiglottic and aryepiglottic regions are parts of the larynx. The larynx is also known as the voice box and keeps food and liquid from entering the trachea (tube to the lungs).

although infectious or inflammatory lymphadenopathy could potentially have a similar appearance.³²

Upon reviewing the CT scan findings, the primary care physician sent the patient to the facility's urgent care clinic for evaluation. The urgent care physician documented the patient was not in distress nor short of breath. Although the physician documented enlarged neck lymph nodes, the patient's lungs were clear on examination. The urgent care physician consulted the on-call ENT physician for the patient to be evaluated in the ENT clinic the next day.

The patient presented to the ENT clinic for further evaluation of the neck masses identified the day before. He admitted to difficulty swallowing, painful swallowing, 15-pound unintentional weight loss, and a 30 plus pack-year smoking history. The ENT physician documented that the previous day's CT scan showed "bilateral necrotic [lymph nodes] and likely left pyriform sinus mass." Physical examination revealed enlarged lymph nodes on both sides of the neck with the left nodes approximately three to four centimeters in diameter. After an informed consent was obtained, a biopsy was performed of one lymph node. The ENT physician discussed with the patient a possible preliminary diagnosis of squamous cell cancer. An appointment for a positron emission tomography/CT scan and an ENT follow-up appointment were scheduled for one week. A consult referral was made to palliative care.

The day after the biopsy, the lymph node biopsy pathology result confirmed a diagnosis of metastatic squamous cell carcinoma (also known as squamous cell cancer).

In late May, the patient underwent positron emission tomography/CT scanning. Findings included a significant mass lesion involving the left base of the tongue, epiglottis, left pyriform sinus, and vocal cords. Additional findings included significant cervical (neck) lymph nodes most consistent with metastatic [lymph] nodal disease and a left mid-femoral (thigh) lesion, "most consistent with an osseous [bone] metastatic lesion."

In early summer 2016, the patient was seen by the palliative care service in its clinic for the diagnosis of metastatic squamous cell cancer. The patient was given information on support and other aspects of care. The patient was seen for a follow-up appointment the same day in the ENT clinic where the positron emission tomography/CT results were discussed. A plan was made for biopsy of the lesion in the left femur. The ENT physician explained to the patient that a metastatic lesion in the femur may alter future therapy options.

Approximately two weeks later, the patient underwent a biopsy of the left femur lesion that returned results of metastatic squamous cell cancer.

³² This is a shortened version of the second 2016 CT scan report. It was shortened to include the critical sections that are directly quoted from the report. Malignant is a term that describes cancer.

³³ The pyriform sinus is a pear-shaped area that is located to the side and behind the larynx (voice box) opening on both sides. https://radiopaedia.org/articles/pyriform-sinus?lang=us. (The website was accessed on May 9, 2019.)

One week later, the ENT physician presented the patient's case at a multidisciplinary conference to review and discuss the patient's care options. The conference determined that per National Comprehensive Cancer Network guidelines for definitive (curative) treatment, the patient would need the femur lesion removed by the orthopedic service. If the femur lesion was not resectable, the patient would receive palliative care.

About a week later, the patient saw a palliative care physician in a follow-up clinic visit. During the appointment, the patient's treatment options were discussed, and the patient chose not to pursue treatment of the thigh lesion or other aggressive treatments.

Due to increasing difficulty breathing, a month later, the patient saw the ENT physician for evaluation for a palliative tracheostomy.³⁴ During the ENT clinic visit, the ENT physician discussed with the patient that there was a

... series of missed opportunities for early diagnosis (CT [computed tomography] scan in [early 2016] which was incorrectly read as negative, ENT appts [appointments] where abnormality were [sic] not found). It is unclear whether earlier diagnosis/treatment would have prevented femur metastasis.

The ENT physician admitted the patient to the hospital the same day for observation and planned a palliative tracheostomy. Two days later, the patient had a palliative tracheostomy performed. The patient's hospital course was complicated by multiple medical problems including pneumonia/pneumonitis, atrial fibrillation, and increased oxygen requirements, all due to the underlying cancer and baseline medical condition.

Over the course of the hospital stay, the patient's clinical condition deteriorated. The patient also experienced reduced mental alertness and subsequently died.

³⁴ A tracheostomy is a surgically created hole (stoma) in the windpipe (trachea) that provides an alternative airway for breathing. A tracheostomy tube is inserted through the hole and secured in place with a strap around the neck. https://www.mayoclinic.org/tests-procedures/tracheostomy/about/pac-20384673. (The website was accessed on May 22, 2019.)

Appendix B: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: March 13, 2020

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

Subj: OIG Draft Report, Healthcare Inspection - Radiology Concerns at the VA Illiana Health Care

System, Danville, Illinois (VIEWS 02523002)

To: Assistant Inspector General for Healthcare Inspections (54)

 Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report, Healthcare Inspection - Radiology Concerns at the VA Illiana Health Care System, Danville, Illinois.

- 2. The Veterans Health Administration (VHA) agrees with the need to ensure VHA's correct interpretation of imaging studies and the ability to assess any risks to Veterans. There are six total recommendations, one to the Under Secretary for Health, one to the Veterans Integrated Service Network Director, and four to the Facility Director. An action plan has been developed to address all six of OIG's recommendations. I've also included General and Technical comments from the program office.
- 3. If you have any questions, please email Mark E. Scherber, Deputy Director, GAO- OIG Accountability Liaison at VHA10EGGOALAction@va.gov.

(Original signed by:) Richard A. Stone, M.D. Attachments

Executive in Charge Response

Recommendation 1

The Under Secretary for Health adopts the National Radiology Program Office established guidelines and confers with the National Radiology Program Office to develop and incorporate a risk stratification methodology of the random sample of imaging modalities reviewed, to better inform radiologists' professional practice evaluations.

Concur.

Target date for completion: August 2020

Executive in Charge Comments

Concur.

Existing guidelines for radiology professional competency referenced in this report were developed by the National Radiology Program Office. These guidelines will be revised to incorporate a risk stratification methodology that augments the random sampling process, allowing facilities to better evaluate radiologists' professional competence in imaging modalities of varying complexity.

Appendix C: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: March 4, 2020

From: Network Director, VA Great Lakes Health Care System (10N12)

Subj: Healthcare Inspection—Radiology Concerns at the VA Illiana Health Care System, Danville,

Illinois

To: Director, Office of Healthcare Inspections (54HL03)

Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Healthcare Inspection- Radiology Concerns at the VA Illiana Health Care System, Danville, Illinois.

- 2. Regarding recommendation 2, the Veterans Integrated Service Network Director provided oversight of the National Teleradiology Program expanded review results, which ensured appropriate timely follow-up from VA Illiana Health Care System with Veterans requiring follow-up. VISN provides continual support and oversight to ensure strong practices are sustained and that appropriate actions are taken.
- 3. The VISN 12 Quality Management Officer can be contacted at 708-492-3900, if there are additional questions or if further clarification is needed.¹

(Original signed by:)
Victoria P. Brahm, MSN, RN, VHA-CM
Network Director, VA Great Lakes Health Care System (10N12)

¹ For privacy, the phone extension was changed for this report.

VISN Director Response

Recommendation 2

The Veterans Integrated Service Network Director provides continued oversight of the National Teleradiology Program expanded review results, ensures an appropriate response from VA Illiana Health Care System, and takes action, as indicated.

Concur.

Target date for completion: Complete

Director Comments

The Veterans Integrated Service Network (VISN) Director provided oversight of the National Teleradiology Program expanded review of all 3,484 cases. All appropriate actions, including clinical and institutional disclosures were completed with monthly VISN oversight. On February 3, 2020, the VISN 12 Chief Medical Officer, in addition to other VISN 12 Leadership and VA Illiana Health Care System Leadership, completed a final Clinical Episode Response Team (CERT) call with the Office of the Assistant Deputy Under Secretary for Health for Clinical Operations. There is one patient remaining that has a procedure pending that must be completed before a determination can be made if a disclosure will be indicated. The VISN 12 Network Director, in conjunction with other VISN 12 Leadership, will follow this patient until this determination can be completed.

OIG Comment

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

Appendix D: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: February 26, 2020

From: Director, VA Illiana Health Care System (550/00)

Subj: Healthcare Inspection—Radiology Concerns at the VA Illiana Health Care System, Danville,

Illinois

To: Director, VA Great Lakes Health Care System (10N12)

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Healthcare Inspection, Radiology Concerns at the VA Illiana Health Care System, Danville, Illinois.

- 2. I have reviewed and concur with the recommendations; however, I disagree with the allegation that the facility failed to complete an institutional disclosure. Facility leadership in collaboration with Veteran Integrated Service Network (VISN) leadership discussed this case and determined that an institutional disclosure was not warranted. Although the Computer Tomography (CT) was deemed negative by the radiologist, appropriate clinical follow-up was initiated by the primary provider with a referral to Ear, Nose and Throat (ENT). The clinical disclosure was completed by ENT physician from the Richard L Roudebush VA Medical Center, Indianapolis, IN. The provider documented disclosure to the patient regarding the incorrect interpretation of the CT Scan from [early] 2016. The provider stated that it was unclear if earlier diagnosis would have prevented metastasis. The patient chose not to proceed with treatment of the thigh lesion or other aggressive treatments.
- 3. VA Illiana Health Care System is committed to providing exceptional care and has implemented all of the recommendations.
- 4. If additional information is needed, please contact my office at (217) 554-3000.1

(Original signed by:)
Shawn M. Bransky
Medical Center Director

¹ For privacy, the phone extension was changed for this report.

Facility Director Response

Recommendation 3

The VA Illiana Health Care System Director verifies that appropriate patient follow-up occurs, disclosures are conducted for events that meet disclosure criteria, and compliance with Veterans Health Administration policy is monitored.

Concur.

Target date for completion: Complete

Director Comments

VA Illiana Health Care System has completed all follow-up on the radiology look back. Appropriate clinical disclosures have been completed; one potential institutional disclosure remains and is awaiting results of a biopsy.

VA Illiana Health Care System has verified that appropriate patient follow-up occurs, and disclosures are conducted when events that meet disclosure criteria are identified. These are tracked and trended through the quarterly report to Veterans Integrated Service Network.

OIG Comment

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

Recommendation 4

The VA Illiana Health Care System Director ensures the Radiology Service follows VA Illiana Health Care System policy to develop and implement a quality assurance and performance plan and monitors for compliance.

Concur.

Target date for completion: Complete

Director Comments

VA Illiana Health Care System has implemented a Radiology Quality Improvement Committee. This is a reoccurring monthly meeting and reports up to the Clinical Executive Board.

OIG Comment

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

Recommendation 5

The VA Illiana Health Care System Director considers following the National Guidelines for Radiology Professional Competency for radiologist competency reviews.

Concur.

Target date for completion: Complete

Director Comments

National Radiology Program Office provided the professional competency guidelines in October 2018, these were implemented at the next Ongoing Professional Practice Evaluation for Radiologists in March 2019.

OIG Comment

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

Recommendation 6

The VA Illiana Health Care System Director evaluates the final findings of the National Teleradiology Program review to determine what additional steps are required, including large-scale disclosure and reporting to outside agencies.

Concur.

Target date for completion: Complete

Director Comments

VA Illiana Health Care System Leadership discussed the final findings on the National Clinical Episode Response Team (CERT) call, and it was determined that a large-scale disclosure was not indicated, but rather individual clinical or institutional disclosures were to be completed (as

indicated). The CERT has closed this issue and is no longer requiring updates from VA Illiana Health Care System.

OIG Comment

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

Glossary

adverse events. Untoward incidents, diagnostic or therapeutic misadventures, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services. VHA requires clinicians to disclose to a patient or a patient's representative, harmful or potentially harmful adverse events. Disclosure of adverse events includes a discussion between the patient and the patient's providers or other VHA personnel regarding clinically significant facts that have or could result in harm to the patient in the future. VHA provides for three types of adverse event disclosures—clinical, institutional, and large-scale.¹

computed tomography (CT). A combined series of x-ray images to create cross-sectional images of the body.²

imaging service. A branch of medicine that uses imaging to diagnose and treat disease.³

institutional disclosure. A formal process of notification to a patient or patient's personal representative that an adverse event has happened during the patient's care that has or is expected to result in serious injury or death. Facility leaders, in conjunction with clinicians and other appropriate individuals, are to initiate the institutional disclosure as soon as reasonably possible and this type of disclosure is to occur regardless of whether it was a result of an error. Large-scale disclosures generally involve facility-based issues that affect multiple patients and adverse events which are clinically significant and involve actual or potential harm.⁴

magnetic resonance imaging (MRI). An imaging study to visualize internal organs that employs a powerful magnetic field as well as radiofrequency electromagnetic fields.⁵

National Teleradiology Program (NTP). A program that provides VA medical facilities with secure, remote radiology procedure interpretations. VA medical facilities utilize NTP in cases where the medical facility has limited or no radiology interpretation services (such as rural facilities, recruitment issues, lack of subspecialty, or leave coverage issues).⁶

ongoing professional practice evaluation (OPPE). A process that continuously evaluates a practitioner's professional performance to identify practice issues that may impact quality of care

¹ VHA Handbook 1004.08.

² (https://www.merriam-webster.com/dictionary/computed%20tomography. (The website was accessed on July 12, 2019.)

³ My HealtheVet. (https://www.myhealth.va.gov/mhv-portal-web/my-healthevet-va-radiology. (The website was accessed on May 30, 2019.)

⁴ VHA Handbook 1004.08.

⁵ VHA Directive 1105.05, Magnetic Resonance (MR) Safety, May 29, 2018.

⁶ National Teleradiology Program. This is an internal VA website that is not accessible to the public. (The website was accessed on July 12, 2019.)

and patient safety. Ongoing professional practice evaluation is an evidence-based privilege renewal and decision-making process calling for an ongoing review of a provider's practice. Prior to or at the end of each review period (every six months), a decision is made to continue, limit, or revoke a provider's existing privileges or scope of practice.⁷

peer review. A confidential and non-punitive clinical review process to aid in quality management efforts at the individual provider level. The goal is improvement in the care provided to veterans through a review of individual provider decisions and actions.⁸

Professional Standards Board. A standing committee of the medical staff established to evaluate and improve health care quality, review the professional qualifications of applicants for medical staff privileging, and report variances to accepted standards of clinical performance by individual practitioners. The Professional Standards Board is chaired by the Chief of Staff and reviews applications for appointment to the medical staff and the recommendations of service chiefs to include the status and appropriateness of clinical privileges.⁹

radiologist. A doctor who reads and interprets exams and prepares a report of the medical findings and possible diagnosis. ¹⁰

reprivileging. A process by which the institution grants the practitioner permission to independently provide specified medical or other patient care services, within the scope of the practitioner's license and/or an individual's clinical competence. VHA requires that ongoing monitoring and renewal of clinical privileges occur at a minimum of every six months (usually through the ongoing professional practice evaluation process).¹¹

risk stratification. A process of assigning a risk status to and dividing patient cases into groups of similar complexity levels. ¹²

⁷ Facility Memorandum 11-88.

⁸ VHA Directive 2010-025. VHA Directive 1190.

⁹ Facility Medical Staff Bylaws and Rules of the Medical Staff, May 2017.

¹⁰ My HealtheVet VA Radiology. (The website was accessed on May 30, 2019.)

¹¹ VHA Handbook 1100.19, Credentialing and Privileging, October 15, 2012.

¹² Population Health Management Risk Stratification. (The website was accessed on February 6, 2020.)

OIG Contact and Staff Acknowledgments

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