US DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficiencies in Quality Management Processes and Delays in the Communication of Test Results and Follow-Up Care at the Phoenix VA Health Care System in Arizona

Healthcare Inspection | **22-03599-07** | **October 31, 2023**

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess an allegation that facility leaders failed to complete clinical and institutional disclosures at the Phoenix VA Health Care System (facility) in Arizona. Additionally, the OIG found concerns related to deficiencies in quality management and safety processes, and in the communication of test results.

According to the Veterans Health Administration (VHA), a clinical disclosure happens when a provider notifies a patient, as part of routine care, that a harmful or potentially harmful adverse event occurred during the patient's care.[1] Clinical disclosures are to be conducted face-to-face by the provider, as soon as possible, and documentation of the clinical disclosure in the patient's electronic health record (EHR) is required when harm is determined to be more than minor.

VHA states that an institutional disclosure is a formal process where VA facility leaders and clinicians inform a patient, or representative, that an adverse event that occurred during the patient's care resulted in or is expected to result in the patient's death or serious injury, and provide specific information on the patient's rights and recourse.[2] An institutional disclosure must be initiated as soon as realistically possible and is required regardless of when an adverse event is discovered, even if a clinical disclosure occurred, and must be documented in the patient's EHR.

The OIG reviewed the care rendered to three identified patients (Patient A, Patient B, and Patient C) to determine if clinical and institutional disclosures were warranted and if the disclosures were conducted when required.

Patient Case Summaries

Patient A

In early spring 2021 (day 0), Patient A, who is in their 60's, had an appointment with a primary care provider (provider) during which routine laboratory tests were completed.[3] Six days later, a primary care clinic registered nurse called the patient about a newly elevated prostate-specific antigen (PSA) result. The provider prescribed antibiotics for presumed prostatitis (an inflamed prostate gland) and wanted to meet with the patient in three months for a prostate exam and repeat PSA testing. Patient A returned to the primary care clinic following completion of the

[1] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

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

[3] The OIG uses the singular form of they (their) in this instance for privacy purposes.

laboratory tests on day 107 and again on day 188. During those encounters, the patient complained of back pain, leg numbness, and painful urination. The provider ordered a lumbar spine magnetic resonance image (MRI), physical therapy, medications, and possible steroid injections. A prostate exam was not documented during either encounter, nor was a PSA test ordered.

In early spring 2022 (day 358), following a hospitalization for urinary retention requiring urinary catheter placement, Patient A met with the provider for a primary care appointment, and the provider ordered routine laboratory testing, including a PSA. Five days later, the primary care clinic registered nurse informed Patient A that the laboratory test results showed an elevated PSA, and the provider was recommending a repeat PSA test in two to three months.[4] The following day, Patient A failed a voiding trial after removal of a urinary catheter, and the provider placed a urology consult. During the urology appointment (day 372), the urologist documented the digital rectal exam was suspicious for cancer. Based on the exam findings, past PSA level results, and more recent issues with urinary retention and leg pain, the urologist discussed with the patient a need to evaluate for prostate cancer. The urologist ordered a biopsy, bone scan, and computerized tomography (CT) scan. On day 378, the patient completed a biopsy and four days later the urologist notified the patient that the results showed metastatic prostate cancer. The urologist coordinated hormone therapy and an oncology referral. Approximately two weeks later, an oncologist recommended that Patient A undergo radiation treatment and continue hormone therapy. Patient A completed radiation therapy in early summer 2022 and continues hormone therapy as of spring 2023.

In late fall 2022 (day 584), facility leaders conducted an institutional disclosure with Patient A related to the delay in diagnosis of prostate cancer.

Patient B

In early fall 2021, Patient B, who is in their 50's and has a history of chronic low back pain (requiring two previous lumbar surgeries), presented to the primary care clinic with complaints of worsening and radiating lower back pain. A primary care provider (provider) ordered a lumbar spine x-ray and a lumbar MRI, and documented a plan to refer the patient to the chronic pain clinic.

In mid-fall (day 0), Patient B completed the lumbar MRI, which showed a bulging disk at the lumbar second and third vertebrae, as well as a new lesion in the right kidney concerning for renal cell carcinoma. The radiologist recommended a follow-up renal ultrasound to further evaluate for renal cell carcinoma. On day 3, the provider informed Patient B only that the lumbar

[4] The patient's PSA level increased from 0.73 nanograms per milliliter (ng/mL) in mid-spring 2019, to 1.69 ng/mL in summer 2020, to 6.86 ng/mL (high) in early spring 2021, and to 22.72 ng/mL (high) in early spring 2022.

MRI showed a new bulging disk and that an orthopedic consult had been placed to discuss treatment options.

On day 147, a supervising physician, who was covering for the provider, became aware that Patient B had not been informed of the previously identified abnormal right kidney lesion in the MRI report.[5] Later that same day, the supervising physician conducted a clinical disclosure by notifying the patient of the abnormal right kidney lesion suspicious for renal cell carcinoma and placed an expedited order for a renal ultrasound. Approximately a month later, Patient B had the renal ultrasound and an abdominal CT scan, and a urologist ordered an MRI of the kidneys and referred Patient B to a urology surgeon.

In early summer 2022, after Patient B completed the MRI, the radiologist reported two right kidney lesions that were consistent with papillary renal cell carcinoma and a less than one centimeter left kidney lesion. In mid-summer, an interventional radiologist met with Patient B and recommended observation of the cystic lesion in the right kidney along with a biopsy and ablation therapy of the solid mass in the right kidney that were completed 11 days later. The biopsy confirmed that Patient B had papillary renal cell carcinoma.

In late summer, a urology surgeon met with Patient B and discussed further treatment options and the recommendation to continue with observation of the remaining lesions with the patient.

Patient C

In early spring 2021, Patient C, who is in their late 60's, called the primary care clinic registered nurse to request a urine test after a work physical showed blood in the urine. The same day, the nurse advised Patient C to complete the ordered urinalysis test and to follow up with the primary care provider (provider) for evaluation.[6]

In late summer (day 0), after receiving the provider's secure message that laboratory tests were ordered, Patient C completed the testing. The results showed that Patient C had an elevated PSA level and a large amount of blood in the urine. Later that same day, the provider mailed a letter with the laboratory results to Patient C; however, the letter did not contain instructions for follow-up related to the elevated PSA level.

On day 91, Patient C moved to another state and transferred care to another VA facility. On day 139, during a primary care clinic visit at the new VA facility, Patient C reported a recent 15-pound weight loss and nocturia despite use of medication. During this appointment, the new primary care provider documented conducting a clinical disclosure after reviewing the elevated late-summer PSA levels. Patient C reported being unaware of the elevated PSA levels. The

[5] The supervising physician could not recall who informed them of the missed MRI results.

[6] The patient did not complete the laboratory testing at the time it was ordered.

primary care provider entered a community care urology consult for further evaluation. Through community care, Patient C had a cystoscopy and a prostate biopsy.[7] Patient C was diagnosed with stage IIC prostate cancer requiring hormone therapy and radiation treatment. As of early winter 2022, Patient C completed hormone therapy and radiation treatment.

Inspection Results

The OIG substantiated that Patient A did not receive a clinical disclosure based on EHR documentation but did receive a delayed institutional disclosure. Patients B and C received clinical disclosures. Moreover, the OIG identified deficiencies in quality management processes, including failure to enter patient safety events into the Joint Patient Safety Reporting (JPSR) system and review adverse events, failure to initiate a required root cause analysis (RCA), and insufficient documentation and explanation within Peer Review Committee meeting minutes. The OIG determined that facility providers failed to communicate abnormal imaging and laboratory test results to patients as required by policy.

Lack of Clinical Disclosure and Delay of Institutional Disclosure for Patient A

The OIG determined that Patients A, B, and C experienced delayed cancer diagnoses due to lack of provider follow-up, and that clinical disclosures were warranted. The OIG found facility leaders and staff conducted clinical disclosures for Patients B and C. The OIG found no evidence that a clinical disclosure occurred for Patient A after the provider failed to follow-up with the patient for elevated PSA levels, even though the provider developed a treatment plan. In an interview with the OIG, the provider reported speaking with the patient about the failure to follow-up but could not explain why there was no documentation of the discussion in Patient A's EHR.

The OIG determined that Patient A also warranted an institutional disclosure because of the metastatic prostate cancer diagnosis. Patient A received an institutional disclosure; however, a delay occurred due to practices instituted by the Chief of Staff. The OIG found that the provider did not ensure appropriate follow-up of the elevated PSA results, despite having three encounters with the patient after the abnormal results were known. Through a review of email correspondence, the OIG learned that the risk manager notified the Chief of Staff of Patient A's adverse event in spring 2022 and recommended an institutional disclosure. However, the OIG found the Chief of Staff implemented a practice to have peer reviews completed before deciding

[7] A delay in care occurred between the period of when the patient's primary care provider entered a community care urology consult in early winter 2021 and when the patient was seen by the community care urologist in late spring 2022 due to the patient's request for a specific community care provider.

if an institutional disclosure should occur. The OIG recognizes adverse events may require reviews to be completed to have a comprehensive understanding of what occurred. However, VHA policy states that "Decisions regarding institutional disclosure are made by facility leadership and are not part of the Peer Review for Quality Management process."[8] VHA policy further states that information obtained through a peer review is protected and cannot be included in an institutional disclosure.[9] The Chief of Staff's established process to have peer reviews completed prior to determining if an institutional disclosure was warranted did not align with VHA policy and caused a delay in conducting the institutional disclosure with Patient A.

Failure to Enter an Event in the Joint Patient Safety Reporting System

VHA states that staff are required to report any unsafe condition to the patient safety manager through the JPSR system or other methods, which allows the patient safety manager to track events from submission to closure.

The OIG found no evidence that staff entered patient safety reports into the JPSR system as required for Patients B's or C's adverse events. Although the patient safety manager and the risk manager were aware Patients B and C experienced delays in care, neither entered a patient safety report into the JPSR system. The patient safety manager could not explain why the JPSRs were not entered for Patients B and C. As a result, the patient safety manager failed to initiate the patient safety process, assign safety assessment code (SAC) scores, or determine the need for further reviews. The failure to perform the required patient safety reviews precluded a detailed analysis of these patient safety events to identify causal factors that could have resulted in opportunities for improvements in patient care.

Failure to Initiate a Root Cause Analysis

VHA states that patient safety events with SAC scores of 3 require an RCA.[10] An RCA is a specific type of review that "focuses primarily on systems and processes rather than individual performance."[11] The OIG determined that although staff entered Patient A's event into the JPSR system and the patient safety manager assigned a high-risk SAC score and recommended an

[8] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

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

[10] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The handbook and directive contain same or similar language related to SAC scores.

[11] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The handbook and directive contain same or similar language related to focus on systems and processes.

RCA be completed, an RCA was not completed; instead, the risk manager recommended a peer review be completed prior to initiating an RCA. However, upon completion of the peer review, the OIG found that an RCA was not reconsidered because there was no existing mechanism to trigger the patient safety manager to reconsider Patient A's case for an RCA. By not conducting an RCA related to Patient A's case, the facility missed an opportunity to potentially identify systems and processes that could reduce the recurrence of similar adverse events.

Lack of Discussion in Peer Review Committee Meeting Minutes

According to VHA, a peer review committee is required to review the initial rating of a peer review, evaluate and capture formal discussions of all level 2 and 3 initial peer reviews, provide final level ratings, and make recommendations to improve the quality of health care.[12]

The peer reviews of the three identified providers and the corresponding Peer Review Committee meeting minutes showed two of the three peer review levels were changed by the Peer Review Committee. However, the Peer Review Committee meeting minutes did not reflect formal discussion about the changes as required, thus weakening the peer review process.

Deficiencies in the Communication of Test Results

VHA states test results requiring action must be communicated by the ordering provider to the patient within seven calendar days to ensure high quality patient centered care. In addition, the ordering provider is responsible for communicating test results in a way that allows "the patient to be informed and engaged in their healthcare."[13] VHA also states that automated methods of communicating test results, such as letters, can be used if the test result does not require further follow-up or intervention by the provider.

For Patient B, the OIG determined the provider failed to timely communicate the MRI finding of a right kidney lesion to the patient despite the radiologist listing "possible malignancy" as the first item on the EHR imaging report. During an interview, the provider acknowledged overlooking the MRI result of the right kidney lesion and as such, failed to communicate that result to Patient B.

[12] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. The levels are based on what the peer reviewer would have done under the same set of circumstances. "Level 1 is the level at which most experienced and competent clinicians would have managed the case in a similar manner. Level 2 is the level at which most experienced and competent clinicians might have managed the case differently, but it remains within the standard of care. Level 3 is the level at which experienced and competent clinicians would have managed the case differently."

[13] VHA Directive 1088, *Communicating Test Results to Providers and Patients,* October 7, 2015, replaced by VHA Directive 1088(1), *Communication of Test Results to Providers and Patients*, October 7, 2015, amended January 24, 2022. These directives contain similar language and requirements for communicating test results to patients and providers.

For Patient C, the OIG determined the provider communicated the abnormal PSA level to the patient through a letter; however, the letter did not contain an explanation of the abnormal test result or a follow-up plan. In an interview, the provider reported expecting Patient C to have scheduled a follow-up appointment, and that during the follow-up appointment, the provider would have discussed the abnormal PSA result. After learning of the delay for Patient C, the provider reported a change in personal practice to add instructions in abnormal laboratory results letters for patients to schedule a follow-up appointment to discuss results further.

The OIG made five recommendations to the Facility Director related to ensuring that providers are educated on conducting clinical disclosures and documenting the discussion in patients' EHRs; evaluating quality management practices that impede the timeliness of institutional disclosures; confirming the Peer Review Committee records formal discussions in meeting minutes; making certain that adverse events or close calls are entered into the JPSR system and the facility patient safety manager completes reviews, assigns a SAC score, and conducts RCAs; and evaluating the process for the communication of abnormal test results to patients.

VA Comments and OIG Response

The Veterans Integrated Service Network and Facility Directors concurred with the findings and recommendations and provided acceptable action plans (see appendixes A and B). The OIG will follow up on the planned actions until they are completed.

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Assistant Inspector General
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Contents

Abbreviations

CT	computerized tomography
EHR	electronic health record
JPSR	Joint Patient Safety Reporting
MRI	magnetic resonance imaging
OIG	Office of Inspector General
PSA	prostate-specific antigen
RCA	root cause analysis
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Phoenix VA Health Care System (facility) in Arizona to determine if facility leaders failed to complete clinical and institutional disclosures on three identified patients.

Background

The facility is within Veterans Integrated Service Network (VISN) 22 and includes 12 community-based outpatient clinics that provide primary care and specialty care services.[1] The Veterans Health Administration (VHA) classifies the facility as a level 1a, highest complexity.[2] From October 1, 2021, through September 30, 2022, the facility provided care to 116,361 patients.

Disclosure of Adverse Events

VHA requires discussion between providers and patients or their personal representative about harmful events that occur while receiving care within the VA healthcare system, including harm that "may not be obvious, or where there is a potential for harm to occur in the future."[3] This discussion is referred to as disclosure of an adverse event.[4] Adverse events that require disclosure are defined broadly, and include those that have affected a patient or increased a patient's risk of future health consequences, and are expected to cause death or permanent disability. The disclosure of an adverse event may not always be "a singular event, but may involve a series of conversations," particularly if additional information is learned regarding the event.[5] VHA has different types of disclosures depending on the circumstances. Clinical disclosures are part of routine clinical care and occur between a patient and provider when a harmful or potentially harmful adverse event occurred. An institutional disclosure is a formal process whereby facility leaders and providers meet with a patient or a patient's representative to discuss that an adverse event occurred and that the adverse event may or potentially may have resulted in a patient's death or serious injury.

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[1] The facility provides outpatient services in the following Arizona cities: Gilbert, Globe, Mesa, Payson, Phoenix (five clinics), Scottsdale, Show Low, and Surprise.

[2] VHA Office of Productivity, Efficiency and Staffing (OPES), "Facility Complexity Level Model Fact Sheet," December 15, 2017. The VHA Facility Complexity Model categorizes medical facility by complexity level based on patient population, clinical services offered, and educational and research missions. Complexity Levels include 1a, 1b, 1c, 2 or 3. Level 1a facilities are considered the most complex.

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

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

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

Prior OIG Reports

Over the past three years, five OIG reports have been published related to the facility. One open recommendation was relevant to institutional disclosure.[6]

Allegations and Related Concerns

In May 2022, the OIG received an allegation that facility leaders were not conducting clinical and institutional disclosures as required by VHA policy. The confidential complainant provided the OIG with names of three patients who allegedly did not receive clinical and institutional disclosures and received care from three different primary care providers. The OIG reviewed the care of the three patients and identified additional concerns regarding deficiencies in quality management and safety processes and in the communication of test results.

Scope and Methodology

The OIG initiated the inspection on August 12, 2022, conducted a site visit October 3–6, 2022, and interviewed selected VISN and facility leaders, providers, and staff.

The OIG reviewed relevant VHA and facility policies and procedures, human resources information, peer reviews and Peer Review Committee meeting minutes, the identified providers' credentialing and privileging documents, Joint Patient Safety Reporting (JPSRs) system incident data, institutional disclosures, and the identified patients' electronic health records (EHRs).

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 substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. 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

[6] VA OIG, *Comprehensive Healthcare Inspection of the Phoenix VA Health Care System in Arizona*, Report No. 22-00051-136, June 29, 2023.

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.

Patient Case Summaries

Patient A

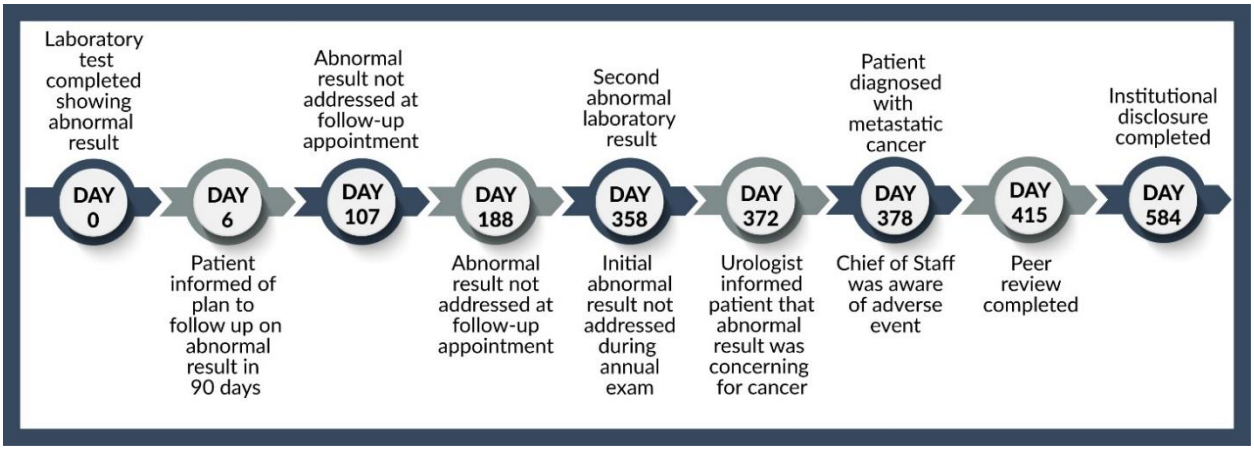

Figure 1. *A timeline of Patient A's care and completion of an institutional disclosure.*
Source: OIG review of Patient A's EHR.

In early spring 2021 (day 0), a patient, in their 60's with a past medical history of high blood pressure, chronic low back pain, and primary hyperparathyroidism, met with a primary care provider (provider) and had laboratory testing done.[7] Six days later, the primary care clinic registered nurse called the patient about a newly elevated prostate-specific antigen (PSA) result. The patient was prescribed antibiotics for a presumed prostatitis (an inflamed prostate gland) and the plan was for a prostate exam and repeat PSA testing in three months.

Approximately three months later (day 107), the patient presented to the primary care clinic with complaints of radiating back pain, left leg numbness, and painful urination. The provider documented mild tenderness of the low back and lower abdomen. The provider ordered physical therapy, a lumbar spine magnetic resonance image (MRI), urinalysis, a course of antibiotics, and an anti-inflammatory medication for the patient. The patient completed the lumbar spine MRI the following month showing degenerative arthritis and spinal stenosis. The primary care clinic registered nurse informed the patient of the MRI results three days later.

[7] The OIG uses the singular form of they (their) in this instance for privacy purposes.

Two months later (day 188), the patient returned to see the provider due to persistent radiating back pain despite following the previously outlined plan. The provider further discussed the MRI results and referred the patient to the physical medicine and rehabilitation clinic for evaluation and consideration of spinal steroid injections.

In early spring 2022 (day 358), the patient met with the provider for an annual appointment and follow-up to a recent hospitalization for urinary retention and placement of an indwelling urinary catheter. The provider educated the patient on benign prostatic hypertrophy, ordered laboratory testing, including PSA, and recommended removal of the urinary catheter in five to seven days. Five days later, the primary care clinic registered nurse advised the patient of elevated PSA results and that, according to the provider, this was possibly due to the recent catheter placement. The provider recommended the PSA test be repeated in two to three months. The next day, the patient had an unsuccessful voiding trial for urinary retention, and a urology consult was placed three days later.

The patient met with the urologist five days later (day 372). During the visit, the urologist discussed the patient's previous PSA levels from 2019 through 2022, the recent urinary retention, and the leg pain that woke the patient up at night for a couple months.[8] The urologist documented that the digital rectal exam and leg pain were suspicious and informed the patient about a concern for prostate cancer. The urologist arranged for a prostate biopsy and ordered a bone scan and a computerized tomography (CT) scan of the abdomen and pelvis.

In mid-spring 2022, the patient had a prostate biopsy and CT scan. Upon completion of the biopsy (day 378), the urologist notified the patient that the test results indicated metastatic prostate cancer. During this time, the urologist also arranged for the patient to start hormone therapy and placed an oncology referral.

In mid-spring, an oncologist evaluated the patient's metastatic stage IV prostate cancer and recommended radiation treatment with a referral to radiation oncology and continued hormone therapy. Since the evaluation, the patient completed radiation therapy in early summer 2022 and as of early spring 2023, continued treatment of the cancer with hormone therapy.

In late fall 2022 (day 584), facility leaders conducted an institutional disclosure with the patient.

[8] The patient's PSA level increased from 0.73 nanograms per milliliter (ng/mL) in mid-spring 2019, to 1.69 ng/mL in summer 2020, to 6.86 ng/mL (high) in early spring 2021, and to 22.72 ng/mL (high) in early spring 2022.

Patient B

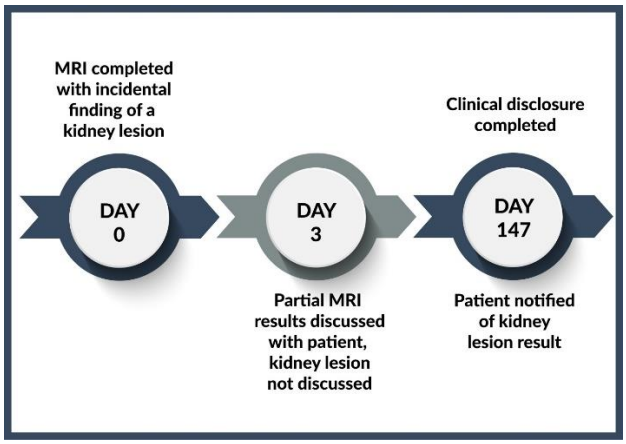

***Figure 2**. A timeline of Patient B's care and completion of clinical disclosure. Source: OIG review of Patient B's EHR.*

A patient, in their early 50's with a past medical history of chronic low back pain (requiring two previous lumbar surgeries), high blood pressure, and benign prostatic hypertrophy, presented to primary care with complaints of worsening and radiating lower back pain in early fall 2021. A primary care provider (provider) ordered a lumbar spine x-ray, a lumbar MRI, and a transcutaneous electrical nerve stimulation unit, and planned for a referral to the chronic pain clinic.

In mid-fall (day 0), the patient completed the lumbar MRI. In the imaging report, a radiologist noted a new lesion in the right kidney that was suspicious for renal cell carcinoma and recommended a follow-up renal ultrasound. Additionally, the radiologist noted post-operative changes to spinal hardware, degenerative changes to the lumbar spine, a bulging disk, and spinal canal stenosis. Three days later (day 3), the provider called the patient and discussed that the lumbar MRI showed a new bulging disk and an orthopedic consult had been placed to discuss treatment options. In early winter, the patient was evaluated by the orthopedic surgeon who referred the patient for non-surgical treatment of low back and leg pain.

In early spring 2022 (day 147), a supervising physician, who was covering for the provider, received notification of the patient's mid-fall 2021 abnormal finding in the MRI report. Later that same day, the supervising physician conducted a clinical disclosure by notifying the patient of the abnormal right kidney lesion suspicious for renal cell carcinoma and placed an expedited order for a renal ultrasound.

In spring 2022, the patient had a renal ultrasound and an abdominal CT scan. The provider referred the patient to urology in late spring. The urologist ordered an MRI of the kidneys and referred the patient to a urology surgeon.

In early summer, the patient completed the MRI. The radiologist reported two right kidney lesions: a kidney cyst in the front, upper pole measuring 2 centimeters; and one solid mass measuring 2.1 centimeters in the back, upper pole consistent with papillary renal cell carcinoma. The radiologist also reported a small (less than 1 centimeter) left kidney lesion.

Nine days later, a urology surgeon saw the patient for the renal mass and lesions. After discussion, the urology surgeon and patient developed a treatment plan that included a referral to interventional radiology.

In mid-summer, an interventional radiologist met with the patient and recommended observation of the cystic lesion in the right kidney along with a biopsy, and ablation therapy of the solid mass in right kidney. Eleven days later, the patient underwent successful biopsy and ablation of the solid mass in right kidney. The pathology results returned three days later showed papillary renal cell carcinoma.

In late summer, the patient met with the urology surgeon after the right kidney biopsy and ablation. The urology surgeon discussed further treatment options and the recommendation to continue with observation of the remaining lesions with the patient.

Patient C

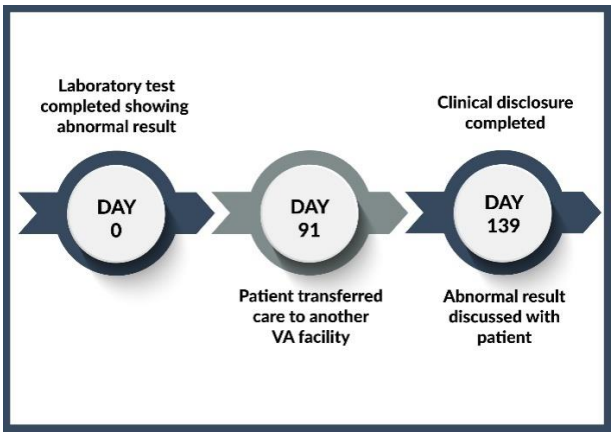

***Figure 3**. A timeline of Patient C's care and completion of clinical disclosure. Source: OIG review of Patient C's EHR.*

In early spring 2021, a patient, in their late 60's with a past medical history of enlarged prostate, chronic low back pain, morbid obesity, and cardiac (heart) conditions, called the primary care clinic registered nurse to request a urine test to check for blood after a work physical showed blood in the urine. The same day, the nurse advised the patient to have laboratory testing done and to follow up with the primary care provider (provider) for evaluation.[9]

[9] The patient did not complete the laboratory testing at the time it was ordered.

In mid-summer 2021, the patient requested to have laboratory testing completed. The same day, the nurse responded asking the patient to make an appointment with the provider. A few days later, the provider ordered laboratory testing and notified the patient of the order through secure messaging. The next day (day 0), the patient completed the laboratory testing, and later that same day, the provider mailed the laboratory results to the patient. The results showed patient had an elevated PSA level and a large amount of blood in the urine.

In late fall (day 91), the patient transferred care to a VA facility in another state. In early winter (day 139), during a primary care visit at the new VA facility, the patient reported a recent 15-pound weight loss and concern with nocturia despite use of medication. During this appointment, the new primary care provider conducted a clinical disclosure when reviewing the elevated mid-summer 2021 PSA levels with the patient. The patient reported being unaware of the elevated PSA levels. The new primary care provider entered a community care urology consult for further evaluation. In late spring 2022, the patient had a cystoscopy and in early summer, had a prostate biopsy performed through community care.[10] The patient was diagnosed with stage IIC prostate cancer requiring hormone therapy and radiation treatment. As of early winter 2022, the patient completed hormone therapy and radiation treatment.

Inspection Results

Allegation. Failure to Follow VHA's Disclosure Policy

The OIG substantiated that Patient A did not receive a clinical disclosure based on EHR documentation but did receive a delayed institutional disclosure. Patients B and C received clinical disclosures. During the inspection, the OIG identified a concern with the facility's practice to complete peer reviews prior to determining if an institutional disclosure was warranted.

Clinical Disclosures and the Lack of Documentation for Patient A

The OIG determined Patient A, Patient B, and Patient C experienced delayed cancer diagnoses due to lack of provider follow-up and that clinical disclosures were warranted. The OIG found EHR documentation that when providers became aware of the adverse events, clinical disclosures occurred for Patients B and C; however, for Patient A, the OIG found no documentation of a clinical disclosure.

[10] A delay in care occurred between when the patient's new primary care provider entered a community care urology consult in early winter 2021, and when the patient was seen by the community care urologist in late spring 2022 due to the patient's request for a specific community care provider.

According to VHA, a clinical disclosure happens when a patient's provider notifies the patient, as part of routine care, that a harmful or potentially harmful adverse event occurred during the course of the patient's care.[11] Clinical disclosures are to be conducted face-to-face by the provider, as soon as possible, and documentation of the clinical disclosure in the EHR is required when harm is determined to be more than minor.

The OIG found that Patient A's provider failed to initiate follow-up actions for an elevated PSA result. The patient was informed of the elevated PSA result on day 6 and the provider's plan was to follow-up with a repeat PSA in three months. However, at the patient's subsequent appointments, the OIG found no documentation in the EHR that the provider implemented the follow-up plan. On day 380, the urologist notified Patient A that the test results indicated a metastatic prostate cancer diagnosis.

In accordance with VHA policy, upon becoming aware of the delay in care and the subsequent metastatic prostate cancer diagnosis, the provider was required to complete and document a clinical disclosure in the patient's EHR. The OIG reviewed Patient A's EHR and found no documentation of a clinical disclosure.

In an interview, the provider acknowledged failing to implement the patient's elevated PSA follow-up plan. The provider reported talking to Patient A about the lack of follow-up care but did not document the discussion in the patient's EHR.

For Patient B, the OIG found that in early spring 2022, the supervising physician received notification that in mid-fall 2021, Patient B's provider failed to inform the patient about the entire results of the MRI report. The supervising physician conducted a clinical disclosure informing the patient of the abnormal right kidney lesion and ordered an expedited renal ultrasound.

The OIG found that although Patient C's provider sent a letter in late summer 2021 that informed the patient of recent laboratory test results, including elevated PSA levels, Patient C reported being unaware of the results. In early winter, during a routine primary care appointment, Patient C's new primary care provider conducted a clinical disclosure while reviewing the patient's history of elevated PSAs. The new primary care provider referred the patient to a community care urologist for further evaluation.

The OIG concluded the three identified patients had adverse events related to delays in care and that clinical disclosures were warranted per policy. The OIG found documentation of clinical disclosures for Patients B and C but did not find documentation in Patient A's EHR. Clinical disclosures ensure that patients are informed when adverse events occur.

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

Institutional Disclosure and Delay in Notification for Patient A

Although facility leaders conducted an institutional disclosure for Patient A in late fall 2022, the OIG identified a facility process that delayed patient notification of institutional disclosures.

VHA states that an institutional disclosure is a formal process where VA facility leaders and clinicians inform a patient, or representative, that an adverse event occurred during the patient's care and provide specific information on the patient's rights and recourse.[12] An institutional disclosure must be initiated as soon as realistically possible and is intended to be ongoing, which allows for additional information to be shared. An institutional disclosure is required no matter when an adverse event was discovered, even if a clinical disclosure occurred. An institutional disclosure and subsequent communication must be documented in the patient's EHR.

At the direction of the provider, a primary care clinic registered nurse notified Patient A on day 6 of elevated PSA results and the provider's plan to follow-up with the patient in three months. Although the patient attended primary care follow-up appointments on day 107 and day 188, the OIG found that the provider failed to follow-up on Patient A's elevated PSA results at these appointments. On day 358, the patient met with the provider for an annual appointment and had laboratory tests completed, including a repeat PSA test. The provider did not discuss Patient A's initial elevated PSA result. Patient A's repeat PSA test was also elevated. The provider attributed the elevated repeat PSA level to a recent catheter placement. The primary care clinic registered nurse discussed the provider's plan to repeat the PSA test in two to three months with Patient A. However, due to an unsuccessful voiding trial, the provider entered a urology consult. The urologist reviewed Patient A's PSA levels, urinary retention, and complaints of leg pain. On day 372, the urologist conducted a digital rectal exam and informed the patient about a concern for prostate cancer. Patient A underwent a prostate biopsy and a CT scan of the abdomen and pelvis. Upon completing the prostate biopsy on day 378, the urologist informed Patient A that the test results indicated a metastatic prostate cancer diagnosis.

Also, on day 378, the risk manager notified the Chief of Staff of Patient A's adverse event and recommended an institutional disclosure. The OIG found that the Chief of Staff had a process for completion of a peer review prior to determining if an institutional disclosure was warranted. This process is discussed further in the section below. As a result of this process, Patient A's institutional disclosure occurred 584 days after the initial elevated PSA level.

The OIG concluded that Patient A experienced a delay in follow-up care that may have contributed to an advanced cancer diagnosis, and a further delay of the adverse event being disclosed. The facility's delay in conducting the institutional disclosure was not only a failure to

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

follow VHA policy, but also a failure to inform the patient that an adverse event occurred and to explain the rights and recourse to the patient.

Use of Peer Reviews to Determine Institutional Disclosures

The OIG found that the Chief of Staff implemented a practice to obtain a completed peer review of the provider(s) involved in a patient care event before determining if an institutional disclosure was warranted.

VHA states that disclosure of adverse events are separate actions from quality reviews.[13] Information provided in disclosures should not include quality management reviews as they are protected from disclosure and may contain information protected under other confidentiality statutes. Peer reviews are a type of quality management review "intended to promote confidential and non-punitive assessments of care at the individual clinician level."[14] The focus of the peer review is to determine if a provider's clinical decisions met the standard of care.

In early spring 2022, the risk manager emailed the Chief of Staff stating that the three identified patients experienced adverse events and recommended an institutional disclosure for Patient A. In a follow-up email nine days later, the risk manager wrote that Patient A's case was sent for a peer review per the Chief of Staff's request, and was initiated later that same month and completed approximately a month later.[15]

In interviews, the Chief of Staff stated the three identified patient care occurrences qualified as adverse events due to significant misses or bad outcomes and required reviews. The Chief of Staff stated the determination of an institutional disclosure should not be made without fully understanding the patients' cases and that these types of cases should go through peer review. The Chief of Staff could not recall an instance where an institutional disclosure was conducted without a peer review occurring first.

The OIG recognizes adverse events may require reviews to be completed in order to have a thorough understanding of what occurred. However, VHA states that "Decisions regarding institutional disclosure are made by facility leadership and are not part of the Peer Review for Quality Management process."[16] VHA further states that information obtained through a peer

[13] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. Quality reviews include peer review for quality management (peer review) and root cause analyses (RCA).

[14] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

[15] As part of the Chief of Staff's process, the providers for Patient B and Patient C both underwent peer reviews in spring 2022. The OIG found that no further discussion occurred regarding Patient B or Patient C following completion of the peer reviews.

[16] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

review is protected and cannot be included in an institutional disclosure.[17] Although the Chief of Staff initially told the OIG that peer reviews and institutional disclosures are independent of one another, the OIG found that the Chief of Staff established a process for first completing a peer review before determining if an institutional disclosure was warranted. This established process did not align with VHA policy and caused a delay in conducting the institutional disclosure with Patient A.

The OIG identified a lapse of 169 days between the spring 2022 completion of the peer review of care provided to Patient A and when the Chief of Staff conducted the institutional disclosure with Patient A in late fall 2022. This delay was due to the Chief of Staff's reliance on a completed peer review to determine whether an institutional disclosure was warranted.

The Chief of Staff identified a gap in the established review process, which contributed to the delay in determining if an institutional disclosure was warranted for Patient A. The Chief of Staff explained that peer reviews and the Peer Review Committee do not normally focus on adverse events or disclosures as it is not their responsibility to determine the need for an institutional disclosure. As such, a breakdown occurred after the peer review process was completed because there was no trigger for a follow-up discussion on an institutional disclosure. Upon recognition of this breakdown in processes with lack of follow-up discussion on institutional disclosures, the Chief of Staff explained that a monthly meeting was initiated to evaluate completed peer review cases to determine if disclosures were necessary.[18] The OIG recognizes that facility leaders attempted to address the gap in process by establishing monthly meetings to discuss patient cases undergoing peer review. However, the OIG concluded the facility process to have a peer review completed prior to determining if an institutional disclosure was warranted does not align with VHA's policy and contributed to a delay in Patient A's institutional disclosure and being informed of rights and recourses.

Concern 1. Deficiencies in Quality and Safety Processes

The OIG determined that the Chief of Staff and the quality management staff became aware of the three identified patients' adverse events in spring 2022. Although facility staff and leaders conducted disclosures and peer reviews, the OIG identified deficiencies in quality management process including,

- failure to enter patient safety events into the JPSR system and review adverse events,
- failure to initiate a required root cause analysis (RCA), and

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

[18] The facility began initiating the monthly meetings around the time of the OIG's site visit.

- insufficient documentation and explanation within Peer Review Committee meeting minutes.

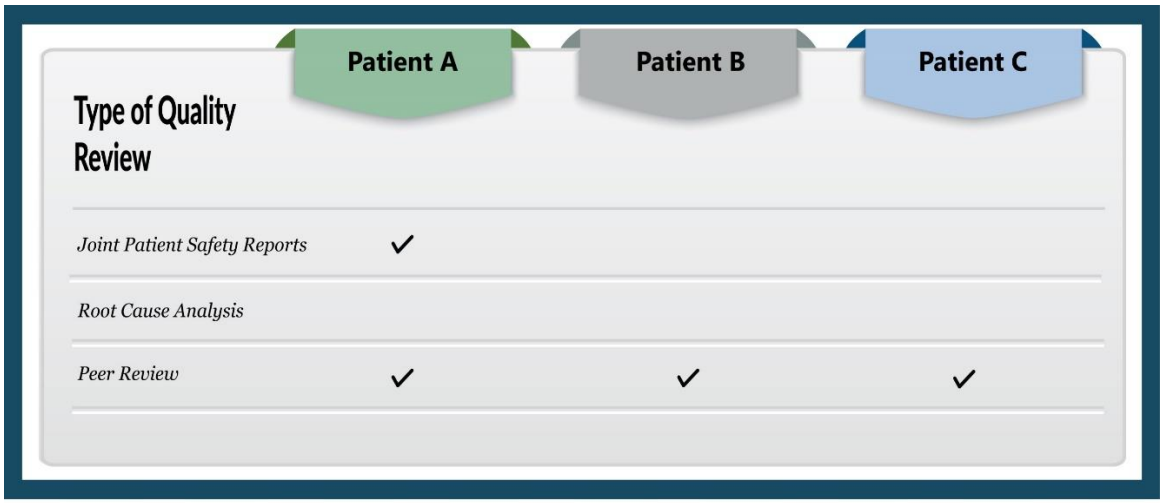

Figure 4. *Type of quality review completed per patient.*
Source: OIG review of documents provided by the facility.

Failure to Enter Patient Safety Events into the JPSR System and Review Adverse Events for Patients B and C

The OIG found no evidence that staff entered patient safety events into the JPSR system for Patient B's or Patient C's adverse events. As a result, the patient safety manager did not assign safety assessment code (SAC) scores or initiate further reviews.[19]

VHA states that the reporting of adverse events is a primary mechanism to identify system vulnerabilities.[20] Reported events provide opportunities for evaluation of root causes and contributing factors that guide actions to prevent recurrence. Staff are required to report any unsafe condition to the patient safety manager. Reports can be submitted by entering an event

[19] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. The handbook was rescinded and replaced with VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The handbook and directive contain same or similar language regarding SAC scores. A SAC score is "when a severity category is paired with a probability category for either an actual event or close call, a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk) results." SAC scores "can then be used for doing comparative analysis and for deciding who needs to be notified about the event."

[20] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The handbook and directive contain same or similar language regarding reporting adverse events.

into the JPSR system or other established methods.[21] Utilizing the JPSR system allows the patient safety manager to track event reports from submission through closure and assign a SAC score that helps determine if further action is required.

The OIG found that Patient B and Patient C experienced delays in care, which may have led to delays in cancer diagnoses. Although the patient safety manager and the risk manager were aware of the delays, neither entered patient safety reports into the JPSR system.

In an interview with the OIG, the patient safety manager reported becoming aware of the adverse events for Patient B and Patient C in spring 2022. Although staff were trained to enter a patient safety event into the JPSR system or contact the patient safety manager when a patient safety event occurs, a patient safety event was not entered into the JPSR system for either Patient B or Patient C. The patient safety manager, the risk manager, and the VISN quality management officer stated that if staff failed to enter a patient safety event into the JPSR system but notified the patient safety manager or risk manager of an event, then the patient safety manager or risk manager should enter the event into the JPSR system. Despite awareness of Patient B's and Patient C's events, the patient safety manager and the risk manager failed to enter either event into the JPSR system. The patient safety manager could not explain why the JPSRs were not entered for Patient B and Patient C.

As a result, the patient safety manager failed to initiate the patient safety process, assign SAC scores, or determine the need for further reviews. In an interview, the patient safety manager acknowledged that Patient B's and Patient C's cases were not assigned a SAC score because these cases "fell off [the patient safety manager's] radar," and were not entered into the JPSR system.

The OIG concluded that the lack of a JPSR entry contributed to a missed opportunity to consider if an RCA was warranted. The failure to perform the required patient safety reviews precluded a detailed analysis of these patient safety events to identify causal factors that could have resulted in opportunities for improvements in patient care.

Failure to Initiate a Root Cause Analysis for Patient A

The OIG determined that although staff entered Patient A's event into the JPSR system and the patient safety manager assigned a SAC score of high risk, an RCA was not completed. The risk manager recommended a peer review be completed prior to initiating an RCA. However, upon completion of the peer review, the OIG found that an RCA was not considered.

[21] Other established methods at the facility include emailing, sending a Teams message, or speaking with the patient safety manager about an unsafe condition.

VHA states that patient safety events with SAC scores of 3 require an RCA.[22] An RCA is a specific type of review that "focuses primarily on systems and processes rather than individual performance."[23] The RCA "identifies changes that could be made in systems and processes" to "reduce the risk of the adverse event or close call" recurring, whereas peer reviews focus on an individual clinician's decision-making.[24]

The OIG confirmed that in spring 2022, an anonymous event was entered into the JPSR system for Patient A's care failures. Through emails, the OIG confirmed that the patient safety manager reviewed the JPSR, assigned a high-risk SAC score, and recommended an RCA. Through email discussion with the patient safety manager, the risk manager decided to defer initiating an RCA and instead recommended a peer review of Patient A's provider. Following completion of the peer review in the following few weeks, the OIG found no evidence an RCA was reconsidered.

In an interview, the patient safety manager reported that the Peer Review Committee did not provide feedback of action items that would inform the patient safety staff if an RCA was indicated. The patient safety manager acknowledged that an RCA should have been chartered.

Although the patient safety manager assigned the JPSR entry a SAC score that warranted RCA implementation, the OIG determined the risk manager decided to conduct a peer review instead of the required RCA. By not conducting an RCA related to Patient A's case, the facility missed an opportunity to potentially identify systems and processes that could reduce the recurrence of a similar adverse event.

Lack of Discussion in Peer Review Committee Meeting Minutes

The OIG found that the facility Peer Review Committee meeting minutes lacked case-specific formal discussions regarding changes to peer review ratings.

[22] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The handbook and directive contain same or similar language regarding SAC scores and RCA.

[23] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The handbook and directive contain same or similar language regarding SAC scores and RCA.

[24] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The handbook and directive contain same or similar language regarding SAC scores and RCA.

According to VHA, a peer review committee is required to review the initial rating of a peer review, evaluate and capture formal discussions of all level 2 and 3 initial peer reviews, provide final level ratings, and make recommendations to improve the quality of health care.[25]

The OIG reviewed the peer reviews of the three identified providers and the corresponding Peer Review Committee meeting minutes. The OIG found the Peer Review Committee meeting minutes contained general standardized statements related to peer review discussions and the actions for notifying the reviewed providers of the outcome as required by policy. The OIG found that some of the peer review levels were changed by the Peer Review Committee; however, the Peer Review Committee meeting minutes did not reflect formal discussion about the changes. As a result, the OIG was unable to evaluate the rationale for changes in peer review rating levels.

The OIG concluded that by not including the discussion and rationale for changing peer review levels, the peer review process is weakened.

Concern 2: Deficiencies in the Communication of Test Results

The OIG determined the facility providers failed to communicate abnormal imaging and laboratory test results to patients as required by policy.

VHA states that "timely communication of test results to patients is essential for high quality patient centered care," and that a lack of associated follow-up of abnormal test results may lead to poor outcomes.[26] Test results requiring action must be communicated by the ordering provider to the patient within seven calendar days. In addition, the ordering provider is responsible for communicating test results in a way that allows "the patient to be informed and engaged in their healthcare."[27] When test results require follow-up action, the ordering provider is expected to discuss the treatment options with the patient and document the discussion and decision in the patient's EHR. VHA also states that automated methods of communicating test results, such as

[25] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. The levels are based on what the peer reviewer would have done under the same set of circumstance. "Level 1 is the level at which most experienced and competent clinicians would have managed the case in a similar manner. Level 2 is the level at which most experienced and competent clinicians might have managed the case differently, but it remains within the standard of care. Level 3 is the level at which most experienced and competent clinicians would have managed the case differently."

[26] VHA Directive 1088, *Communicating Test Results to Providers and Patients,* October 7, 2015, replaced by VHA Directive 1088(1), *Communication of Test Results to Providers and Patients*, October 7, 2015, amended January 24, 2022. These directives contain similar language and requirements for communicating of test results to patients and providers.

[27] VHA Directive 1088, *Communicating Test Results to Providers and Patients,* October 7, 2015, replaced by VHA Directive 1088(1), *Communication of Test Results to Providers and Patients*, October 7, 2015, amended January 24, 2022. These directives contain similar language and requirements for communicating of test results to patients and providers.

letters, can be used if the test result does not require further follow-up or intervention by the provider.

Deficiencies in the Communication of Imaging Test Results

The OIG determined that although Patient B's diagnostic provider (radiologist) sent the ordering provider (provider) the expected notification regarding the lumbar MRI imaging results, the provider failed to communicate the imaging results related to the right kidney lesion to Patient B.

Patient B had a lumbar MRI in mid-fall 2021 and the radiologist documented a "possible malignancy" and recommended a follow-up renal ultrasound. Three days later, the provider called Patient B and discussed the MRI lumbar findings but failed to communicate the right kidney concern. In early spring 2022 (day 147), the supervising physician became aware of the kidney imaging result and notified Patient B on the same day.[28]

During an interview, the provider stated the lack of communication of Patient B's results was not a system failure as the radiologist listed the possible malignancy as the first item on the EHR imaging report. The urology surgeon, chief of urology, and Chief of Staff informed the OIG that Patient B's treatment options were likely not impacted by the delayed notification of the imaging result.

The OIG concluded the provider failed to timely communicate the abnormal MRI results to Patient B. Although Patient B's options were likely not affected, delays in communicating abnormal imaging results could affect patients' outcomes.

Deficiencies in the Communication of Laboratory Test Results

The OIG determined that the ordering provider (provider) communicated the abnormal laboratory test result to Patient C through a letter; however, the letter did not contain an explanation of the abnormal test results or a follow-up plan.

Patient C had laboratory tests including a PSA in late summer 2021. Upon receiving the laboratory results, the provider sent a letter to Patient C that listed an elevated PSA result of greater than 13 nanograms per milliliter (ng/mL). The provider did not include any comments in the letter identifying the PSA level as abnormal or a plan to address it. The OIG found no EHR documentation that the provider or another primary care team member took any other action to communicate the abnormal PSA result to the patient, such as a telephone call or a secure message. Although the letter was sent to the patient, the patient reported being unaware of the PSA result during an early winter appointment when care was transferred to another VA facility.

[28] In an interview with the OIG, the supervising physician could not recall how the patient's case was referred.

The OIG interviewed Patient C's provider who reported using letters to communicate laboratory results to patients and acknowledged not including additional information in the letters. The provider reported expecting that Patient C would have scheduled a follow-up appointment, and that during the follow-up appointment the provider would have discussed the abnormal PSA result. The provider acknowledged not being diligent in contacting the patient about the abnormal result. After learning about the delayed PSA follow-up care for Patient C, the provider reported a change in personal practice to add a comment to the letter asking patients to schedule appointments to discuss abnormal results.

The OIG concluded the provider sent a letter including the abnormal PSA result but failed to address it or provide a follow-up plan, which contributed to the patient being uninformed and a delay in care.

Conclusion

The OIG substantiated Patient A did not receive a clinical disclosure based on EHR documentation but did receive a delayed institutional disclosure. Patients B and C received clinical disclosures. The OIG determined that Patient A, Patient B, and Patient C experienced care delays that required clinical disclosures. EHR documentation confirmed that Patient B and Patient C received clinical disclosures when providers identified the delays in care. Although Patient A's provider reported conducting a clinical disclosure with the patient, the OIG found no documented evidence that a clinical disclosure occurred.

The OIG determined that Patient A's delay in care was an adverse event requiring institutional disclosure. The OIG further determined the facility did not provide timely disclosure of this adverse event due to the decision to complete a peer review prior to determining the need for institutional disclosure. The OIG discovered upon completion of a peer review the facility had no mechanism in place to trigger discussion evaluating the need for institutional disclosure. Facility leaders identified this gap and initiated a monthly meeting to discuss cases reviewed in the Peer Review Committee to determine if institutional disclosures were warranted.

The OIG identified deficiencies in the facility quality management and safety processes including entry of patient safety events into the JPSR system, initiation of RCAs, and documentation within Peer Review Committee minutes. For Patient B and Patient C, the OIG concluded that although the patient safety manager and the risk manager were aware of these two patient safety events, the patient safety manager and the risk manager failed to enter these events into the JPSR system. The failure to enter these events into the JPSR system impeded the patient safety manager's ability to initiate the patient safety process and created a missed opportunity to identify improvements that could mitigate, if not prevent, future patient safety events. The OIG found that the patient safety manager followed policy when staff submitted a JPSR for Patient A's adverse event, including reviewing the care provided to Patient A and assigning a high-risk

SAC score. Although the patient safety manager relayed to the risk manager an RCA was required, the risk manager decided to refer the case for a peer review instead. The OIG confirmed the Peer Review Committee reviewed the care delivered by Patient A's, Patient B's, and Patient C's providers but found that the meeting minutes contained general standardized statements of committee discussion without rationale for changes to the assigned peer review levels. The lack of documentation resulted in an incomplete record of Peer Review Committee activity and does not comply with VHA policy requirements.

The OIG identified that facility providers failed to communicate abnormal imaging and laboratory test results to patients as required by VHA policy. Patient B's provider failed to timely communicate the abnormal kidney imaging results. While the delayed communication of Patient B's abnormal imaging result did not likely affect the patient's treatment options, the OIG concluded lack of timely communication of abnormal imaging results could affect patients' outcomes. Patient C's provider communicated the abnormal PSA test results to the patient through a letter. However, the letter did not contain an explanation of the abnormal test result or a follow-up plan. Patient C reported being unaware of the PSA result after establishing care at another VA facility. When letters are used as the sole method of communicating abnormal test results that require action, patients may be uninformed and not engaged in their health care, and delays in care may occur.

Recommendations 1–5

1. The Phoenix VA Health Care System Director ensures that providers are educated on conducting clinical disclosures and documenting the discussion in the patient's electronic health record when harm is determined to be more than minor.

2. The Phoenix VA Health Care System Director evaluates quality management practices that impede the timeliness of institutional disclosures, and ensures the current practices are in alignment with Veterans Health Administration policy, and takes action as warranted.

3. The Phoenix VA Health Care System Director confirms that the Peer Review Committee record formal discussions in meeting minutes, including discussion specific to changes in rating levels in accordance with Veterans Health Administration policy, and monitors compliance.

4. The Phoenix VA Health Care System Director makes certain adverse events or close calls are entered into the Joint Patient Safety Reporting system and the facility patient safety manager completes reviews, assigns a safety assessment code score, and conducts root cause analyses in accordance with Veterans Health Administration policy, and monitors compliance.

5. The Phoenix VA Health Care System Director evaluates the process for the communication of abnormal test results to patients and ensures that ordering providers or designees provide timely

notification to patients in a manner that informs patients of the results in accordance with Veterans Health Administration policy, and monitors compliance.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: August 3, 2023

From: Interim Network Director, VA Desert Pacific Healthcare Network (10N22)

Subj: Healthcare Inspection—Deficiencies in Quality Management Processes and Delays in the Communication of Test Results and Follow-Up Care at the Phoenix VA Health Care System in Arizona

To: Director, Office of Healthcare Inspections (54HL08)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. Thank you for the opportunity to review and comment on the Office of Inspector (OIG) report, Deficiencies in Quality Management Processes and Delays in the Communication of Test Results and Follow-Up Care at the Phoenix VA Health Care System in Arizona.
2. Based on the thorough review of the report by VISN 22 Leadership, I concur with the recommendations and submitted action plans of the Phoenix VA Health Care System.
3. If you have additional questions or need further information, please contact the VISN 22 Quality Management Officer.

(*Original signed by:*)

Steven E. Braverman, MD
VISN 22 Interim Network Director

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: August 3, 2023

From: Director, Phoenix VA Health Care System- Carl T. Hayden VAMC (644)

Subj: Healthcare Inspection—Deficiencies in Quality Management Processes and Delays in the Communication of Test Results and Follow-Up Care at the Phoenix VA Health Care System in Arizona

To: Interim Director, VA Desert Pacific Healthcare Network (10N22)

1. Thank you for the opportunity to review and comment on the Office of Inspector General report, Deficiencies in Quality Management Processes and Delays in the Communication of Test Results and Follow-Up Care at the Phoenix VA Health Care System in Arizona. I concur with the findings and recommendations in the report.
2. Phoenix VA Health Care System remains committed to ensuring our Veterans receive exceptional health care.

(*Original signed by*:)

Bryan C. Matthews, MBA
Medical Center Director

Facility Director Response

Recommendation 1

The Phoenix VA Health Care System Director ensures that providers are educated on conducting clinical disclosures and documenting the discussion in the patient's electronic health record when harm is determined to be more than minor.

__X__Concur

____Nonconcur

Target date for completion: November 30, 2023

Director Comments

On July 27, 2023, the Phoenix VA Health Care System (PVAHCS) Chief of Staff provided education on clinical disclosures and the documentation in the patient's electronic health record at the Medical Executive Board Meeting. The following day, on July 28, 2023, the Chief of Staff issued correspondence to the PVAHCS providers on VHA Directive 1004.08, Disclosure of Adverse Events to Patients outlining the tenets of clinical and institutional disclosures including when they are to be conducted. Education of VHA Directive 1004.08, Disclosure of Adverse Events to Patients, will be provided to the PVAHCS providers. Communication and training of VHA Directive 1004.08 and clinical disclosures will be monitored monthly until 90% or greater compliance is achieved. Monitoring of training data will be reported monthly to the Medical Executive Board by PVAHCS Chief of Staff.

Recommendation 2

The Phoenix VA Health Care System Director evaluates quality management practices that impede the timeliness of institutional disclosures, and ensures the current practices are in alignment with Veterans Health Administration policy, and takes action as warranted.

__X__Concur

____Nonconcur

Target date for completion: February 29, 2024

Director Comments

The Patient Safety Manager developed a written process, Standard Operating Procedure 00Q-104 – Sentinel Event Reporting and Procedures, initiated on March 28, 2023, for recognizing and sharing sentinel events with the Director, Chief of Staff, Risk Manager, and other appropriate Phoenix VA Health Care System (PVACHS) leadership for institutional disclosure, as appropriate. Per this process, after review, if an institutional disclosure is warranted, the decision

will be discussed and made by the Chief of Staff and/or Associate Director of Patient Care Services within the time frame outlined by Directive 1004.08, Disclosure of Adverse Events to Patients. The Risk Manager will document the indication and timeliness for the institutional disclosure in a secure database.

The Risk Manager will monitor and report monthly compliance of the completion and timeliness of applicable institutional disclosures to the Quality and Patient Safety Board. The Chief of Quality and Patient Safety will report the Quality and Patient Safety Board meeting minutes monthly at PVAHCS Governing Board meetings, chaired by the Director. Compliance will be monitored until 90% compliance is achieved and sustained for six consecutive months.

Recommendation 3

The Phoenix VA Health Care System Director confirms that the Peer Review Committee record formal discussions in meeting minutes, including discussion specific to changes in rating levels in accordance with Veterans Health Administration policy, and monitors compliance.

__X__Concur

____Nonconcur

Target date for completion: February 29, 2024

Director Comments

The Chair of the Protected Peer Review Committee will ensure that any rating level changes will be discussed and the change in rating with justification will be provided and captured in the meeting minutes completed by the meeting recorder. Protected Peer Review Committee discussions captured in meeting minutes and changes in rating levels will be monitored by the Chair of the Protected Peer Review Committee. The Chair of the Protected Peer Review Committee will report compliance quarterly to the Medical Executive Board. The Medical Executive Board minutes are reported to the Governing Board, chaired by the Director. Compliance will be monitored until 90% compliance is achieved and sustained for six consecutive months.

Recommendation 4

The Phoenix VA Health Care System Director makes certain adverse events or close calls are entered into the Joint Patient Safety Reporting system and the facility patient safety manager completes review, assigns a safety assessment code score, and conducts root cause analyses in accordance with Veterans Health Administration policy, and monitors compliance.

__X__Concur

____Nonconcur

Target date for completion: March 31, 2024

Director Comments

At the Phoenix VA Health Care System PVAHCS) New Employee Orientation, that occurs twice a month, a Patient Safety Manager provides education regarding definitions of adverse events, close calls, and reportable events adverse events, including instructions on entering a JPSR for adverse events or close calls. PVAHCS personnel will also be required to complete Talent Management System (TMS) module #131001298, Joint Patient Safety Reporting System – Reporting a Safety Event. This TMS module training will begin October 1, 2023.

PVAHCS ensures that a Patient Safety Manager completes review of adverse or close calls entered in JPSR system and assigns a Safety Assessment Code score. PVAHCS ensures that a root cause analysis is conducted for patient safety events that are assigned a Safety Assessment Code score of three (3).

PVAHCS will ensure monitoring of JPSR training, review of adverse and close calls, assignment of the Safety Assessment Code by a Patient Safety Manager and completion of RCAs, in accordance with VHA policy. Completion of TMS module #131001298, Joint Patient Safety Reporting System, will be monitored monthly until 90% or greater compliance is achieved. The Patient Safety Manager will provide a monthly report to the Quality and Patient Safety Board (QPSB) of finalized patient safety events with a Safety Assessment Code score of three (3) and pertinent follow-up actions, including root cause analysis. The QPSB meeting minutes are reported to the Governing Board, chaired by the Director. Compliance will be monitored until 90% compliance is achieved and sustained for six consecutive months.

Recommendation 5

The Phoenix VA Health Care System Director evaluates the process for the communication of abnormal test results to patients and ensures that ordering providers or designees provide timely notification to patients in a manner that informs patients of the results in accordance with Veterans Health Administration policy, and monitors compliance.

__X__Concur

____Nonconcur

Target date for completion: February 29, 2024

Director Comments

On October 23, 2022, the Phoenix VA Health Care System (PVAHCS) initiated a process for lab values to be sent via automated letter with instructions for Veterans to contact the ordering provider with any questions. On November 2, 2022, the Clinical Executive Board voted to have all lab values sent to Veterans via automatic lab letter with instructions for the Veteran to contact

the ordering provider with any questions. This letter occurs in parallel with a contact from ordering provider to discuss the abnormal lab values within seven days (in accordance with VHA Directive 1088). The documented treatment plan discussion will entail treatment options, risk versus benefits, subsequent referrals, and shared decision-making.

The above process is monitored via a dashboard developed on October 26, 2022, which displays Veterans with abnormal Prostate-Specific Antigen (PSA) values, ordering provider and status of follow-up consults. Registered Nurses (RN) review all abnormal PSA values and complete an extensive chart review for documentation from the ordering provider regarding the abnormal PSA discussions, treatment plan and evidence of follow-up action. If the Veteran had been informed of the result and declined treatment options, that information is also assessed by the RN team. The dashboard is reviewed on a continuous basis for appropriate follow-up to the ordering provider, as needed and until each abnormal value has been resolved. The PVAHCS Quality department RNs will conduct ongoing monthly inter-rater reliability chart reviews, sampling 30 medical records for compliance and trending.

The Chief of Staff will instruct the Service Chiefs to review and verify procedures identifying a chain of responsibility within their departments, for receipt of test results and communication of abnormal test results to patients. Education will also be provided to all PVAHCS providers on VHA Directive 1088 for monitoring of abnormal results and the appropriate timely communication to patients.

PVAHCS will ensure monitoring of the training and timely communication of abnormal test results to patients, per guidance in VHA Directive 1088, Communicating Test Results to Providers and Patients. Communication and training of VHA Directive 1088 will be monitored monthly until 90% or greater compliance is achieved. Monitoring of training data will be reported by the Chief of Staff monthly to the Clinical Executive Board. In addition, the Chief of Staff will also report monthly compliance of timely communication of abnormal test results to patients to the Clinical Executive Board until 90% or greater compliance has been achieved for six consecutive months. The Clinical Executive Board meeting minutes will be reported to the Governing Board by the Chief of Staff.

Glossary

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

ablation therapy. "A type of minimally invasive procedure doctors use to destroy abnormal tissue that can be present in many conditions."[1]

abnormal. Deviating from the normal or average.[2]

adverse event. "Untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers."[3]

benign prostatic hypertrophy. A non-cancerous condition "in which an overgrowth of prostate tissue pushes against the urethra and the bladder, blocking the flow of urine."[4]

biopsy. The removal and examination of tissue, cells, or fluids from the living body.[5]

blood pressure. "Measures the pressure in your arteries as your heart pumps."[6]

bulging disk. "Over time, disks dehydrate and their cartilage stiffens. These changes can cause the outer layer of the disk to bulge out fairly evenly all the way around its circumference."[7]

community care. A VA program where care is provided to veterans through community providers when the VA cannot provide the needed care.[8]

computerized tomography. "Combines a series of X-ray images taken from different angles around [the] body and uses computer processing to create cross-sectional images (slices) of the bones, blood vessels and soft tissues."[9]

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[1] Mayo Clinic, "Ablation therapy," accessed November 28, 2022, https://www.mayoclinic.org/tests-procedures/ablation-therapy/about/pac-20385072.

[2] *Merriam-Webster.com Dictionary,* "abnormal," accessed November 28, 2022, https://www.merriam-webster.com/dictionary/abnormal.

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

[4] National Cancer Institute, "benign prostatic hypertrophy," accessed November 30, 2022, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/benign-prostatic-hypertrophy.

[5] *Merriam-Webster.com Dictionary*, "biopsy," accessed November 30, 2022, https://www.merriam-webster.com/dictionary/biopsy.

[6] Mayo Clinic, "Blood Pressure Test," accessed June 14, 2018, https://www.mayoclinic.org/tests-procedures/blood-pressure-test/about/pac-20393098.

[7] Mayo Clinic, "Bulging disk vs. herniated disk: What's the difference?," accessed April 4, 2023, Bulging disk vs. herniated disk: What's the difference? - Mayo Clinic.

[8] "Community Care," VA Community Care, accessed November 30, 2022, https://www.va.gov/communitycare/#.

[9] Mayo Clinic, "CT Scan," accessed August 17, 2022, https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675.

cystoscopy. Examination of the bladder using a "thin tube-like instrument with a light and lens for viewing." The instrument may also be able to "remove tissue to be checked under a microscope for signs of disease."[10]

degenerative arthritis. The most common form of spinal arthritis, developed through wear and tear, usually affecting the lower back.[11]

digital rectal exam. "An examination in which a doctor inserts a lubricated, gloved finger into the rectum to feel for abnormalities."[12]

hormone therapy. "Treatment that adds, blocks, or removes hormones. Hormones can also cause certain cancers to grow…To slow or stop the growth of cancer, synthetic hormones or other drugs may be given to block the body's natural hormones."[13]

indwelling urinary catheter. A tube placed and left in the bladder to drain urine.[14]

joint patient safety reporting. A system that "standardizes event capture and data management on medical errors and close calls/near misses" for VHA.[15]

kidney cyst. A round fluid filled pouch that develops in or on the kidneys.[16]

lesion. An abnormal change of an organ or part due to injury or disease.[17]

lumbar spine. Includes the five bones in the lower back.[18]

[10] National Cancer Institute, "cystoscopy," accessed November 30, 2022, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cystoscopy.

[11] Johns Hopkins Medicine, "spinal arthritis," accessed November 30, 2022, https://www.hopkinsmedicine.org/health/conditions-and-diseases/spinal-arthritis#:~:text=Spinal%20arthritis%20is%20inflammation%20of%20the%20facet%20joints,tendons%20attach%20to%20the%20bones%20of%20the%20spine.

[12] National Cancer Institute, "digital rectal examination," accessed November 29, 2022, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/digital-rectal-examination.

[13] National Cancer Institute, "hormone treatment," accessed November 30, 2022, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/hormone-treatment.

[14] National Institutes of Health, "urinary catheters," accessed November 30, 2022, https://medlineplus.gov/ency/article/003981.htm.

[15] "Frequently Asked Questions National Center for Patient Safety," VHA National Center for Patient Safety, accessed December 13, 2022, https://www.patientsafety.va.gov/about/faqs.asp.

[16] Mayo Clinic, "Kidney cysts," accessed November 29, 2022, https://www.mayoclinic.org/diseases-conditions/kidney-cysts/symptoms-causes/syc-20374134.

[17] *Merriam-Webster.com Dictionary*, "lesion," accessed December 2, 2019, https://www.merriam-webster.com/dictionary/lesion#other-words.

[18] Cleveland Clinic, "Lumbar spine," accessed November 30, 2022, https://my.clevelandclinic.org/health/articles/22396-lumbar-spine.

magnetic resonance imaging. "A non-invasive imaging technology that produces three dimensional detailed anatomical images. It is often used for disease detection, diagnosis, and treatment monitoring."[19]

metastatic. "The spread of cancer cells from the place where they first formed to another part of the body."[20]

nocturia. Urination at night.[21]

oncology. A branch of medicine focused on the prevention, diagnosis, treatment, and study of cancer.[22]

orthopedic. Orthopedic services are diagnostic tests and treatments that involve the musculoskeletal system including bones, joints, ligaments, tendons, and muscles.[23]

papillary renal cell carcinoma. A type of cancer that involves the tubes in the kidneys that help remove waste products from the blood.[24]

peer reviews. Peer reviews serve as a confidential, non-punitive process for evaluating health care provided by an individual and are designed to promote patient safety, organizational improvements, and optimal patient outcomes.[25]

primary hyperparathyroidism. The enlargement of "one or more of the parathyroid glands causes overproduction of parathyroid hormone," resulting in "high calcium levels in the blood."[26]

prostate cancer. A type of cancer that forms in the prostate tissue and is one of the most common types of cancer in men.[27] Some prostate cancers grow slowly, stay within the prostate

[19] National Institute of Biomedical Imaging and Bioengineering, "Magnetic Resonance Imaging," accessed November 30, 2022, https://www.nibib.nih.gov/science-education/science-topics/magnetic-resonance-imaging-mri.

[20] National Cancer Institute, "metastasis," accessed November 29, 2022, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/metastasis.

[21] *Merriam-Webster.com Dictionary*, "nocturia," accessed November 30, 2022, https://www.merriam-webster.com/medical/nocturia.

[22] *Merriam-Webster.com Dictionary*, "oncology," accessed June 4, 2020, https://www.merriam-webster.com/dictionary/oncology.

[23] U.S. National Library of Medicine, Medline Plus, "Orthopedic services," accessed February 26, 2019, https://medlineplus.gov/ency/article/007455.htm.

[24] National Cancer Institute, "Papillary Renal Cell Carcinoma," accessed November 29, 2022, https://www.cancer.gov/pediatric-adult-rare-tumor/rare-tumors/rare-kidney-tumors/papillary-renal-cell-carcinoma.

[25] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

[26] Mayo Clinic, "Hyperparathyroidism," accessed November 30, 2022, https://www.mayoclinic.org/diseases-conditions/hyperparathyroidism/symptoms-causes/syc-20356194.

[27] National Cancer Institute, "prostate cancer," accessed November 29, 2022, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/prostate-cancer; Mayo Clinic, "Prostate cancer," accessed August 16, 2022, https://www.mayoclinic.org/diseases-conditions/prostate-cancer/symptoms-causes/syc-20353087.

gland, and may need limited or no treatment; however, others prostate cancers are "aggressive and can spread quickly."[28] The average 5-year survival rates range from nearly 100 percent survival rate for localized and regional cancers to 31 percent for patients with metastatic disease.[29]

prostate-specific antigen. PSA testing is a method of prostate cancer screening that measures a substance produced by the prostate gland. A PSA level of 4.0 nanograms per milliliter (ng/mL) or lower is considered normal, if the PSA level is "more than 10.0 ng/mL, the chance of having prostate cancer is over 50 percent."[30]

radiation oncology. A type of cancer treatment utilizing "high energy, penetrating waves, or particles to destroy cancer cells or keep them from reproducing."[31]

renal cell carcinoma. The most common type of cancer that begins in the kidneys.[32] If the tumor is small, non-surgical treatments such as ablation therapy (ablation) may be used to destroy the tumor.[33]

root cause analysis. "A process for identifying the basic or contributing causal factors that underlie variations in performance associated with averse events or close calls."[34]

spinal stenosis. Occurs "when the space inside the backbone is too small." This can result in "pressure on the spinal cord and the nerves that travel through the spine."[35]

stage IIC prostate cancer. Cancer found in one or both sides of the prostate without spreading "outside of the prostate."[36]

[28] Mayo Clinic, "Prostate cancer," accessed August 16, 2022, https://www.mayoclinic.org/diseases-conditions/prostate-cancer/symptoms-causes/syc-20353087.

[29] American Cancer Society, "*Prostate Cancer Early Detection, Diagnosis, and Staging*," accessed August 16, 2022, https://www.cancer.org/content/dam/CRC/PDF/Public/8795.00.pdf.

[30] American Cancer Society, "*Prostate Cancer Early Detection, Diagnosis, and Staging*," accessed August 16, 2022, https://www.cancer.org/content/dam/CRC/PDF/Public/8795.00.pdf.

[31] Johns Hopkins Medicine, "Types of Treatment," accessed November 30, 2022, https://www.hopkinsmedicine.org/radiation_oncology/treatments/.

[32] Mayo Clinic, "Kidney cancer," accessed August 16, 2022, https://www.mayoclinic.org/diseases-conditions/kidney-cancer/symptoms-causes/syc-20352664.

[33] Mayo Clinic, "Kidney cancer," accessed August 16, 2022, https://www.mayoclinic.org/diseases-conditions/kidney-cancer/diagnosis-treatment/drc-20352669.

[34] VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, March 4, 2011.

[35] Mayo Clinic, "Spinal stenosis," accessed November 30, 2022, https://www.mayoclinic.org/diseases-conditions/spinal-stenosis/symptoms-causes/syc-20352961.

[36] National Cancer Institute, "stage II prostate cancer," accessed November 30, 2022, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/stage-ii-prostate-cancer.

stage IV prostate cancer. "Cancer that begins in the prostate and spreads to nearby lymph nodes or other areas of the body." "Treatments may slow or shrink an advanced prostate cancer," but for most people cancer at this stage is not curable.[37]

transcutaneous electrical nerve stimulation unit. A pain treatment that uses electrical impulses to ease pain and stimulate nerve endings.[38]

ultrasound. A procedure that uses high-energy sound waves to form pictures of tissues and organs on a computer screen.[39]

urinalysis. A urine test used to detect and manage a wide range of disorders.[40]

urology. A branch of medicine dealing with the urinary or urogenital organs.[41]

voiding trial. "Assesses a patient's ability to urinate after removal of an indwelling catheter."[42]

x-ray. A photograph obtained by use of x-rays.[43]

[37] Mayo Clinic, "Stage 4 prostate cancer," accessed November 30, 2022, https://www.mayoclinic.org/diseases-conditions/stage-4-prostate-cancer/symptoms-causes/syc-20377966#.

[38] *Merriam-Webster.com Dictionary*, "transcutaneous electrical nerve stimulation," accessed November 29, 2022, https://www.merriam-webster.com/medical/transcutaneous%20electrical%20nerve%20stimulation.

[39] National Cancer Institute, "ultrasound," accessed November 30, 2022, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/ultrasound.

[40] Mayo Clinic, "Urinalysis," accessed November 30, 2022, https://www.mayoclinic.org/tests-procedures/urinalysis/about/pac-20384907.

[41] *Merriam-Webster.com Dictionary*, "urology," accessed November 30, 2022, https://www.merriam-webster.com/medical/urology.

[42] Thees K, Dreblow L., "Trial of voiding: what's the verdict?" *Urologic Nursing*. 1999 Mar;19(1):20-2, https://pubmed.ncbi.nlm.nih.gov/10373988/.

[43] *Merriam-Webster.com Dictionary*, "x-ray," accessed April 4, 2023, https://www.merriam-webster.com/dictionary/x-ray#medicalDictionary.

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