



DEPARTMENT OF VETERANS AFFAIRS  
**OFFICE OF INSPECTOR GENERAL**

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*Office of Healthcare Inspections*

VETERANS HEALTH ADMINISTRATION

Multiple Failures in Test  
Results Follow-up for a  
Patient Diagnosed with  
Prostate Cancer at the  
Hampton VA Medical  
Center in Virginia



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## Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess concerns related to facility providers' failures to communicate, act on, and document abnormal test results that led to a delay in a patient's diagnosis of prostate cancer at the Hampton VA Medical Center (facility) in Virginia. The OIG also evaluated the facility's quality management processes in response to identified deficiencies in the patient's care.

The OIG identified multiple providers' failures to communicate, act on, and document abnormal test results from July 2019 to April 2021. The patient, a male in his 60s with a history of [prostatitis](#) and [benign prostatic hyperplasia](#) (BPH), was diagnosed with [metastatic](#) prostate cancer in April 2021.<sup>1</sup> Prostate cancer, one of the most common types of cancer in male patients, can grow slowly and stay within the prostate gland, or spread quickly.<sup>2</sup> In early stages, prostate cancer may not cause symptoms, but in more advanced stages, prostate cancer may cause urological symptoms, such as trouble urinating and decreased flow of urine, and symptoms related to metastatic disease, such as bone pain.<sup>3</sup> While the OIG noted missed opportunities for earlier diagnosis, earlier diagnosis may not have impacted the patient's outcome.

### Surgeon's Failure to Respond to an Abnormal Computed Tomography

The OIG determined that in July 2019, a vascular surgeon failed to communicate and act on the patient's abnormal [computerized tomography](#) (CT) scan result as required by Veterans Health Administration (VHA) policy.<sup>4</sup> In the CT report, a radiologist noted a potentially malignant lesion in the patient's prostate gland and recommended correlation of the finding with clinical history and a prostate-specific antigen (PSA) test (prostate cancer screening). The vascular surgeon offered the OIG several clinical explanations for why there was no communication or action taken, none of which were documented in the patient's electronic health record or negated the need to communicate the results to the patient. The July 2019 test results were not

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<sup>1</sup> The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

<sup>2</sup> The prostate, is "a small walnut-shaped gland in males that produces the seminal fluid that nourishes and transports sperm." Mayo Clinic, "prostate cancer," accessed October 25, 2021, <https://www.mayoclinic.org/diseases-conditions/prostate-cancer/symptoms-causes/syc-20353087>.

<sup>3</sup> Mayo Clinic, "prostate cancer."

<sup>4</sup> VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.

communicated to the patient until after this inspection was opened, when the facility's Chief of Staff informed the patient during an institutional disclosure conducted in September 2021.<sup>5</sup>

## Provider's Failure to Communicate and Act on an Abnormal PSA

The OIG determined that the patient's primary care provider (Provider 2) failed to communicate test results to the patient and to act on the patient's abnormal PSA test result in fall 2020 by not performing follow-up tests and consulting with a urologist. In October 2020, the patient completed a PSA test originally ordered by his previous primary care provider (Provider 1) three months earlier.<sup>6</sup> Provider 2 first noted the elevated PSA in November 2020, and documented in the patient's electronic health record the need for an [ultrasound](#), but did not communicate the abnormal PSA result to the patient.<sup>7</sup> The OIG found the patient was not notified of the October 2020 PSA test result until March 2021. Provider 2 reported that based on the symptoms the patient was experiencing, follow-up actions for the abnormal PSA result should have included a repeat PSA and an in-person visit to complete a [digital rectal exam](#).<sup>8</sup> However, Provider 2 could not recall why no action was taken.

The OIG determined that Provider 2 failed to refer the patient to Urology Service and coordinate timely imaging. During a telephone visit with the patient in August 2020, Provider 2 documented a plan to treat the patient's urinary symptoms including ordering a pelvic ultrasound and then consulting Urology Service. Due to the COVID-19 pandemic, the ultrasound was scheduled for December 2020.<sup>9</sup> The patient requested the ultrasound appointment be postponed. The ultrasound was completed in March 2021, seven months after the order was originally placed.<sup>10</sup> In interviews, Provider 2 expressed difficulties with urology consults being canceled for lack of

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<sup>5</sup> VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. "Institutional disclosure of adverse events, sometimes referred to as administrative disclosure, is a formal process by which VA medical facility leader(s), together with clinicians and others as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse."

<sup>6</sup> Based on information from the facility, Provider 1 ordered the patient's PSA test in July 2020, prior to leaving the facility later that month. Due to COVID-19, the facility's laboratory was completing tests by appointment only between July and November 2020. The patient contacted the facility in early October 2020, to schedule the lab appointment and was seen later that month (within 30 days).

<sup>7</sup> Provider 2 could not recall if the test results were communicated to the patient.

<sup>8</sup> In late summer and early fall 2020, the patient was experiencing symptoms including "slow urinary flow with c/o [complaint of] incomplete bladder empty feelings" and "urgency to go to bathroom, but very slow stream and small amount of urine."

<sup>9</sup> World Health Organization, *WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020*, accessed November 22, 2021, <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>. Merriam-Webster.com Dictionary, "pandemic," accessed March 1, 2022, <https://www.merriam-webster.com/dictionary/pandemic>. A pandemic is a disease outbreak over a wide geographic area that affects most of the population.

<sup>10</sup> The radiologist's ultrasound report noted bladder wall thickening and an enlarged prostate gland.

prerequisite imaging. However, Provider 2 did not attempt to consult Urology Service or expedite an ultrasound.

### **Provider's Failure to Act on Community Care Recommendations**

The OIG determined that Provider 2 failed to enter a urology consult when a community care provider recommended that the patient follow up with a urologist. In mid-January 2021, Provider 2 documented receipt of a note stating that a non-VA discharge summary recommended the patient follow up with a urologist for a voiding trial.<sup>11</sup> Provider 2 was unable to recall acknowledging receipt of the discharge note. Provider 2 told the OIG that normal practice would have been to read the discharge summary, determine if a facility urologist could see the patient within a week, and if a facility urologist was unavailable, ask if the patient wanted to see a non-VA urologist. Provider 2 did not facilitate a urology follow-up and could not recall why.

The OIG also determined that Provider 2 failed to correctly enter a [three-phase bone scan](#) (bone scan) order for the patient after the facility received a non-VA surgeon's recommendation to evaluate for infection or loosening of the patient's hip implant. In early March 2021, Provider 2 placed the order incorrectly, and a facility nuclear medicine technologist (technologist) contacted Provider 2 to correct the order, which Provider 2 incorrectly revised. On the day of the scan, the technologist attempted to correct this error; however, the technologist entered a facility registered nurse, who had no knowledge of the patient, as the ordering provider. Consequently, the notification of the results, which showed possible diffuse metastatic bone disease, was not sent to a provider. In early April 2021, the patient's new primary care provider (Provider 3) became aware of the bone scan findings and communicated the results to the patient.

### **Nurse Practitioner's Inadequate Telephone Triage**

The OIG determined that a nurse practitioner failed to adequately address the patient's urologic complaints during a post-discharge telephone triage call in September 2020. The patient complained of continued urinary symptoms, and a patient aligned care team nurse referred the concerns to a nurse practitioner. The nurse practitioner informed the OIG it is not uncommon for patients to have these urinary symptoms if they have known prostate enlargement and are on BPH medication. The nurse practitioner did not contact the patient to assess the acuity, nature, and cause of the symptoms.

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<sup>11</sup> National Institute of Health, "Voiding Trial," accessed March 1, 2022, <https://clinicaltrials.gov/ct2/show/NCT02886143>. A voiding trial is a test used to assess a patient's ability to empty their bladder after a urinary catheter is removed.

## Quality Management and Patient Safety Failures

The OIG determined that the facility's quality management staff did not initiate peer reviews and patient safety event reporting as required by VHA policy.<sup>12</sup> The Chief of Quality, Safety and Value (QSV) reported becoming distracted by other work and forgetting to inform the Risk Manager of the need for peer reviews. In addition, neither the Chief of QSV nor the Patient Safety Manager could explain the lack of patient safety event reporting.

In May 2021, the OIG sent a request for response to the facility outlining multiple concerns with providers' outpatient management of the patient's urological symptoms from July 2019 to April 2021. Upon receiving this request, the facility's Chief of QSV coordinated a review, which identified multiple deficiencies in the patient's care. On June 21, 2021, the Facility Director signed a written response to the OIG substantiating deficiencies in the patient's care and stated that the facility would initiate peer reviews.

The OIG determined that facility leaders did not screen and initiate peer reviews within three days of identifying deficiencies in the patient's care as required by VHA policy.<sup>13</sup> Peer reviews were not initiated until September 2021, after the facility leaders were notified of the opening of this OIG inspection. Facility policy assigns the responsibility of coordinating the peer review process to the Risk Manager.<sup>14</sup> Both the Chief of QSV and the Risk Manager informed the OIG that the Chief of QSV did not alert the Risk Manager of the need for peer reviews until after the opening of this inspection.

The OIG determined that facility staff and leaders were aware of deficiencies in the patient's care as early as June 2021; however, they took no action to initiate or submit patient safety reports.

According to VHA, the Patient Safety Program aims to prevent harm to patients by reporting and reviewing adverse events, identifying underlying causes, and implementing changes to reduce the likelihood of recurrence.<sup>15</sup> Facility policy requires that all staff complete patient safety reports as soon as adverse events are discovered.<sup>16</sup>

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<sup>12</sup> For the purposes of this report, the OIG used the term *quality management staff* to refer to the Chief of Quality Safety and Value, the Risk Manager, and the Patient Safety Manager.

<sup>13</sup> VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

<sup>14</sup> Facility Policy 590-11-04, Risk Management Program, February 25, 2021.

<sup>15</sup> VHA Handbook 1050.01, *VHA National Safety Improvement Handbook*, March 4, 2011. VHA defines adverse events as "untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or service provided within the jurisdiction of a medical facility, outpatient clinic, or other VHA facility."

<sup>16</sup> Facility Policy 590-11-28, *Patient Safety Improvement Program*, April 30, 2020.

The OIG made seven recommendations to the Facility Director related to test results, clarity in urology consults, nuclear medicine orders, patient safety reporting, and initiation of quality management reviews.

### **VA Comments and OIG Response**

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



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# Contents

Executive Summary .....	i
VA Comments and OIG Response .....	v
Abbreviations .....	vii
Introduction.....	1
Scope and Methodology .....	3
Patient Case Summary .....	4
Inspection Results .....	7
1. Surgeon’s Failure to Respond to an Abnormal CT .....	7
2. Provider’s Failure to Communicate and Act on an Abnormal PSA .....	9
3. Provider’s Failure to Act on Community Care Recommendations .....	13
4. Additional Finding: Nurse Practitioner’s Inadequate Telephone Triage .....	14
5. Quality Management and Patient Safety Failures .....	15
Conclusion .....	17
Recommendations 1–7 .....	18
Appendix A: VISN Director Memorandum .....	19
Appendix B: Facility Director Memorandum.....	20
Glossary .....	25
OIG Contact and Staff Acknowledgments .....	27
Report Distribution .....	28



## Abbreviations

BPH	benign prostatic hyperplasia
CT	computerized tomography
EHR	electronic health record
MRI	magnetic resonance imaging
OIG	Office of Inspector General
PACT	patient aligned care team
PSA	prostate-specific antigen
QSV	quality, safety and value
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



## Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess concerns related to facility providers' failures to communicate, act on, and document abnormal test results that led to a delay in a patient's diagnosis of prostate cancer at the Hampton VA Medical Center (facility) in Virginia.

## Background

The facility, part of the Veterans Integrated Services Network (VISN) 6, is a complexity level 1c facility serving eastern Virginia and northeastern North Carolina.<sup>1</sup> The facility provides an array of inpatient care, surgery, comprehensive primary and specialty outpatient care services including urology and diagnostic imaging. From October 1, 2020, through September 30, 2021, the facility served 64,019 patients.

## Prostate Cancer

Prostate cancer, one of the most common types of cancer in male patients, occurs in the prostate, "a small walnut-shaped gland in males that produces the seminal fluid that nourishes and transports sperm."<sup>2</sup> Some prostate cancers grow slowly and stay within the prostate gland; however, others are "aggressive and can spread quickly."<sup>3</sup> In early stages, prostate cancer may not cause symptoms, but in more advanced stages, prostate cancer may cause urological symptoms, such as trouble urinating and decreased flow of urine, and symptoms related to [metastatic](#) disease such as bone pain.<sup>4</sup>

Prostate-specific antigen (PSA) testing is a method of prostate cancer screening.<sup>5</sup> PSA is a substance produced by the prostate gland.<sup>6</sup> The bloodstream normally contains a small amount of

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<sup>1</sup> The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered the most complex and Level 3 facilities are the least complex. VHA Office of Productivity, Efficiency and Staffing.

<sup>2</sup> Mayo Clinic, "Prostate Cancer," accessed October 25, 2021, <https://www.mayoclinic.org/diseases-conditions/prostate-cancer/symptoms-causes/syc-20353087>.

<sup>3</sup> Mayo Clinic, "Prostate Cancer."

<sup>4</sup> Mayo Clinic, "Prostate Cancer." The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

<sup>5</sup> Mayo Clinic, "Prostate cancer screening: Should you get a PSA test?," accessed November 19, 2021, <https://www.mayoclinic.org/tests-procedures/psa-test/in-depth/prostate-cancer/art-20048087>.

<sup>6</sup> Mayo Clinic, "Prostate Cancer – Diagnosis and Treatment," accessed November 19, 2021, <https://www.mayoclinic.org/diseases-conditions/prostate-cancer/diagnosis-treatment/drc-20353093>.

PSA.<sup>7</sup> Usually, prostate cancer cells make more PSA than noncancerous cells.<sup>8</sup> Elevated PSA levels can have other causes, such as [benign prostatic hyperplasia](#) (BPH), prostate infection, or prostate inflammation.<sup>9</sup> Therefore, other factors are considered when evaluating the PSA result, such as a patient's age, the size of prostate, how quickly the PSA levels change, and the patient's medications.<sup>10</sup> PSA testing is sometimes combined with a [digital rectal exam](#) to check the prostate for irregularities.<sup>11</sup> Further tests may be ordered to determine if there is prostate cancer, such as an [ultrasound](#), [magnetic resonance imaging](#) (MRI), and [prostate biopsy](#).<sup>12</sup> Prostate cancer that is confirmed by biopsy is assigned a Gleason score.<sup>13</sup> Gleason scores, a common scale used to evaluate prostate cancer cells, can range from 2 (nonaggressive) to 10 (very aggressive).<sup>14</sup> Cancer cells, associated with scores of 8–10, are likely to grow and spread quickly.<sup>15</sup> The average 5-year survival rates range from nearly 100 percent survival rate for localized and regional cancers to 30 percent for patients with metastatic disease.<sup>16</sup>

## Concerns

In April 2021, the OIG received allegations regarding the patient's care at the facility earlier in the month. The original allegations centered around delays in care, poor communication, and inappropriate treatment by facility staff when the patient was receiving an initial diagnosis and treatment for [kidney failure](#), [osteoblastic](#) lesions, and prostate cancer. During this initial review, the OIG identified concerns regarding the patient's care prior to April 2021. The OIG sent a request to Veterans Health Administration (VHA) for response on May 14, 2021, and received the facility's response on July 19, 2021. Although the OIG determined the original allegations were unsupported, the OIG found the facility's response to the OIG's concerns insufficient.

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<sup>7</sup> Mayo Clinic, "Prostate cancer screening: Should you get a PSA test."

<sup>8</sup> Mayo Clinic, "Prostate cancer screening: Should you get a PSA test."

<sup>9</sup> Mayo Clinic, "Prostate cancer screening: Should you get a PSA test."

<sup>10</sup> Mayo Clinic, "Prostate cancer screening: Should you get a PSA test."

<sup>11</sup> Mayo Clinic, "Prostate cancer screening: Should you get a PSA test."

<sup>12</sup> Mayo Clinic, "Prostate cancer – Diagnosis and Treatment."

<sup>13</sup> Mayo Clinic, "Prostate cancer – Diagnosis and Treatment."

<sup>14</sup> Mayo Clinic, "Prostate cancer – Diagnosis and Treatment."

<sup>15</sup> American Cancer Society, "Understanding your pathology report: Prostate Cancer," accessed November 26, 2021, <https://www.cancer.org/treatment/understanding-your-diagnosis/tests/understanding-your-pathology-report/prostate-pathology/prostate-cancer-pathology.html>.

<sup>16</sup> American Cancer Society, "Survival Rates for Prostate Cancer," accessed December 7, 2021, <https://www.cancer.org/cancer/prostate-cancer/detection-diagnosis-staging/survival-rates.html>.

The OIG opened an inspection to evaluate the patient's care prior to April 2021, including

- a surgeon's response to the patient's abnormal [computerized tomography](#) (CT) scan results in July 2019,
- a provider's communication and action on the patient's abnormal PSA test in late 2020,
- the need for the patient to be referred to a urologist,
- communication of the patient's abnormal [three-phase bone scan](#) in March 2021, and
- quality management reviews and patient safety reporting after facility staff identified deficiencies in the patient's care.

During the inspection, the OIG also determined that a nurse practitioner inadequately managed a telephone triage call related to the patient's care.

## Scope and Methodology

The OIG initiated the inspection on August 16, 2021, and conducted a virtual site visit September 27–30, 2021.<sup>17</sup>

The OIG team virtually interviewed facility leaders, managers, and staff familiar with the patient's care and relevant processes; including the Chief of Staff; department chiefs and providers for General Surgery, Primary Care, Vascular, and Urology Services. Also interviewed were the Chief of Quality, Safety and Value (QSV); the Patient Safety Manager; the Risk Manager (Peer Review Coordinator); Diagnostic Imaging personnel including the Chief, technologists, a sonographer, an administrative officer; and a registered nurse.

The OIG reviewed relevant VHA policies and facility policies, service agreements and other written guidance documents, COVID-19 scheduling guidance, quality management documents, and email messages and attachments. The OIG reviewed relevant entries in the patient's electronic health record (EHR) from July 2019 through April 2021. Other items reviewed included professional literature related to prostate cancer.

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).

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<sup>17</sup> OIG interviews were conducted virtually using online meetings due to the COVID-19 pandemic. World Health Organization, *WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020*, accessed November 22, 2021, <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>. Merriam-Webster.com Dictionary, "pandemic," accessed March 1, 2022, <https://www.merriam-webster.com/dictionary/pandemic>. A pandemic is a disease outbreak over a wide geographic area that affects most of the population.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1101, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. 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 Summary

The patient, a male in his 60s with a history of [prostatitis](#) and BPH, was diagnosed with metastatic prostate cancer in April 2021.

In July 2019, a primary care provider (Provider 1) evaluated the patient for back, shoulder, and hip pain. Labs obtained that day included a PSA test that was 1.61 nanogram per milliliter (ng/ml) (normal). Later in July, the patient was treated for a right buttock abscess in the facility Emergency Department. A few days later, the patient underwent a [CT angiogram](#) as ordered by a vascular surgeon to evaluate the status of a previously completed lower extremity bypass surgery for peripheral artery disease. The radiologist noted a finding of a “hyperdense lesion at posterior lateral aspect of prostate gland, differential includes malignancy or possibly posttreatment changes. Correlation with PSA and clinical history is recommended.” The patient’s EHR does not reference follow up or discussion with the patient relative to the prostate lesion.<sup>18</sup> Two CT scans of the abdomen and pelvis with contrast, performed later in 2019, did not include discussion of a prostate lesion.

The patient had a telephone visit with Provider 1 in July 2020 to discuss hip pain. The patient also complained of issues with urination during the call. Provider 1 documented “slow urine output with hesitancy upon urination.” Provider 1 noted that the patient was taking a medication for BPH and that a PSA performed in 2019 was normal. Provider 1 attributed the patient’s symptoms to BPH and increased the dosage of the BPH medication. Provider 1 ordered a PSA test and noted in the EHR that the patient “may need prostate/DRE [digital rectal exam] next visit.”

During an August 2020 telephone visit, another primary care provider (Provider 2) documented the patient’s symptoms as “slow urinary flow with c/o [complaint of] incomplete bladder empty feelings last 4 days” and that “[the patient] thinks something is wrong with his bladder or prostate again.” Provider 2 noted that the patient was on a medication for BPH, and informed the

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<sup>18</sup> During an interview, the vascular surgeon who ordered the CT angiogram informed the OIG that he did not pursue evaluating the prostate lesion, because he attributed the prostate finding to recent treatment of a “perirectal abscess” and the earlier normal PSA result. The Emergency Department note does not specify that the right buttock abscess was “perirectal.”

patient that urinary retention could be a side effect from an opioid medication the patient was taking for hip pain. Provider 2 ordered an ultrasound of the patient's bladder with a plan to order a urology consult when the ultrasound result was available. Provider 2 also submitted a Community Care Orthopedic referral for hip replacement surgery. The following week, a medical support assistant entered a note in the EHR stating that due to the COVID-19 pandemic, the next available ultrasound appointment was in December. Provider 2 signed the note, acknowledging receipt of the information.

In September 2020, the patient reported an "urgency to go to bathroom, but very slow stream and small amount of urine" to a nurse during a telephone follow-up for an Emergency Department visit (for low blood pressure). A nurse practitioner recommended continuing the BPH medication, drinking 64 ounces of water daily, and presenting to the Emergency Department if problems persisted or blood was seen in the urine. The nurse practitioner did not address the patient's urinary complaints.

In October 2020, the patient completed the PSA test that Provider 1 ordered in July, and the PSA was elevated at 5.75 ng/ml (normal range is 0–4 ng/ml). Provider 2 had a phone visit with the patient mid-November to discuss abdominal pain and the results of an ultrasound, which showed a gallstone.<sup>19</sup> Provider 2 referred the patient to the facility's [gastroenterology](#) clinic. There was no documented discussion of urinary symptoms or mention of the abnormal PSA test in Provider 2's note.

Later in November 2020, Provider 2 documented the results of the abnormal PSA test and ordered an additional ultrasound to "rule out [prostate] bladder pathology for urology consult purpose." Provider 2 asked a nurse to contact the patient to schedule an ultrasound. The nurse documented one attempt to call the patient and left a voicemail requesting that the patient call regarding an important message from the provider.

An ultrasound tech canceled the second ultrasound order, characterizing it as a duplicate of the first ultrasound order entered by Provider 2 in August and scheduled for December. In early December, the patient canceled the ultrasound appointment, because it conflicted with a hip replacement surgery scheduled at a non-VA facility. The ultrasound was rescheduled for March 2021.

The patient underwent hip replacement surgery in December at a non-VA facility. The postoperative course was notable for urinary retention, and a urologist was consulted for difficult [urinary catheter](#) placement. A recommendation was made in the discharge summary to "Follow up with a urologist in 7-10 day(s) for [VOIDING Trial](#)." On the day of discharge, a VA community care nurse documented that the non-VA discharge summary was scanned into the

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<sup>19</sup> The patient underwent cholecystectomy (gallbladder removal) in August 2019. The stone was located in a remnant of the gallbladder neck (the portion of the gallbladder that remained after surgery).

EHR. Provider 2 acknowledged receipt of the note from the community care nurse but did not schedule a urology appointment or submit a consult for a voiding trial.

The patient had a telephone consult with a nurse practitioner in the gastroenterology clinic in February 2021 regarding abdominal pain and the remaining gallstone. The nurse practitioner ordered an MRI and surgical consultation. During the call, the patient complained of a slow urine stream and the need to “push” to urinate. The nurse practitioner also noted that the patient was on a BPH medication.

The patient saw a non-VA orthopedic surgeon for follow-up in early March and reported persistent hip pain. The surgeon submitted a request to the facility for a three-phase bone scan (bone scan) to “R/o [rule out] loosening, infection Right THR [total hip replacement].” Provider 2 was alerted to the request and entered an order for a bone scan.

The following week, a facility surgeon evaluated the patient for abdominal pain. The patient informed the surgeon of urinary complaints. The patient also told the surgeon that a urologist had to insert a urinary catheter after recent hip surgery and informed the patient that there was a “blockage” from the prostate. The surgeon noted the patient “had PSA done oct [sic] 2020 which was > [greater than] 5; reports no f/u [follow up].” The surgeon documented that the patient’s discomfort was related to urinary symptoms and constipation and not from the gallstone. The surgeon referred the patient to the facility’s urology clinic, and an appointment was scheduled for August.

Later in March, bone scan findings were concerning for “diffuse osseous metastatic disease” and “bilateral hydroureteronephrosis.”<sup>20</sup> The radiologist recommended further evaluation with CT scans of the patient’s head, chest, abdomen, and pelvis. An alert was sent to a facility registered nurse who did not act on the radiologist’s findings. The bladder ultrasound, ordered in August 2020, was performed the day after the bone scan. The ultrasound report noted bladder wall thickening and an enlarged prostate gland. Another primary care provider (Provider 3) sent a letter with the bladder ultrasound results to the patient and encouraged the patient to keep the urology appointment scheduled in August.

In April, the MRI ordered by the gastroenterology nurse practitioner in February showed enlarged lymph nodes and “findings in keeping with the patient’s suspected diffuse osseous metastatic disease.”<sup>21</sup> The gastroenterology nurse practitioner alerted Provider 3 to the results. Provider 3 also noted in the EHR that a recent blood test showed abnormal kidney function. Provider 3 contacted the patient and advised him to go to the Emergency Department. The

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<sup>20</sup> Diffuse osseous metastatic disease implies that cancer that has spread to bone. Hydroureteronephrosis denotes abnormal dilatation of the area in the center of the kidney that collects urine (*nephrosis*) and the tubes (*ureters*) that carry urine from the kidney to the bladder (*uretero*).

<sup>21</sup> Cancer can cause lymph node enlargement.

patient was then admitted to the facility for treatment of acute kidney failure and evaluation of osseous metastatic disease.<sup>22</sup>

A urologist determined that the patient's kidney failure was caused by obstruction of the urinary tract. The urologist also noted that a PSA test obtained on admission was 73 ng/ml and that prostate cancer was suspected. The urologist documented that the patient's "calculated PSA doubling time of less than 3 months carries a very poor prognosis if CaP [prostate cancer] is involved." The urologist performed a prostate biopsy, which confirmed prostate cancer with a Gleason score of 10. A bone biopsy was also positive for prostate cancer, establishing the diagnosis of metastatic cancer.

## Inspection Results

The OIG identified multiple concerns with the patient's care. In July 2019, a vascular surgeon failed to communicate and act on the patient's abnormal CT result as required by VHA policy.<sup>23</sup> The OIG determined that Provider 2 failed to communicate test results to the patient and to act on the patient's abnormal PSA test result in fall 2020 by not performing follow-up tests and consulting with a urologist. Additionally, Provider 2 failed to enter a urology consult, when a community care provider recommended that the patient follow up with a urologist. Provider 2 also failed to correctly enter bone scan orders for the patient after a non-VA orthopedic surgeon sent a request to the facility for a three-phase bone scan. In addition, a nurse practitioner failed to adequately address the patient's urologic complaints during a post-discharge telephone triage call. Finally, facility leaders did not initiate peer reviews within three days as required by VHA policy and facility staff did not submit patient safety reports as required. The patient's Gleason Score and PSA doubling time indicated a poor prognosis and suggested an aggressive cancer. While the OIG noted missed opportunities for earlier diagnosis, earlier diagnosis may not have impacted the patient's outcome.

### 1. Surgeon's Failure to Respond to an Abnormal CT

The OIG determined that in July 2019, a vascular surgeon failed to communicate and act on the patient's abnormal CT result as required by VHA policy.<sup>24</sup>

VHA requires providers to communicate abnormal test results requiring action to patients within seven calendar days.<sup>25</sup> In addition, the ordering provider is to discuss options with the patient,

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<sup>22</sup> The patient informed Provider 3 that he had a urology appointment that morning. The OIG did not find a scheduled urology appointment or community care referral for urology in the EHR.

<sup>23</sup> VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.

<sup>24</sup> VHA Directive 1088.

<sup>25</sup> VHA Directive 1088.



initiate action when indicated, and document the patient notification as well as subsequent clinical actions in the patient's EHR.<sup>26</sup> VHA specifically states

Lack of timely follow-up of abnormal test results has been identified as a contributor to poor outcomes and can be a source of considerable anxiety to patients and families. Patient involvement in test result follow-up is fundamental to improve safety in this area and is consistent with personalized proactive patient-driven care. Patients have a right to access personal health information and expect to be notified of test results in a timely manner.<sup>27</sup>

In July 2019, a radiologist noted a potentially malignant lesion in the patient's prostate gland on a CT scan and recommended correlation of the finding with clinical history and a PSA test.

The ordering provider, a vascular surgeon, reported not informing the patient of the test results thinking that the patient would only hear the word "cancer." The vascular surgeon reported concern that the patient had access to a large amount of prescribed opioids and "would do something foolish." Despite concerns regarding the patient's reaction, the vascular surgeon did not indicate consideration of informing the patient of the imaging study results along with consulting a mental health provider or the patient's primary care provider. In July 2019, when the vascular surgeon received the test results, the patient's EHR showed no history of suicidal ideation in the past 10 years. The OIG determined that the vascular surgeon's actions were inconsistent with VHA policy, and as a result, the patient was precluded from actively participating in decisions about follow-up options.<sup>28</sup>

The vascular surgeon told the OIG that additional evaluation was not necessary, because he attributed the lesion to a recently treated perirectal abscess, a PSA test performed earlier in the month was normal, and the patient did not have a history of cancer. The vascular surgeon further stated that a urologist was not consulted, because it was presumed the urologist would deem this a normal finding given the patient's history of prostatitis and the recent normal PSA test.

In interviews, facility leaders reported an expectation that the vascular surgeon consult with a facility urologist and document the discussion. The facility urologist opined that the lesion likely represented an inflammatory process and not cancer, particularly as the lesion was not seen on subsequent CT scans, but additional testing would have been needed given the limitations of CT scans of the pelvis to diagnose prostate cancer. The urologist stated that a PSA test, digital rectal exam, and additional imaging would have helped to clarify the CT scan finding.

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<sup>26</sup> VHA Directive 1088.

<sup>27</sup> VHA Directive 1088.

<sup>28</sup> VHA Directive 1088. "Patients have a right to access personal health information and expect to be notified of test results in a timely manner."

The OIG determined that the vascular surgeon failed to communicate the abnormal CT results to the patient and failed to complete follow-up actions, as required by VHA.<sup>29</sup> The July 2019 test results were not communicated to the patient until after this inspection was opened, when the facility Chief of Staff informed the patient during an institutional disclosure conducted in September 2021.<sup>30</sup>

## 2. Provider's Failure to Communicate and Act on an Abnormal PSA

The OIG determined that Provider 2 failed to communicate test results to the patient and to act on the patient's abnormal PSA test result in fall 2020 by not performing follow-up tests and consulting with a urologist.

### Communication

The OIG determined that Provider 2 failed to communicate the abnormal PSA result to the patient.

VHA requires that "all test results requiring action must be communicated by the ordering provider, or designee, to patients no later than 7 calendar days from the date on which the results are available."<sup>31</sup> If the provider is unable to communicate test results to a patient, all attempts are to be documented in the EHR, and "at a minimum, a certified letter should be sent for all test results requiring action."<sup>32</sup> Facility policy further delineates that a registered nurse may communicate abnormal results to a patient but only after instructions have been received from the ordering provider.<sup>33</sup>

In October 2020, a PSA test was performed that originally was ordered by Provider 1 three months earlier.<sup>34</sup> The PSA result of 5.75 was outside the normal range (0–4) and had more than tripled since the patient's last PSA test in July 2019 and required follow-up.<sup>35</sup>

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<sup>29</sup> VHA Directive 1088.

<sup>30</sup> VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. "Institutional disclosure of adverse events, sometimes referred to as administrative disclosure, is a formal process by which VA medical facility leader(s), together with clinicians and others as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse."

<sup>31</sup> VHA Directive 1088.

<sup>32</sup> VHA Directive 1088.

<sup>33</sup> Facility Policy 590-11-13, *Communication of Test Results*, June 5, 2019.

<sup>34</sup> Based on information from the facility, Provider 1 ordered the patient's PSA test in July 2020, prior to leaving the facility later that month. Due to COVID-19, the facility's laboratory was completing tests by appointment only between July and November 2020. The patient contacted the facility in early October 2020, to schedule the lab appointment and was seen later that month. (within 30 days).

<sup>35</sup> The patient had a PSA of 1.61 in July 2019; the October 2020 PSA was 3.57 times greater.

The Chief of Primary Care informed the OIG that when Provider 1 left the facility, a surrogate provider was assigned to receive and act on test results notification.<sup>36</sup> Provider 2 was not the designated surrogate, and therefore, was not alerted to test results Provider 1 ordered.<sup>37</sup> In interviews, the surrogate provider denied being notified of the patient's PSA test result. The OIG found documentation that confirmed that the surrogate provider did not receive notification of the patient's PSA test result.<sup>38</sup>

Although, Provider 2 did not receive initial notification of the patient's PSA test result, the OIG determined Provider 2 should have ensured that the test result was communicated to the patient and follow-up actions were initiated when Provider 2 was made aware of the abnormal result. Provider 2 first noted the elevated PSA in November 2020, more than one month after the test result was available in the EHR. Provider 2 documented in the patient's EHR, requesting a nurse inform the patient to complete an ultrasound before a urology consult could be placed for possible prostate "pathology."<sup>39</sup> On the same day, a patient aligned care team (PACT) nurse left a message for the patient to return the call but did not document additional attempts to contact the patient by phone or certified letter as required by VHA.<sup>40</sup> Provider 2 did not specifically instruct the PACT nurse to communicate the abnormal PSA result to the patient.<sup>41</sup>

In interviews, facility leaders reported that Provider 2 should have communicated the PSA test result to the patient. The Chief of Primary Care reviewed the patient's EHR and concurred with the OIG that there was no evidence that the abnormal PSA test result was communicated to the patient. Provider 2 could not explain why the patient was not informed. The OIG found that the patient was not notified of the October 2020 PSA test result until March 2021 during an appointment with a general surgeon.

## Follow-Up Tests Completion

Provider 2 reported that in general, based on the symptoms the patient was experiencing, follow-up actions for the abnormal PSA result should include a repeat PSA in 30–60 days and an in-

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<sup>36</sup> Provider 1 left the facility in late July 2020.

<sup>37</sup> In interviews, the facility Clinical Applications Coordinator reported that when assigning surrogates, alerts were only sent to one provider. The Clinical Applications Coordinator further reported that notifications were not based on patient assignment, but rather based on the surrogate who was chosen. The assigned surrogate for Provider 1 was not Provider 2. The surrogate became the ordering provider and received notifications for tests that were still pending when Provider 1 left the facility.

<sup>38</sup> The OIG reviewed all notifications sent to Provider 2 and the surrogate provider from August through November 2020. No notifications, related to PSA lab results for the patient, were found in either providers' notifications list.

<sup>39</sup> The PACT nurse documented one attempt to contact the patient by phone in late November 2020, leaving a voicemail asking the patient to call back regarding an "important message from the provider."

<sup>40</sup> VHA Directive 1088.

<sup>41</sup> Provider 2 could not recall if the test results were communicated to the patient. The PACT nurse no longer worked for the facility at the time the OIG opened this inspection.

person visit to complete a digital rectal exam.<sup>42</sup> The Chief of Primary Care concurred that the appropriate next step in care would have been a repeat PSA and said that most providers would have completed an in-person visit with the patient. Provider 2 could not recall why a repeat PSA was not ordered or an in-person visit scheduled. The OIG considered that COVID-19 may have had an impact on in-person scheduling. However, according to the Chief of Primary Care, the facility's primary care COVID-19 scheduling was in Phase II with an increased number of in-person appointments and therefore, did not impede scheduling in-person appointments.<sup>43</sup> Provider 2 stated that scheduling processes allowed primary care providers to schedule in-person appointments as needed.

## Urology Consultations

The OIG determined that Provider 2 failed to refer the patient to Urology Service and coordinate timely imaging, which may have contributed to a delay in diagnosing the patient's prostate cancer.

VHA requires primary and specialty care providers to collaborate and ensure that patients receive comprehensive, coordinated, and timely health care.<sup>44</sup> Facility policy requires that providers requesting tests review prerequisite requirements and order necessary tests.<sup>45</sup> The facility urology consult directs providers to obtain "appropriate imaging based on consult guidelines," but does not indicate the specific imaging required for each diagnosis or symptom.

Provider 2 telephoned the patient in mid-August 2020 and documented a plan to treat the patient's urinary symptoms by continuing a medication for BPH, ordering a pelvic ultrasound, and then consulting Urology Service. Six days later, a medical support assistant scheduled the ultrasound, due to the COVID-19 pandemic, for December 2020, and entered a note in the EHR instructing the provider to contact the Diagnostic Imaging Service if there were questions or concerns. Provider 2 acknowledged the note the same day. According to the Chief of Diagnostic Imaging, at the beginning of the COVID-19 pandemic in March 2020, approximately 5,000 imaging orders were put on hold; the facility then slowly increased routine imaging scheduling capacity from 25 percent in June 2020 to 75 percent in January 2021. The Chief of Diagnostic Imaging confirmed that if imaging orders could not be completed within the

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<sup>42</sup> In late summer and early fall 2020, the patient was experiencing symptoms including "slow urinary flow with c/o [complaint of] incomplete bladder empty feelings" and "urgency to go to bathroom, but very slow stream and small amount of urine."

<sup>43</sup> At the facility, Primary Care Phase II COVID-19 scheduling processes were implemented on September 8, 2020. COVID screening and cleaning guidelines remained in place. Primary care physicians were expected to have availability for two in-person visits in the morning and two in-person visits in the afternoon. The remaining appointments could be virtual or by telephone.

<sup>44</sup> VHA Directive 1101.10, *Patient Aligned Care Team (PACT) Handbook*, February 5, 2014, amended May 26, 2017.

<sup>45</sup> Facility Policy 590-11-09, *Clinical Consultations*, April 4, 2019.

requested time frame, scheduling alerts were sent to ordering providers informing them of the earliest possible date and providers could call if sooner imaging was needed. In early December 2020, the patient requested the ultrasound appointment be postponed due to a conflict with a hip surgery. The ultrasound was completed in late March 2021, seven months after the order was originally placed.<sup>46</sup>

Provider 2 expressed difficulties with urology consults being canceled for lack of prerequisite imaging. The OIG reviewed 13 of Provider 2's urology consults from August 2020, through November 2020. Five of the consults were for lower urinary tract symptoms or elevated PSA. Three of the five consults lacked imaging; however, Urology Service completed the consults. Two of the five consults lacked imaging and were discontinued. Provider 2 did not place a urology consult for the patient. The Chief of Primary Care noted that in the case of an elevated PSA, without an ultrasound, the specialist could still provide a consultative opinion. A facility urologist explained that had Provider 2 reached out to request a consult without an ultrasound the patient would have likely been seen in Urology Service.

The OIG determined that Provider 2 was aware the patient's PSA had more than tripled, the patient continued to have urinary symptoms, and the patient's ultrasound was still incomplete. The OIG determined that Provider 2 did not attempt to consult Urology Service or expedite an ultrasound prior to the provider transferring to another VA medical center in mid-March 2021.

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<sup>46</sup> The radiologist's ultrasound report noted bladder wall thickening and an enlarged prostate gland.

### 3. Provider's Failure to Act on Community Care Recommendations

#### Consult with Urology Service

The OIG determined that Provider 2 failed to enter a urology consult, when a community care provider recommended that the patient follow up with a urologist. In mid-January 2021, Provider 2 documented receipt of a note stating that the non-VA discharge summary had been scanned into the EHR and was ready for review. This community care discharge note included a recommendation that the patient follow up with a urologist in 7–10 days for a voiding trial; however, Provider 2 did not order a urology consult or expedite an ultrasound. Provider 2 was unable to recall acknowledging receipt of the discharge note, but told the OIG that normal practice would have been to read the discharge summary, determine if a facility urologist could see the patient within a week, and if a facility urologist was unavailable, ask if the patient wanted to see a non-VA urologist.

#### Bone Scan Orders

The OIG determined that Provider 2 failed to correctly enter a bone scan order for the patient after a non-VA orthopedic surgeon sent a request to the facility for a three-phase bone scan, in early March 2021, to evaluate for infection or loosening of the implant after a total hip replacement. A facility nuclear medicine technologist (technologist) attempted to correct this error by entering a new order; however, the technologist entered a facility registered nurse, who had no knowledge of the patient, as the ordering provider. These errors led to a delay in notifying the patient of the abnormal imaging results.

In early March 2021, Provider 2 responded to the surgeon's request by ordering a [whole-body bone scan](#) to rule out osteoporosis. In response to this order, a facility nuclear medicine technologist (technologist) reported contacting Provider 2 to correct the order, as whole-body bone scans are not used to diagnose osteoporosis. Provider 2 incorrectly revised the order and requested a whole-body bone scan for "bone pathology" instead of the requested three-phase bone scan.

When the patient arrived in late March 2021, for the bone scan, the technologist reported noticing that Provider 2's second order was also incorrect. Facility standard operating procedures allowed technologists to make minor changes to imaging orders, such as changing a bone scan to a three-phase bone scan.<sup>47</sup> The technologist entered a new order for a three-phase bone scan of the patient's legs. A registered nurse, who did not order bone scans and had no knowledge or clinical ties to the patient, was listed as the ordering provider on this third order. Consequently, the notification for the results, which showed possible diffuse metastatic bone disease, was sent

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<sup>47</sup> Facility Policy, *Diagnostic Imaging Services Standard Operating Procedures Modification of Radiology Orders*, April 2018.

to the registered nurse instead of Provider 2. The registered nurse denied seeing the notification of results.

The technologist could not recall how the error occurred but proposed that because Provider 2 no longer worked at the facility on the day the third order was entered, the system may have defaulted to the registered nurse when the technologist entered Provider 2's initials. The technologist also suggested that she may have incorrectly typed Provider 2's initials. The order prints to a computer and the technologist told the OIG that typically the order is reviewed at that time, but she must not have realized that the registered nurse's initials were entered as the ordering provider.

Abnormal test results are to be communicated to the patient within seven days;<sup>48</sup> however, the bone scan results remained uncommunicated from the time the bone scan results were available in late March until early April 2021, 13 days later. At that time, Provider 3 became aware of the bone scan findings after being alerted to an unrelated matter, which referenced the results. Provider 3 then communicated the results to the patient.

The OIG concluded that due to order entry errors and failure to check the order when it was printed, the bone scan results were not communicated and acted upon by a provider until 13 days after the results were available.

#### **4. Additional Finding: Nurse Practitioner's Inadequate Telephone Triage**

During the inspection, the OIG determined that a nurse practitioner failed to adequately address the patient's urologic complaints during a post-discharge telephone triage call.

In early September 2020, a PACT nurse conducted a post-discharge call after the patient visited the Emergency Department for evaluation of low blood pressure. During the call, the patient complained of urinary symptoms, and the nurse referred the concerns to a nurse practitioner. However, the nurse practitioner did not contact the patient to assess the symptoms. Instead, the nurse practitioner recommended that the PACT nurse advise the patient to continue BPH medication and report to the Emergency Department for continued symptoms, pain, or blood in the urine. The nurse practitioner informed the OIG that the patient had BPH, and stated it is not uncommon for patients to have these urinary symptoms if they have prostate enlargement and are on BPH medication. The OIG determined that the nurse practitioner failed to assess the acuity, nature, and cause of the symptoms.

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<sup>48</sup> VHA Directive 1088.

## 5. Quality Management and Patient Safety Failures

The OIG determined that facility leaders did not initiate peer reviews within three days as required by VHA policy and that facility staff did not submit patient safety reports as required. In May 2021, the OIG sent a request for response to the facility describing concerns with providers' outpatient management of the patient's urological symptoms from July 2019 to April 2021. Upon receiving this request, the facility's Chief of QSV coordinated a review of the patient's care. The review, completed by the Risk Manager and service chiefs, was compiled by the Chief of QSV in June and identified multiple deficiencies in the patient's care.

### Peer Reviews

The OIG determined that facility leaders did not screen and initiate peer reviews within three days of identifying deficiencies in the patient's care as required by VHA policy.<sup>49</sup> On June 21, 2021, the Facility Director signed a written response to the OIG substantiating deficiencies in the patient's care. The written response stated the facility would initiate peer reviews across several providers' disciplines as a result. However, the peer reviews were not initiated until September 2021, after the facility leaders were notified of the opening of this OIG inspection.<sup>50</sup>

VHA requires that "information that may require a peer review...should be screened within 3 business days...of its identification" and "a determination made at that time as to whether a peer review" is appropriate.<sup>51</sup> According to VHA, abnormal laboratory or imaging test results not addressed by the responsible provider should be considered for peer review.<sup>52</sup> VHA also requires peer review committees to complete final reviews within 120 calendar days of determination of necessity unless a written request for an extension is approved by the facility director.<sup>53</sup> VHA delineates that the 120-day timeline begins once a designation memorandum is signed by the facility director or their designee initiating the peer review.<sup>54</sup> Facility policy assigns the responsibility of coordinating the peer review process to the Risk Manager.<sup>55</sup>

The Risk Manager acknowledged responsibility for screening the patient's care by auditing the EHR and developing a plan for peer reviews. Both the Chief of QSV and Risk Manager informed the OIG that the Chief of QSV did not alert the Risk Manager of the need for peer reviews until after the opening of this inspection. The Chief of QSV reported becoming distracted by other work and forgetting to inform the Risk Manager of the need for peer reviews.

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<sup>49</sup> VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

<sup>50</sup> VHA Directive 1190.

<sup>51</sup> VHA Directive 1190.

<sup>52</sup> VHA Directive 1190.

<sup>53</sup> VHA Directive 1190.

<sup>54</sup> VHA Directive 1190.

<sup>55</sup> Facility Policy 590-11-04, *Risk Management Program*, February 25, 2021.



The Risk Manager reported reviewing the patient's EHR and developing a written scope for the peer reviews in early September 2021. All peer reviews were initiated on September 8, 2021.<sup>56</sup> The facility's five peer reviews were completed within the required 120-day time frame.<sup>57</sup> The OIG determined that peer reviews were not screened and initiated in a timely manner, consistent with VHA policy, delaying facility leaders' ability to (a) identify staff who may need additional training, (b) improve quality of care, and (c) ensure patient safety.<sup>58</sup>

## Patient Safety Reports

The OIG determined that facility staff did not submit patient safety reports as required despite identifying deficiencies in the patient's care, including failures to notify the patient of abnormal test results. On June 21, 2021, the Facility Director signed a written response to the OIG substantiating deficiencies in the patient's care.

According to VHA, the Patient Safety Program aims to prevent harm to patients by reporting and reviewing adverse events, identifying underlying causes, and implementing changes to reduce the likelihood of recurrence.<sup>59</sup> Facility policy requires that all staff complete patient safety reports as soon as adverse events are discovered.<sup>60</sup>

The OIG found that patient safety reports were not submitted for the failures to communicate and act on test results. The Chief of QSV and Patient Safety Manager informed the OIG that the service-line staff member or employee who discovers an incident is responsible for entering the report. Despite awareness of deficiencies in the patient's care in June 2021, the Chief of QSV did not request that facility staff submit patient safety reports. The Chief of QSV acknowledged not informing the Patient Safety Manager of the deficiencies until September 2021, and the Patient Safety Manager also did not request that staff submit patient safety reports. Neither the Chief of QSV nor the Patient Safety Manager could explain why the request did not occur in this case. The OIG determined that facility staff and leaders were aware of deficiencies in the patient's care as early as June 2021; however, they took no action to initiate or submit patient safety reports. Completion of patient safety reports could have allowed for an earlier, more comprehensive, and accurate review of adverse events to identify root causes, implement changes, and prevent recurrences.<sup>61</sup>

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<sup>56</sup> VHA Directive 1190.

<sup>57</sup> VHA Directive 1190.

<sup>58</sup> VHA Directive 1190.

<sup>59</sup> VHA Handbook 1050.01, *VHA National Safety Improvement Handbook*, March 4, 2011. VHA defines adverse events as "untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or service provided within the jurisdiction of a medical facility, outpatient clinic, or other VHA facility."

<sup>60</sup> Facility Policy 590-11-28, *Patient Safety Improvement Program*, April 30, 2020.

<sup>61</sup> VHA Handbook 1050.01.

## Conclusion

The OIG identified multiple concerns with the patient's care. A vascular surgeon failed to communicate and act on an abnormal CT scan in July 2019. Although the surgeon provided the OIG with explanations for not communicating and acting on the test result, the vascular surgeon's actions were inconsistent with VHA policy.

Provider 2 also failed to communicate test results to the patient and to act on the patient's abnormal PSA test result in fall 2020. Provider 2 first noted the patient had an elevated PSA in late November 2020 and failed to communicate the abnormal PSA result to the patient, who was not notified of the test result until March 2021. Provider 2 reported that based on the symptoms the patient was experiencing, follow-up actions should have included a repeat PSA and an in-person visit but could not recall why no action was taken.

In mid-August 2020, Provider 2 ordered an ultrasound in response to the patient's urinary complaints. Despite Provider 2's awareness that the patient's PSA had more than tripled, the patient continued to have urinary symptoms, and the ultrasound was not yet complete, Provider 2 did not attempt to consult urology or expedite an ultrasound. The ultrasound was completed in late March 2021, seven months after the order was originally placed. Additionally, Provider 2 failed to enter a urology consult when a community care provider recommended that the patient follow up with a urologist.

Provider 2 also failed to correctly enter bone scan orders for the patient after a non-VA orthopedic surgeon sent a request to the facility for a three-phase bone scan. A technologist attempted to correct this error; however, the technologist entered a facility registered nurse with no knowledge of the patient as the ordering provider. Consequently, the notification for the results, which showed possible diffuse metastatic bone disease, was not sent to a provider.

The OIG determined a nurse practitioner failed to adequately address the patient's urologic complaints during a post-discharge telephone triage call in September 2020. During the call, the patient complained of urinary symptoms, and the nurse addressing the call referred the concerns to a nurse practitioner. The nurse practitioner did not contact the patient to assess the acuity, nature, and cause of the symptoms. Finally, facility leaders did not initiate peer reviews within three days as required by VHA policy, and facility staff did not submit patient safety reports as required.

## **Recommendations 1–7**

1. The Hampton VA Medical Center Director ensures that providers communicate, act on, and document a review of test results consistent with Veterans Health Administration policy.
2. The Hampton VA Medical Center Director determines why the abnormal prostate-specific-antigen test results were not alerted to an ordering or surrogate provider and if other patient test results during that time frame also warrant review.
3. The Hampton VA Medical Center Director ensures that abnormal test results are timely communicated to providers or providers' surrogates.
4. The Hampton VA Medical Center Director reviews the urology consult template and, if appropriate, ensures the specific imaging required for consultation is specified in the template.
5. The Hampton VA Medical Center Director ensures that procedures are in place to identify and reduce errors when staff place nuclear medicine orders.
6. The Hampton VA Medical Center Director ensures that facility staff submit patient safety reports consistent with Veterans Health Administration and Hampton VA Medical Center policy.
7. The Hampton VA Medical Center Director ensures that quality management staff initiate timely quality reviews when deficiencies in patient care are identified.

## Appendix A: VISN Director Memorandum

### Department of Veterans Affairs Memorandum

Date: May 5, 2022

From: Acting, VA Mid-Atlantic Health Care Deputy Network Director for VA Mid-Atlantic Health Care Network Director, VISN 6 (15N6)

Subj: Healthcare Inspection—Multiple Failures in Test Results Follow-up for a Patient Diagnosed with Prostate Cancer at the Hampton VA Medical Center in Virginia

To: Director, Office of Healthcare Inspections (54HL10)  
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. I appreciate the opportunity to review the draft report: Multiple Failures in Test Results Follow-Up for a Patient Diagnosed with Prostate Cancer at the Hampton VA Medical Center in Virginia.
2. I would like to thank the OIG Inspection team for a thorough review which identified opportunities for improvement.
3. I have reviewed the OIG recommendations, facility response and action plan and am committed to supporting process improvement and sustainment at Hampton VA Medical Center and throughout VISN 6.

*(Original signed by:)*

George B. Drexel IV  
Acting Deputy Network Director

## Appendix B: Facility Director Memorandum

### Department of Veterans Affairs Memorandum

Date: May 27, 2022

From: Executive Director, Hampton VA Medical Center (590/00)

Subj: Healthcare Inspection—Multiple Failures in Test Results Follow-up for a Patient Diagnosed with Prostate Cancer at the Hampton VA Medical Center in Virginia

To: Director, VA Mid-Atlantic Health Care Network (10N06)

1. Thank you for the opportunity to review and respond to the draft report, *Multiple Failures in Test Results Follow-Up for a Patient Diagnosed with Prostate Cancer at the Hampton VA Medical Center in Virginia*.
2. Since taking this role as the Executive Director of the Hampton VAMC on January 17<sup>th</sup>, 2021, we continuously strive to improve the quality of healthcare for our Veterans at the Hampton VAMC.
3. I have reviewed the draft report and concur with the recommendations. The findings outlined in the OIG report reflect a thorough evaluation.
4. If you have any questions regarding the information provided, please contact Chief, Quality, Safety and Value.

(Original signed by:)

Taquisa K. Simmons, PhD, LCSW  
Executive Director

## Facility Director Response

### Recommendation 1

The Hampton VA Medical Center Director ensures that providers communicate, act on, and document a review of test results consistent with Veterans Health Administration policy.

Concur.

Target date for completion: September 30, 2022

### Director Comments

Since assuming the role of Medical Center Director, the Hampton VA Medical Center has strengthened its oversight of processes for providers to communicate, act on, and document a review of test results consistent with VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015 (Amendment January 24, 2022). On March 1, 2022, the Chief of Staff issued a Standard Operating Procedure (SOP), *Addressing CPRS Alerts*, to reinforce guidelines for communicating, responding to, and documenting test results. Mandatory CPRS View Alert Provider education has been developed and assigned for completion in TMS by June 30, 2022, recurring annually. To monitor compliance, the Chief of Staff will audit 50 electronic health records each month of patients who had diagnostic tests ordered. The review will include if the results were communicated to the patient per VHA Directive 1088 requirements and acted upon appropriately. Data will be collected until 90% compliance has been met for six (6) consecutive months and will be reported to the Medical Executive Council for oversight.

### Recommendation 2

The Hampton VA Medical Center Director determines why the abnormal prostate-specific-antigen test results were not alerted to an ordering or surrogate provider and if other patient test results during that time frame also warrant review.

Concur.

Target date for completion: September 30, 2022

### Director Comments

In October 2021, the Chief of Staff completed a retrospective administrative review of care administered by Provider 1 and Provider 2 during the timeframe of January 1, 2019 - March 13, 2021. All abnormal results were appropriately addressed by the providers. It was determined the ordering providers did not establish a surrogate during their annual leave and the facility did not have a policy for designating surrogates while providers were on leave. To address this

deficiency, the Chief of Staff issued a Standard Operating Procedure (SOP), *Addressing CPRS Alerts*, to establish guidelines for assigning surrogates to review “View Alerts” for test results. All services were required to implement for service level compliance. To monitor compliance, all Service Chiefs will track all providers on leave and ensure a surrogate is assigned to review “View Alerts.” Data will be collected and aggregated until 90% of compliance has been met for six (6) consecutive months and reported to the Medical Executive Council for oversight.

### **Recommendation 3**

The Hampton VA Medical Center Director ensures that abnormal test results are timely communicated to providers or providers’ surrogates.

Concur.

Target date for completion: September 30, 2022

#### **Director Comments**

The Chief of Staff has strengthened the oversight of providers to ensure abnormal test results are communicated timely to the provider/surrogate. On April 27, 2022, the Chief of Staff sent an email to all providers on the requirements for notification of abnormal results within seven (7) days, as required by VHA Directive 1088. The Chief of Staff created a mandatory annual TMS *CPRS View Alerts* training which addresses timely communication to providers/surrogates. This training has been assigned to all providers for completion by June 30, 2022. In addition, the Chief of Staff will inform all Licensed Independent Practitioners of the requirements for timely communication of abnormal test results to the ordering provider or surrogate at the mandatory staff meeting on May 12, 2022. The Chief of Staff will audit 50 electronic health records each month for patients who had diagnostic tests ordered with abnormal results to ensure results were communicated timely to the provider/surrogate. Data will be collected until 90% compliance has been met for six (6) consecutive months and will be reported to the Medical Executive Council for oversight.

### **Recommendation 4**

The Hampton VA Medical Center Director reviews the urology consult template and, if appropriate, ensures the specific imaging required for consultation is specified in the template.

Concur.

Target date for completion: September 30, 2022

#### **Director Comments**

On April 2, 2022, the Urology Service and Clinical Application Coordinators revised the Urology Consult template to include specific testing and imaging required for consultation in accordance with guidelines in VHA Directive 1102.01, *National Surgery Office*. The Chief of Staff notified all providers on the revised Urology Consult template on April 22, 2022, via email and will reinforce this information during the mandatory staff meeting on May 12, 2022. All Licensed Independent Practitioners will be assigned TMS training on the revisions of the Urology Consult template and will self-certify upon completion. The completion rates of the TMS training will be tracked until 90% of LIPs have self-certified review of the Urology Consult template revisions. Completion rates will be reported to Medical Executive Council for oversight.

### **Recommendation 5**

The Hampton VA Medical Center Director ensures that procedures are in place to identify and reduce errors when staff place nuclear medicine orders.

Concur.

Target date for completion: September 30, 2022

### **Director Comments**

The Chief of Staff implemented a new process that requires all nuclear medicine orders will be reviewed by the Radiology Technologist prior to implementation of the orders. Radiology has initiated an educational process for all providers which includes training on the ordering of nuclear medicine testing. *The Ordering Nuclear Medicine PowerPoint* was revised and is being used as a training tool for all providers and this information will be shared by the Chief of Staff during the mandatory staff meeting on May 12, 2022. The Chief of Radiology will conduct monthly record reviews to ensure no errors are in the ordering process until 90% compliance is met for six (6) consecutive months and data will be reported to the Medical Executive Council to ensure leadership oversight.

### **Recommendation 6**

The Hampton VA Medical Center Director ensures that facility staff submit patient safety reports consistent with Veterans Health Administration and Hampton VA Medical Center policy.

Concur.

Target date for completion: September 30, 2022

### **Director Comments**



The Hampton VA Medical Center Director ensures oversight of reporting processes will be accomplished using the Joint Patient Safety Reporting (JPSR) system according to VHA Handbook 1050.01, *VHA National Safety Improvement Handbook*, March 4, 2011. Facility-wide monthly Patient Safety Forums were implemented to increase staff awareness and education of the JPSR process as of September 29, 2021. A second Patient Safety Manager was hired on February 28, 2022. The High Reliability Organization (HRO) Champions will be trained as JPSR Super-Users to provide additional service level support to all staff by May 13, 2022. The JPSR Super-Users will share information during service level huddles and meetings. Effective May 3, 2022, the Patient Safety Managers will establish office hours for JPSR Reporters, Super-Users and JPSR Reviewers. The office hours will allow for information sharing, Just-In-Time (JIT) training and JPSR troubleshooting. A mandatory annual TMS Patient Safety/JPSR training will be initiated for all staff by June 30, 2022. All staff will be required to complete initial JPSR training by September 30, 2022. This required training will be communicated to all staff during the Patient Safety Forums, New Employee Orientation, Director's Town Hall meeting and the All-Leadership Morning Report. Completion rates of the TMS training will be tracked until 90% of all staff have completed the training. The Patient Safety Managers will report the completion of these actions and TMS training compliance to the Quality, Safety, and Value Council to ensure executive leadership oversight.

## **Recommendation 7**

The Hampton VA Medical Center Director ensures that quality management staff initiate timely quality reviews when deficiencies in patient care are identified.

Concur.

Target date for completion: September 30, 2022

## **Director Comments**

The Hampton VA Medical Center Director ensures quality management staff initiates timely quality reviews when patient care deficiencies are identified. The Chief, Quality, Safety and Value, Risk Manager and the Patient Safety Managers will meet biweekly to ensure quality reviews are initiated within three (3) days for any patient care deficiencies resulting from OIG Hotlines, JPSR events and Occurrence Screens. The Risk Manager will monitor and track the timely initiation of quality reviews and report monthly to the Quality, Safety and Value Council. Data will be collected until 90% compliance has been met for six (6) consecutive months.

## Glossary

*To go back, press “alt” and “left arrow” keys.*

**benign prostatic hyperplasia.** An enlargement of the prostate gland.<sup>62</sup>

**computerized tomography.** A cross-sectional, multi-angle using x-rays to produce an internal image of the body, primarily used for diagnostic reasons.”<sup>63</sup>

**computerized tomography angiogram.** A computerized tomography angiogram combines a computerized tomography scan with an injection of dye to produce images of blood vessels and tissue in the body.<sup>64</sup>

**digital rectal exam.** An examination of the back wall of the prostate gland, to assess for lumps, enlargement, hard spots, or tenderness. The exam is performed by a provider inserting a gloved finger into the rectum.<sup>65</sup>

**gastroenterology.** A branch of medicine concerned with the structure, functions, diseases, and pathology of the stomach and intestines.<sup>66</sup>

**kidney failure.** The inability of the kidneys to filter waste from the blood.<sup>67</sup>

**magnetic resonance imaging.** A magnetic field and radio waves produce a cross-sectional, three-dimensional internal image of the body, primarily used for diagnostic reasons.<sup>68</sup>

**metastatic.** The spread of a disease-producing agency (such as cancer cells) from the initial or primary site of disease to another part of the body.<sup>69</sup>

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<sup>62</sup> Mayo Clinic, “Benign Prostatic Hyperplasia (BPH),” accessed December 2, 2021, <https://www.mayoclinic.org/diseases-conditions/benign-prostatic-hyperplasia/symptoms-causes/syc-20370087?p=1>.

<sup>63</sup> Mayo Clinic, “Computerized Tomography (CT),” accessed December 1, 2021, <https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-2039>.

<sup>64</sup> John Hopkins, “Computed Tomography Angiography,” accessed March 7, 2022, <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/computed-tomography-angiography-cta#:~:text=CT%20angiography%20is%20a%20type.in%20your%20arm%20or%20hand>.

<sup>65</sup> Mayo Clinic, “Digital Rectal Exam,” accessed December 1, 2021, <https://www.mayoclinic.org/diseases-conditions/prostate-cancer/multimedia/digital-rectal-exam/img-20006434>.

<sup>66</sup> Merriam-Webster.com Dictionary, “Medical definition of gastroenterology,” accessed March 1, 2022, <https://www.merriam-webster.com/dictionary/gastroenterology>.

<sup>67</sup> Mayo Clinic, “Kidney Failure,” accessed December 1, 2021, <https://www.mayoclinic.org/diseases-conditions/kidney-failure/symptoms-causes/syc-20369048>.

<sup>68</sup> Mayo Clinic, “Magnetic Resonance Imaging,” accessed December 1, 2021, <https://www.mayoclinic.org/tests-procedures/mri/about/pac-20384768>.

<sup>69</sup> Merriam-Webster.com Dictionary, “Metastatic,” accessed December 2, 2021, <https://www.merriam-webster.com/dictionary/metastatic>.

**osteoblastic.** A bone-forming cell.<sup>70</sup>

**prostate biopsy.** A procedure to remove tissue from the prostate.<sup>71</sup>

**prostatitis.** Swelling and inflammation of the prostate gland.<sup>72</sup>

**three-phase bone scan.** Used to diagnose a fracture when not detected on x-ray. In addition, it can diagnose bone infection, bone pain, and osteomyelitis.<sup>73</sup>

**ultrasound.** Uses high-frequency sound waves to produce an internal image of the body.<sup>74</sup>

**urinary catheter.** A thin, flexible catheter used to drain urine from the bladder by way of the urethra.<sup>75</sup>

**voiding trial.** Testing to assess a patient's ability to empty their bladder after a urinary catheter is removed.<sup>76</sup>

**whole-body bone scan.** Used "to detect areas of abnormal bone growth due to fractures, tumors, infection, or other bone diseases."<sup>77</sup>

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<sup>70</sup> Merriam-Webster.com Dictionary, "osteoblastic," accessed December 1, 2021, <https://www.merriam-webster.com/dictionary/osteoblastic>.

<sup>71</sup> Mayo Clinic, "Prostate biopsy," accessed December 6, 2021, <https://www.mayoclinic.org/tests-procedures/prostate-biopsy/about/pac-20384734?p=1>.

<sup>72</sup> Mayo Clinic, "Prostatitis," accessed December 1, 2021, <https://www.mayoclinic.org/diseases-conditions/prostatitis/symptoms-causes/syc-20355766>.

<sup>73</sup> Cleveland Clinic, *Three Phase Bone Scan*, accessed December 13, 2021, <https://my.clevelandclinic.org/health/diagnostics/17554-three-phase-bone-scan>.

<sup>74</sup> Mayo Clinic, "Ultrasound," accessed December 1, 2021, <https://www.mayoclinic.org/tests-procedures/ultrasound/about/pac-20395177>.

<sup>75</sup> Merriam-Webster.com Dictionary, "foley catheter," accessed December 1, 2021, <https://www.merriam-webster.com/dictionary/Foley%20catheter>.

<sup>76</sup> National Institute of Health, "Voiding Trial," accessed March 1, 2022, <https://clinicaltrials.gov/ct2/show/NCT02886143>. A voiding trial is a test used to assess a patient's ability to empty their bladder after a urinary catheter is removed.

<sup>77</sup> Cleveland Clinic, *Whole Body Bone Scan*, accessed October 25, 2021, <https://my.clevelandclinic.org/health/diagnostics/17642-whole-body-bone-scan>.

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