Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 17-02678-107

Healthcare Inspection

Alleged Failure in Patient Notification of Test Results
VA Connecticut Healthcare System
West Haven, Connecticut

February 27, 2018

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess an alleged failure in patient notification of test results at the VA Connecticut Healthcare System, West Haven VA Medical Center (facility), West Haven, CT.

The complainant alleged that: (a) a urologist failed to advise a patient of his prostate-specific antigen (PSA) results, and the lack of notification allowed prostate cancer to spread to his lymph nodes and seminal vesicles; (b) a provider failed to inform the patient of a high PSA reading (greater than (>) 9.0) collected in mid–2015; and (c) 6 months elapsed before he was informed that his PSA was >11.0, and he had prostate cancer.

We did not substantiate that a provider[1] failed to notify the patient in mid–2015 that the patient's PSA test result was elevated. A PSA was ordered and completed on Day 1. According to the patient in an interview, the provider notified him the PSA test result was elevated during a clinic visit on Day 3 and instructed him to return to the facility in 2 weeks for further testing. According to the patient's electronic health record (EHR), the provider documented a plan of care that the patient return the next week for a repeat PSA. The significance of the PSA test was not known on Day 3; additional testing was needed to determine the reason for the elevated level. The patient did not return in the recommended time frame. The provider(s) at issue was/were no longer employed at VA and therefore we did not have the authority to compel the provider(s) to speak with the OIG. Thus, we were unable to fully evaluate the extent of the provider-patient interaction/communication on Day 3 when the patient was informed of the PSA results.

At the time of the mid–2015 episodes of care, Veterans Health Administration (VHA) policy required that results be communicated to patients no later than 14 calendar days from the date on which the results are available to the ordering provider. For abnormalities that required immediate attention, the 14-day limit was irrelevant, as the communication should occur in the timeframe that minimizes risk to the patient.[2]

We reviewed the laboratory results in the patient's electronic health record that reflected an elevated PSA test result (>9.0 ng/mL) on Day 1.[3,4] We noted that the provider documented an assessment and a plan of care during the clinic visit on Day 3, which included a urinalysis, urine culture, and a "…repeat PSA next week, no ejaculation 48 hours prior to sample being obtained."

[1] While the term "urologist" was used in the allegation, the provider who evaluated the patient in mid-2015 on the days in question was not a urologist.
[2] VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009. This Directive expired in March 2014; it was rescinded and replaced by VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015, which modified time frames and documentation requirements.
[3] The facility normal PSA range was 0–4 ng/mL.
[4] Some medical tests report results in nanograms (ng) per milliliter (mL). A nanogram is one-billionth of a gram. https://metrohealth.net/healthwise/nanograms-per-milliliter-ngml/. Accessed June 19, 2017.

A urinalysis was ordered and done on Day 3. We did not find evidence that the patient was notified of the results of the Day 3 urinalysis, which were abnormal.[5] As noted above, we were not able to interview the provider(s), so we do not know why the patient was not notified of the urinalysis results.

We did not find evidence of a scheduled return appointment or visit the next week for a repeat PSA as documented in the provider's Day 3 plan of care. The next scheduled appointment was several months later on Day 134 for a Mental Health Pharmacy visit. The patient attended the Day 134 appointment. During an OIG interview, in reference to the Day 3 recommendation to return for a repeat PSA, the patient stated "… if I knew I had cancer, I would have been there in a minute, in a second." The patient also told us that his recollection of the Day 3 visit included being told he had a "high PSA," that he should return to the facility in 2 weeks, and not "masturbate" prior to his return.

On Day 147, the patient presented to the Emergency Department/Urgent Care Clinic (ED/UCC). The patient verbalized symptoms of dry cough for 5 months and a fever. The ED/UCC provider ordered a chest x-ray and other laboratory tests including a urinalysis which was abnormal with white blood cells, red blood cells, and bacteria. He was treated with an oral antibiotic for possible pneumonia or urinary tract infection. Documentation also included a recommendation for follow-up within 1 to 2 weeks and return to the ED/UCC sooner if symptoms worsened.

On Day 162, the patient returned to the ED/UCC with a chief complaint of persistent cough. An ED/UCC provider documented, "subacute hematuria without clear evidence renal inflammtory [sic] process."[6] The provider documented a plan for the patient to return within 48 hours.

On Day 164, the patient returned to the ED/UCC and received the results of the Day 162 laboratory tests. The provider documented a plan of care that stated, "f/u [follow up] with PMD [primary medical doctor] in one week to evalaute [sic] to painless hematuria > 3 months.''

On Day 170, the patient returned for a primary care visit; the primary care provider ordered a PSA. The PSA was completed and the patient was notified that the PSA was elevated (>11.0 ng/mL) on the day of the primary care visit. On Day 174, a primary care provider entered a request for routine urology consult in the patient's EHR.

On Day 189, a urology provider assessed the patient for hematuria and an elevated PSA. The plan of care included a cystoscopy and a prostate biopsy (diagnostic test).[7,8] The provider noted in the EHR: "The risks and benefits of the studies have been

[5] The abnormalities were hazy rather than clear and 1+ blood rather than negative blood.
[6] Hematuria is a term that denotes blood in the urine.
[7] Cystoscopy is an examination of the bladder and urethra using a cystoscope, inserted into the urethra. A cystoscope is a thin, tube-like instrument with a light and a lens for viewing. It may also have a tool to remove tissue to be checked under a microscope for signs of disease.
[8] A biopsy is the removal of cells or tissues for examination by a pathologist.

explained and the pt [patient] wishes to proceed." On Day 227, a urologist performed a cystoscopy and a prostate biopsy.

On Day 260, during a follow-up appointment, a urology provider reviewed the diagnostic test results, informed the patient of a prostate cancer diagnosis, and developed a plan of care that included surgery. On Day 318, the patient underwent a prostatectomy.[9] He subsequently completed adjuvant radiation therapy and androgen deprivation therapy. Approximately 9 months later, a urologist documented that a PSA test result was less than (<) 0.01 ng/mL. In late 2017, the PSA was <0.01 ng/ml.

The VHA policy effective in June 2015 required providers to communicate results to patients no later than 14 calendar days from the date on which the results were available to the ordering provider. The policy also required providers to document the patient received and understood the results.[10] VHA policy effective in October 2015 requires providers to communicate test results requiring action no later than 7 calendar days from the date on which the results are available along with documentation of patient notification and clinical actions.[11]

Although we found the patient was informed of the results of his mid–2015 PSA testing done on Day 1, we did not find documentation of patient notification regarding the Day 3 abnormal urinalysis test result.

We recommended that the Facility Director ensure providers follow the VHA policy related to patient notification of test results.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendation and provided an acceptable action plan. (See Appendixes B and C, pages 11–13 for the Directors' comments.) We will follow up on the planned action until completed.

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

[9] A prostatectomy is a surgery to remove part or all of the prostate and some of the tissue around it. Nearby lymph nodes may also be removed. The surgery may be done through an open incision (cut) made in the wall of the lower abdomen or the perineum, or by using a laparoscope (a thin, tube-like instrument with a light and lens for viewing).
[10] VHA Directive 2009-019.
[11] VHA Directive 1088.

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess an alleged failure in patient notification of test results at the VA Connecticut Healthcare System, West Haven VA Medical Center (facility), West Haven, CT.

Background

Facility Profile

The facility, part of the VA New England Healthcare System, Veterans Integrated Service Network (VISN) 1, has 191 beds, including 119 in-patient beds, 32 domiciliary beds, and 40 community living center beds. The facility is associated with six community based outpatient clinics located in Danbury, New London, Stamford, Waterbury, Willimantic, and Winsted.

Prior reports for this facility include *Review of Community Based Outpatient Clinics and Other Outpatient Clinics of VA Connecticut Healthcare System, West Haven, Connecticut* (Report No. 16-00027-318) published June 10, 2016 with two recommendations related to notification of test results.

- **Recommendation 4**. We recommended that the Facility Director ensure that the facility's written policy for the communication of laboratory results includes all required elements.
- **Recommendation 5**. We recommended that clinicians consistently notify patients of their laboratory results as required by VHA.

The Veterans Integrated Service Network and Facility Directors agreed with the findings and recommendations and provided acceptable plans for improvement. Recommendation 4 was closed October 7, 2016 and Recommendation 5 was closed September 29, 2017.

Prostate-Specific Antigen

Prostate-specific antigen (PSA) is a glycoprotein that is expressed by both normal and abnormal prostate tissue. The prostate is an organ of the male reproductive system located directly below the bladder and above the muscles of the pelvic floor.[12] While PSA is consistently expressed in nearly all prostate cancers, benign conditions such as prostatitis (inflammation of the prostate), urinary tract infections, and benign prostatic hyperplasia are also frequently associated with an elevated PSA level. A provider may perform a physical exam, urinalysis, and urine culture and sensitivity to confirm whether an infection is causing the elevated PSA level.[13,14] Recent ejaculation can cause an

[12] Pub Med Health, *How does the prostate work?* August 23 2016. https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0072475. Accessed May 4, 2017.
[13] UA is an acronym for urinalysis, which is a urine test that includes chemical and microscopic analysis.

elevation in PSA level, and patients with a PSA elevation may be asked to repeat testing after refraining from sexual activity for several days.

Once a patient has biopsy-proven prostate cancer, the PSA level is useful for determining the extent of prostate cancer and assessing the response to prostate cancer treatment; its use as a screening method to detect prostate cancer is also common, although controversial. As prostate size increases with increasing age, the PSA concentration also rises; it increases at a faster rate in elderly men.[15]

In 2012, the U.S. Preventive Service Task Force (USPSTF) published an updated clinical guideline recommendation against PSA-based screening for prostate cancer.[16] As a result, the VHA National Center for Health and Disease Prevention published the following guidelines for providers:

> *The past common use of PSA for prostate cancer screening and/or concerns about potential increased risk or exposures may lead some Veterans to request screening and clinicians to provide it…VHA recommends that any decision to initiate or continue prostate cancer screening with PSA for any man should be based on a decision between the patient and the provider…about whether screening is appropriate for the patient, based on his values about the potential small reduction in prostate cancer mortality and associated moderate to large potential harms of screening and subsequent treatment for most men.*
>
> *VHA does not recommend prostate cancer screening with PSA for men ages 45-70 who are not at increased risk of prostate cancer, men younger than age 45 or older than 70, and men of any age or risk status who have an estimated life expectancy of less than approximately 15 years.* ***However, if screening is specifically requested by the patient and discussed with his provider as above, screening may be done*** *[emphasis added].*
>
> *VHA makes no recommendations for or against screening for prostate cancer with PSA for men ages 45-70 years who may be at increased risk of prostate cancer and who also have an estimated life expectancy of more than approximately 15 years.*
>
> *Those who may be at increased risk include African American men, men with a family history of prostate cancer in a first degree relative, and potentially, men who may have been exposed to Agent Orange.*

[14] UCx is an acronym for urine culture, which involves propagation of microorganisms on or in media of various kinds followed by sensitivity testing, which involves the application of specific antibiotics to determine which antibiotic inhibits or kills the microorganisms..
[15] Up To Date, *Measurement of Prostate-specific Antigen*, April 18, 2017, https://www.uptodate.com/contents/measurement-of-prostate-specific-antigen/print?source. Accessed May 3, 2017.
[16] Boyer, Virginia A. on behalf of the U.S. Preventive Services Task Force, *Clinical Guideline: Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement*, May 22, 2012.

> *Although these men may be at increased risk of prostate cancer, there is insufficient evidence about the balance between benefits and harms of screening for prostate cancer in these men.*[17]

Ordering and Reporting Test Results

VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009 was in effect at the time of the events discussed in this report. The Directive required providers to document treatment actions in response to critical, emergent or abnormal test results in the patient's electronic health record (EHR), and communicate outpatient test results in accordance with the following standards:[18]

> *Results are communicated to patients no later than 14 calendar days from the date on which the results are available to the ordering practitioner. Significant abnormalities may require review and communication in shorter timeframes and 14-days represents the outer acceptable limit. For abnormalities that require immediate attention, the 14-day limit is irrelevant, as the communication should occur in the timeframe that minimizes risk to the patient.*

The Directive also stated that communication may occur in person, by telephone, or in writing. Providers were to document communication of the test results to patients outside of the setting of an outpatient visit in the patient's EHR . Providers were also to:

> *Document that the communication was received and understood, for communications where it is important for the patient to quickly take some kind of actions, such as a change in medication or a return to the medical center for further evaluation.*

Providers with responsibility over resident physicians who order tests must ensure that required communication and documentation occurs.

The 2009 Directive was rescinded and replaced by VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015. The 2015 Directive requires that, generally, test results are to be communicated to patients within 7 calendar days for results requiring action and 14 days for those that do not require any action. The 2015 Directive does not require that providers document that the communication was received and understood; the 2015 Directive states: "the extent of documentation may vary depending on the context of the test result and resultant action plan or therapeutic interventions."

Allegation. In March 2017, OIG received a complaint alleging failure in notification of test results. The complainant alleged that: (a) a urologist failed to advise a patient of his PSA results, and the lack of notification allowed prostate cancer to spread to his lymph nodes and seminal vessels; (b) a provider failed to inform the patient of his high PSA

[17] VHA National Center for Health Promotion and Disease Prevention (NCP), *Screening for Prostate Cancer*. The source of this information is an internal VA website not available to the public. Accessed May 2, 2017.
[18] VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009. This Directive expired on March 31, 2014; it was rescinded and replaced by VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.

reading (>9.0) collected in mid-2015; and (c) 6 months elapsed before he was informed that his PSA was >11.0, and he had prostate cancer.

Scope and Methodology

We initiated our inspection in May 2017. We did not conduct a site visit. We telephonically interviewed the complainant. We were not able to interview the provider(s) at issue as they were no longer employed at VA; we did not have authority to compel the provider(s) to speak with us. We reviewed the patient's EHR, relevant VHA and local facility policies, clinical guidelines for prostate cancer screening and select articles from the medical literature.

VHA Directive 2006-041, *Veterans Health Care Service Standards*, June 27, 2006, cited in this report expired on June 30, 2011.[19] In a June 29, 2016, memorandum to supplement policy provided by VHA Directive 6330(3),[20] the VA Under Secretary for Health (USH) mandated the "…continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."[21] The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "…the timely rescission or recertification of policy documents over which their program offices have primary responsibility."[22]

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

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

[19] VHA Directive 2006-041, *Veterans Health Care Service Standards*, June 27, 2006.
[20] VHA Directive 6330(3), *Controlled National Policy/Directives Management System*, June 24, 2016.
[21] VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.
[22] Ibid.

Patient Case Summary

The patient is a male in his 60s with a past medical history significant for anxiety and chronic back pain. He was seen regularly in primary care (PC) and mental health clinics at the facility since 2011. In 2013, during a PC clinic visit, the provider reviewed laboratory results and discussed lifestyle modifications to improve cholesterol and glucose levels, as well as weight loss with the patient. Documentation of the laboratory results showed the patient's PSA was < 2.5 ng/mL.

The patient's next PC visit was in mid-2015 (Day 1) when he presented as a walk-in to a PC urgent clinic reporting finger pain. The provider evaluated and treated the finger pain and ordered routine laboratory studies[23] and a PSA. The provider instructed the patient to return in 2 days for follow-up.

On Day 3, the patient attended a follow-up appointment with the same PC urgent clinic provider.[24] In an EHR note, the provider documented several Day 1 laboratory results, including an elevated PSA of >9.0 ng/mL, as well as findings related to the injured finger, and recommendations for pain management for the finger. In the Assessment and Plan section of the patient's EHR, the provider noted:

> *high PSA:*
>
> *-UA/UCx[25,26]*
> *-repeat PSA next week, no ejaculation 48 hours prior to sample being obtained*

In accordance with the plan, the PC urgent clinic provider entered orders for a UA (urinalysis)/UCx (urine culture) and a repeat PSA. The urinalysis was completed on Day 3 before the patient left the facility.

The patient's next visit to the facility was about 4 months later for a scheduled Mental Health pharmacy appointment on Day 134. On Day 147, the patient called the facility call center complaining of headaches, fatigue, and "problems remembering things." Approximately one hour later, he presented to the facility's Emergency Department/Urgent Care Center (ED/UCC). The patient was evaluated and treated with antibiotics for a urinary tract infection and advised to follow-up in 1 to 2 weeks with his

[23] Laboratory Studies included a chemistry 7 panel (a group of blood tests that provides information about the body's metabolism which includes blood urea nitrogen (BUN), chloride (CO2), creatinine, serum chloride, serum potassium, serum sodium), a lipid panel (a group of blood test that measures fats and fatty substances used as a source of energy for the body which includes cholesterol, triglycerides, high density lipoprotein (HDL) and low density lipoprotein (LDL), and an A1c (a blood test that provides average levels of blood glucose, also called blood sugar, over the past 3 months and is used for diabetes management).
[24] While the term "urologist" was used in the allegation, the provider who evaluated the patient in mid-2015 on the days in question was not a urologist.
[25] UA is an acronym for urinalysis, which is a urine test that includes chemical and microscopic analysis.
[26] UCx is an acronym for urine culture, which involves propagation of microorganisms on or in media of various kinds followed by sensitivity testing, which involves the application of specific antibiotics to determine which antibiotic inhibits or kills the microorganisms.

PC provider. On Day 162, the patient again presented to the facility's ED/UCC. Documentation shows a chief complaint of persistent cough. A chest CT and bloodwork were ordered. The ED/UCC physician diagnosed him with a viral syndrome and recommended fluids and rest. At the follow-up appointment 2 days later on Day 164, the ED/UCC physician reviewed the imaging and blood work from Day 162 and noted blood in the patient's urine (hematuria). The physician recommended follow-up with the PC provider in one week for further management.

The patient attended a PC appointment on Day 170. During that appointment, the PC provider placed a referral to Urology Service to further evaluate the patient's elevated PSA and hematuria. On Day 189, a urology provider assessed the patient and scheduled a prostate biopsy and a flexible cystoscopy. On Day 227, the flexible cystoscopy showed a normal bladder, with no evidence of a tumor. The prostate biopsy, which was performed the same day, confirmed that the patient had prostate cancer. On Day 318, the patient underwent a prostatectomy. Since the cancer had extended into the seminal vesicles, and one lymph node, the patient also completed adjuvant radiation therapy and androgen deprivation therapy. The patient continued to receive follow-up treatment in the Urology Clinic in 2017.

Inspection Results

Issue: Notification of Test Results

We did not substantiate that the provider failed to notify the patient about a mid-June 2015 (Day 1) elevated PSA test result. Based on our interview with the patient, we determined that the provider notified the patient that his PSA test result was elevated on Day 3, and instructed the patient to return to the facility for further testing.

At the time of the Day 3 episode of care, VHA policy required that results be communicated to patients no later than 14 calendar days from the date on which the results were available to the ordering provider. For abnormalities that required immediate attention, the 14-day limit was irrelevant, as the communication should occur in the timeframe that minimizes risk to the patient.[27]

We reviewed the laboratory results in the patient's EHR which reflected an elevated PSA test result (>9.0 ng/mL) on Day 1.[28,29] We noted that the provider documented an assessment and a plan of care during the clinic visit on Day 3, which included a urinalysis, urine culture, and a "…repeat PSA next week, no ejaculation 48 hours prior to sample being obtained."

A urinalysis was ordered and done on Day 3. We did not find evidence that the patient was notified of the results of the Day 3 urinalysis, which were abnormal.[30]

We did not find evidence of a scheduled return appointment or visit the next week as documented in the provider's Day 3 plan of care. The next scheduled appointment was about 4 months later on Day 134 for a Mental Health Pharmacy visit. The patient attended the Day 134 appointment. During an OIG interview, in reference to the Day 3 recommendation to return for a repeat PSA, the patient stated, "… if I knew I had cancer, I would have been there in a minute, in a second." The patient further recounted his recollection of the Day 3 visit which included being told that he had a "high PSA," that he should return to the facility in 2 weeks, and not "masturbate" prior to his return.

On Day 147, the patient presented to the ED/UCC. The patient verbalized symptoms of dry cough for 5 months and a fever. The ED/UCC provider ordered a chest x-ray and other laboratory tests including a urinalysis which was abnormal with white blood cells, red blood cells, and bacteria. He was treated with an oral antibiotic for possible pneumonia or urinary tract infection. Documentation also included a recommendation

[27] VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009. This Directive expired in March 2014; it was rescinded and replaced by VHA Directive 1088, *Ordering and Reporting Test Results*, October 7, 2015 which modified time frames and documentation requirements.
[28] The facility normal PSA range was 0–4 ng/mL.
[29] Some medical tests report results in nanograms (ng) per milliliter (mL). A nanogram is one-billionth of a gram. https://metrohealth.net/healthwise/nanograms-per-milliliter-ngml/. Accessed June 19, 2017.
[30] The abnormalities were hazy rather than clear and 1+ blood rather than negative blood.

for follow-up within 1 to 2 weeks and return to the ED/UCC sooner if symptoms worsened.

On Day 162, the patient returned to the ED/UCC with a chief complaint of persistent cough. An ED/UCC provider documented, "subacute hematuria without clear evidence renal inflammotry [sic] process."[31] The provider documented a plan for the patient to return within 48 hours.

Two days later, on Day 164, the patient returned to the ED/UCC and received the results of the laboratory tests done on Day 162. The provider documented a plan of care that stated, "f/u [follow up] with PMD [primary medical doctor] in one week to evalaute [sic] to painless hematuria > [greater than] 3 months.''

On Day 170, the patient returned for a primary care visit; the primary care provider ordered a PSA. The PSA was completed and the patient was notified that the PSA was elevated (>11.0 ng/mL) on the day of the visit (Day 170). On Day 174, a primary care provider entered a request for a routine urology consult in the patient's EHR.

On Day 189, a urology provider assessed the patient for hematuria and an elevated PSA. The plan of care included a cystoscopy and a prostate biopsy (diagnostic test).[3233] We found documentation stating, "[t]he risks and benefits of the studies have been explained and the pt [patient] wishes to proceed." On Day 227, a urologist performed a cystoscopy and a prostate biopsy.

On Day 260, during a follow-up appointment, a urology provider reviewed the diagnostic test results, informed the patient of his prostate cancer diagnosis, and developed a plan of care that included surgery. On Day 318, the patient underwent a prostatectomy.[34] He subsequently completed adjuvant radiation therapy and androgen deprivation therapy. Approximately 9 months later, a urologist documented a PSA test result less than 0.01 ng/mL.[35]

The VHA policy effective in June 2015 required providers to communicate results to patients no later than 14 calendar days from the date on which the results are available to the ordering provider. The policy also required providers to document the patient

[31] Hematuria is a term that denotes blood in the urine.
[32] Cystoscopy is an examination of the bladder and urethra using a cystoscope, inserted into the urethra. A cystoscope is a thin, tube-like instrument with a light and a lens for viewing. It may also have a tool to remove tissue to be checked under a microscope for signs of disease.
[33] A biopsy is the removal of cells or tissues for examination by a pathologist. The pathologist may study the tissue under a microscope or perform other tests on the cells or tissue. There are many different types of biopsy procedures. The most common types include: (1) incisional biopsy, in which only a sample of tissue is removed; (2) excisional biopsy, in which an entire lump or suspicious area is removed; and (3) needle biopsy, in which a sample of tissue or fluid is removed with a needle. When a wide needle is used, the procedure is called a core biopsy. When a thin needle is used, the procedure is called a fine-needle aspiration biopsy.
[34] A prostatectomy is a surgery to remove part or all of the prostate and some of the tissue around it. Nearby lymph nodes may also be removed. The surgery may be done through an open incision (cut) made in the wall of the lower abdomen or the perineum, or by using a laparoscope (a thin, tube-like instrument with a light and lens for viewing).
[35] In late 2017, the PSA was <0.01 ng/ml.

received and understood the results.[36] VHA policy effective in October 2015 requires providers to communicate test results requiring action no later than 7 calendar days from the date on which the results are available along with documentation of patient notification and clinical actions.[37]

Conclusions

We did not substantiate that the provider failed to notify the patient about an elevated PSA test result in mid-2015. Based on our interview with the patient, we determined that the provider notified the patient that his mid-2015 PSA test result was elevated 2 days after the test was done, and instructed the patient to return to the facility. According to the EHR, the provider documented in his plan of care that the patient return the next week for a repeat PSA. The significance of the PSA test was not known in mid-2015; additional testing was needed to determine the reason for the elevated level. The patient did not return in the recommended time frame. The provider(s) at issue was/were no longer employed at VA and therefore we did not have the authority to compel the provider(s) to speak with us. Thus, we were unable to fully evaluate the extent of the provider-patient interaction/communication on Day 3.

Although we found the patient was informed of his mid-2015 PSA results, we did not find documentation of patient notification regarding the Day 3 abnormal urinalysis test result.

Recommendation

We recommended that the Facility Director ensure providers follow the Veterans Health Administration policy related to patient notification of test results.

[36] VHA Directive 2009-019.
[37] VHA Directive 1088.

Appendix A

Prior OIG Reports June 1, 2013 – June 1, 2017

Facility Reports

Audit of VA's Recruitment, Relocation, and Retention Incentives
1/5/2017 | 14-04578-371

Combined Assessment Program Review of the VA Connecticut Healthcare System, West Haven, Connecticut
6/23/2016 | 16-00116-323

Review of Community Based Outpatient Clinics and Other Outpatient Clinics of VA Connecticut Healthcare System, West Haven, Connecticut
6/10/2016 | 16-00027-318

VA's Federal Information Security Modernization Act Audit for Fiscal Year 2015
3/15/2016 | 15-01957-100

Healthcare Inspection – Potential Exposure to Creutzfeldt-Jakob Disease, VA Connecticut Healthcare System, West Haven, Connecticut
7/1/2014 | 13-04520-201

Topic Related Reports

Review of Community Based Outpatient Clinics and Other Outpatient Clinics of Amarillo VA Health Care System, Amarillo, Texas
6/23/2016 | 16-00028-337

Combined Assessment Program Review of the Amarillo VA Health Care System, Amarillo, Texas
6/14/2016 | 16-00118-321

Healthcare Inspection – Alleged Substandard Prostate Cancer Screening, VA Eastern Colorado Health Care System, Denver, CO
9/3/2015 | 14-03833-385

Combined Assessment Program Review of the Amarillo VA Health Care System, Amarillo, Texas
9/13/2013 | 13-02313-310

Healthcare Inspection – Review of a Patient with Medication-Induced Acute Renal Failure, Amarillo VA Health Care System, Amarillo, Texas
7/29/2013 | 13-01988-253

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Appendix B

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: November 17, 2017

From: Director, VA New England Healthcare System (10N1)

Subj: **Healthcare Inspection**— Alleged Failure in Patient Notification Test Results, VA Connecticut Healthcare System, West Haven, Connecticut

To: Director, Chicago Office of Healthcare Inspections (54CH)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank you for the opportunity to review the draft report. I have reviewed and concur with the action plan regarding the Healthcare Inspection — Alleged Failure in Patient Notification of Test Results, VA Connecticut Healthcare System, West Haven, Connecticut.

2. If you have any questions, please contact the Quality Management Officer for VISN 1 at (781) 687-4979.

(original signature on file:)
Michael F. Mayo-Smith, MD, MPH

Appendix C

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: November 17, 2017

From Director, VA Connecticut Healthcare System, West Haven Campus (689/00)

Subj: **Healthcare Inspection**— Alleged Failure in Patient Notification of Test Results, VA Connecticut Healthcare System, West Haven, Connecticut

To: Director, VA New England Healthcare System (10N1)

1. VA Office of Inspector General (OIG) conducted a healthcare inspection in 2017 to assess an allegation of failure in patient notification of test results.

2. We have reviewed the OIG's draft report and recommendation. We concur with the recommendation, and we are providing an action plan to address it.

3. Thank you for the opportunity to review and address the allegations and findings. If you have any questions concerning this matter, please contact the Chief of Staff at 203-937-3825.

(original signature on file:)
Gerald Culliton

Comments to OIG's Report

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

OIG Recommendation

Recommendation. We recommended that the Facility Director ensure providers follow the Veterans Health Administration policy related to patient notification of test results.

Concur

Target date for completion: February 28, 2018

Facility response: VA Connecticut Healthcare System (VACT) immediately convened the appropriate stakeholders for review of VHA Directive and our health system policy regarding patient notification of test results. VACT has been monitoring reporting of test results monthly to ensure compliance using a random sampling methodology since 2016. VACT maintains overall compliance of 97% since April 2017 and will continue to evaluate quarterly compliance and report it through Quality Management.

Appendix D

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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Appendix E

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