



**Department of Veterans Affairs  
Office of Inspector General**

**Office of Healthcare Inspections**

**Report No. 14-03833-385**

## **Healthcare Inspection**

# **Alleged Substandard Prostate Cancer Screening VA Eastern Colorado Health Care System Denver, Colorado**

**September 3, 2015**

**Washington, DC 20420**

**To Report Suspected Wrongdoing in VA Programs and Operations:**

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## Executive Summary

At the request of Congressman Mike Coffman, the VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to determine the quality of care provided to a patient who alleged that substandard prostate cancer screening delayed his diagnosis of prostate cancer at the VA Eastern Colorado Health Care System (facility), Denver, CO.

We did not substantiate that the patient received substandard prostate cancer screening.

We found that accepted guidelines for prostate cancer screening vary. Prostate-specific antigen (PSA) testing without a digital (finger) rectal examination (DRE) for prostate cancer screening of an asymptomatic patient from 2007 to present was consistent with U.S. Preventive Services Task Force (USPSTF) guidelines, VA guidance, and 2013 American Urological Association (AUA) guidelines. Past guidelines, such as the 2009 AUA Best Practice Statement, differ from recent publications.

Test results in September 2011 showed that the patient had an elevated PSA level. A DRE performed in March 2012 revealed the patient had an enlarged prostate. Further testing later in March 2012 showed the PSA level was within normal range. The patient had a urology visit in April, a prostate biopsy in May, and a referral to radiation oncology in June 2012. The patient was reportedly cancer free at the time of this review.

We made no recommendations.

### Comments

The Veterans Integrated Service Network and Facility Directors concurred with the report. (See Appendixes A and B, pages 8–9 for the Directors' comment.) No further action is required.



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

## Purpose

At the request of Congressman Mike Coffman, the VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to determine the quality of care provided to a patient who alleged that substandard prostate cancer screening delayed his diagnosis of prostate cancer at the VA Eastern Colorado Health Care System (facility), Denver, CO.

## Background

**Facility Profile.** The facility provides primary, tertiary, and long-term care and offers a broad range of inpatient and outpatient health care services. It is part of Veterans Integrated Service Network (VISN) 19 and serves a patient population of approximately 350,000 throughout the Front Range of Colorado and into Wyoming. The facility operates 10 primary care clinics in Colorado and provided care to 847,827 veterans in 2013.

**Prostate Cancer.** Prostate cancer is a cancer that forms in tissues of the prostate—a gland in the male reproductive system found below the bladder and in front of the rectum. Prostate cancer usually occurs in older men. The National Cancer Institute estimated there will be 233,000 new cases of prostate cancer resulting in 29,480 deaths in 2014.<sup>1</sup>

**Trends in Prostate Cancer Screening.** Medical and professional organizations such as the American Urological Association (AUA), the U.S. Preventive Services Task Force (USPSTF), and the Veterans Health Administration (VHA) have published guidelines for prostate cancer screening. The guidelines for prostate cancer screening have evolved over the past 15 years.

The 2008 USPSTF guidelines made no specific recommendation for or against the digital (finger) rectal examination (DRE) in prostate cancer screening, while the 2009 AUA statement recommended both a prostate-specific antigen (PSA) test and a DRE for patients who wished to be screened. While the 2009 AUA statement<sup>2</sup> advocated for DRE testing, it also noted that data from the largest randomized study on screening for prostate cancer found, “. . . that DRE did not improve prostate cancer screening over PSA testing alone.”<sup>3</sup>

Concerns about overdiagnosis and overtreatment of prostate cancer have been noted for at least a dozen years. In its 2002 recommendation statement, the USPSTF concluded that “...although potential harms of screening for prostate cancer can be established, the presence and magnitude of potential benefits cannot be determined.”

<sup>1</sup> National Cancer Institute at the National Institutes of Health. Prostate Cancer. <http://www.cancer.gov/cancertopics/types/prostate>. Accessed August 22, 2014.

<sup>2</sup> Greene KL et al. Prostate Specific Antigen Best Practice Statement: 2009 Update. *J Urol*. 2009 Nov; 182(5):2232–41.

<sup>3</sup> European Randomized Study of Screening for Prostate Cancer. <http://www.erspc.org>. Accessed January 13, 2015.

Early on, the detection of prostate cancer through screening was considered beneficial. As long-term follow-up data for patients in screening studies became available, researchers have been able to observe outcomes after screening in addition to the rates of detection of prostate cancer. In reviewing such data, concerns arose about the balance of benefit and harm from screening, specifically that prostate cancer detected through screening would have remained otherwise undetected during the patient's life (overdiagnosis) and that such patients could be harmed by an unnecessary, invasive procedure (overtreatment).<sup>4</sup>

**VHA Prostate Cancer Screening.** VHA guidance is similar to many clinical guidelines in that it seeks to balance the risks and benefits of screening and promote sharing of information and decision-making between the health care provider and patient.<sup>5,6,7,8,9</sup> According to VHA guidance published for providers on an internal intranet site, "The past common use of PSA for prostate cancer screening and/or concerns about potential increased risk of exposures may lead some Veterans to request screening and clinicians to provide it."<sup>10,11</sup> 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."

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 greater than 70, or men of any age or risk status who have an estimated life expectancy of less than approximately 15 years.<sup>12</sup> However, if screening is specifically requested by the patient and discussed with provider, screening may be done.

VHA makes no recommendations for or against screening with PSA for men ages 45–70 who may be at increased risk of prostate cancer and who also have a life expectancy of 15 years or more. VHA guidance further states, "Although this statement

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<sup>4</sup> Bangma CH, Roemeling S, Schroder FH. Overdiagnosis and Overtreatment of early detected prostate cancer. *World J Urol.* 2007 Mar, 25(1); 3–9.

<sup>5</sup> VHA National Center for Health Promotion and Disease Prevention. Prostate Cancer Screening. [http://vaww.prevention.va.gov/Prostate\\_Cancer\\_Screening.asp](http://vaww.prevention.va.gov/Prostate_Cancer_Screening.asp). Accessed August 22, 2014.

<sup>6</sup> National Cancer Institute at the National Institutes of Health Prostate Cancer Treatment (PDQ®). [http://www.cancer.gov/cancertopics/pdq/treatment/prostate/HealthProfessional#Section\\_1679](http://www.cancer.gov/cancertopics/pdq/treatment/prostate/HealthProfessional#Section_1679). Accessed August 22, 2014.

<sup>7</sup> U.S. Preventive Services Task Force. Prostate Cancer: Screening, May 2012. <http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/prostate-cancer-screening>. Accessed August 22, 2014.

<sup>8</sup> American Urological Association. Early Detection of Prostate Cancer: AUA Guideline, April 2013. <https://www.auanet.org/education/guidelines/prostate-cancer-detection.cfm>. Accessed August 25, 2014.

<sup>9</sup> American Cancer Society. Prostate Cancer Early Detection. Revision February 25, 2014. <http://www.guideline.gov/content.aspx?id=24814>. Accessed August 22, 2014.

<sup>10</sup> VHA National Center for Health Promotion and Disease Prevention. Prostate Cancer Screening. [http://vaww.prevention.va.gov/Prostate\\_Cancer\\_Screening.asp](http://vaww.prevention.va.gov/Prostate_Cancer_Screening.asp). Accessed August 22, 2014.

<sup>11</sup> A PSA test measures the blood level of PSA, a protein that is produced by the prostate gland. A PSA is often elevated in men with prostate cancer; however, a number of benign (not cancerous) conditions may cause a PSA level to rise.

<sup>12</sup> VHA National Center for Health Promotion and Disease Prevention. Prostate Cancer Screening. [http://vaww.prevention.va.gov/Prostate\\_Cancer\\_Screening.asp](http://vaww.prevention.va.gov/Prostate_Cancer_Screening.asp). Accessed August 22, 2014.

concerns PSA-based prostate cancer screening, there is no evidence to recommend screening with other means, for example, with digital rectal exams (DRE).”<sup>13</sup>

**Allegation.** The patient alleged he received substandard prostate cancer screening that subsequently delayed his diagnosis of prostate cancer.

## Scope and Methodology

The period of review was from July 1, 2014, through March 5, 2015. We conducted a site visit July 16, 2014. We interviewed the patient, Chief of Urology, urology staff, primary care providers (PCPs), a patient advocate, and the University of Colorado Medical Center (University) physician who provided radiation oncology services to the patient. We also interviewed surgical and non-surgical VHA national subject matter experts and a non-VHA urologist on prostate cancer screening.

We reviewed the patient’s electronic health record (EHR) and non-VA hospital records. We also reviewed clinical guidelines, VHA and facility policies, pertinent medical literature, and other relevant documents related to prostate cancer screening, as well as applicable patient advocate reports.

We received other allegations related to intimidation and personally identifiable information that were outside the scope of this inspection and not addressed in this report.

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.

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<sup>13</sup> VHA National Center for Health Promotion and Disease Prevention. Prostate Cancer Screening. [http://vaww.prevention.va.gov/Prostate\\_Cancer\\_Screening.asp](http://vaww.prevention.va.gov/Prostate_Cancer_Screening.asp). Accessed August 22, 2014.

## Case Summary

The patient, a male in his sixties, was diagnosed with prostate cancer in 2012. A first degree relative died of prostate cancer in 2005.

The patient has received care at the facility since 2005. In December 2008, the patient's primary care provider (PCP A) moved from outpatient care at the facility to a community based outpatient clinic (CBOC) within the Denver metropolitan area. The patient continued his care at the CBOC until May 2010 when he requested to be assigned to a new PCP (PCP B) at the facility since he lived nearby.

The patient had annual PSAs and received counseling about the risks and benefits of screening for prostate cancer from 2007 to 2011, except for 2010. In 2010, the patient made phone calls to discuss his care, stopped by periodically, and visited PCP B for problem-focused care, such as back pain. In September 2010, the patient called the facility primary care clinic and reported a brief stay at a community hospital for "...a syncope episode which resulted in an ultrasound showing an enlarged prostate." The patient requested diagnostic tests including a PSA and was advised to see his PCP. We found no evidence in the EHR that the patient made an appointment during this time frame to see his PCP.

In September 2011, PCP B ordered a PSA test. PCP B sent the patient a letter informing him that his PSA level was elevated and that the universal range for a PSA does not take into account an individual's age or the fact that as one ages, PSA levels normally increase.<sup>14</sup> The provider recommended the PSA test be repeated in 6 months.

In March 2012, PCP B conducted a DRE, noting that the left lobe of the prostate was harder than the right, and ordered a urology consult. The PSA test was repeated later in March, and results showed a PSA level in the normal range. The urologist saw the patient in April, noting the prostate was nodular and documenting that this could be a prostate cancer or possibly benign prostate hypertrophy without obstruction. The urologist recommended a prostate biopsy and discussed the procedure with the patient in detail.

In mid-May 2012, the patient had an ultrasound-guided prostate biopsy that revealed high-grade prostate cancer.<sup>15</sup> Four days later, the patient's PSA level was elevated; however, this elevated value was attributed to his recent prostate biopsy. One week after the biopsy, the urology resident spoke to the patient about his prostate cancer diagnosis and explained that the next steps in his care would be to obtain a computerized tomography and/or bone scan, a creatinine, and a repeat PSA. In addition, a cancer consult was ordered.

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<sup>14</sup> Richardson TD, Oesterling JE. Age-specific reference ranges for serum prostate-specific antigen. *Urol Clin North Am.* 1997 May; 24(2): 339-51.

<sup>15</sup> Prostate cancer is graded on its microscopic features. High grade cancers are more likely to spread and have a worse prognosis.

At the beginning of June, the patient met with the urology chief resident. A lengthy discussion ensued regarding treatment options, including all risks and benefits. Options included radical surgery (robotic or open), external beam radiotherapy, brachytherapy, hormonal ablation therapy, or active surveillance. The patient expressed a preference to proceed with radiation and hormone therapy. A referral was made to the radiation oncology department at a non-VA facility.

Three days later, the patient informed a VA care provider of his prostate cancer diagnosis and stated he was not going to have treatment. According to the care provider's notes in the EHR, the patient expressed anger towards PCP B because he had refused to perform a DRE. The patient requested and was assigned another PCP (PCP C). In mid-June, PCP C saw the patient and noted the patient expressed frustration about delays in the non-VA medical care referral process and his unhappiness with PCP B.

At the end of June, a radiation oncologist at the non-VA facility met with the patient to plan his radiation treatment. The radiation oncologist noted the patient's diagnosis was a high-grade prostate adenocarcinoma.<sup>16</sup>

Image guided radiotherapy<sup>17</sup> was completed before November. In addition, the patient received 6 months of hormone therapy with a pre-radiation PSA level that had decreased. The radiation oncologist told us at the time of our interview with him that the patient was cancer free. As of December 2014, the patient's last two PSAs were within normal limits.

## Inspection Results

We did not substantiate that the patient received substandard prostate cancer screening.

PCP B started seeing the patient in 2010. The patient told us that PCP B refused to perform a requested DRE—the test that ultimately led to the patient's diagnosis of prostate cancer. The patient told us he did not discuss his concerns regarding the DRE with other providers prior to his diagnosis. We interviewed PCP B who told us that the patient did not request a DRE, and he would not have refused a request for a DRE. We reviewed the patient's EHR and did not find documentation that the patient requested a DRE or that the PCP refused to perform a DRE.

Because we could not confirm what discussions occurred between the patient and the provider(s) by reviewing the patient's EHR, we reviewed current and past prostate cancer screening guidance to determine whether PSA testing without a DRE is an indicator of low quality care.

<sup>16</sup> An adenocarcinoma is a type of cancer.

<sup>17</sup> Image guided radiation therapy involves the use of imaging technology such as X-ray, ultrasound, or optical imaging to accurately direct the delivery of radiation during radiation therapy treatment and reduce irradiation of normal tissue thus reducing collateral damage.



Current VHA guidance published in August 2013 recommends PSA testing after shared decision making with the patient, but not a DRE. Prior to August 2013, VHA providers generally followed the USPSTF recommendations. Between 2010 and 2012, while the patient received primary care from PCP B, the USPSTF guidance did not make a recommendation for the use of DRE in addition to PSA testing.

VHA subject matter experts reported that outcome-based studies looking at combining the DRE with PSA testing have not shown a significant benefit from the combination testing. In its most recent prostate cancer screening guidelines in 2013, the AUA changed its position from its 2009 guidance and did not recommend DRE testing for initial screening:<sup>18</sup> “Although DRE has been considered the mainstay of screening together with PSA, the Panel could find no evidence to support the continued use of DRE as a first line screening test.”<sup>19</sup>

The patient had annual PSAs from 2007–2011, except for 2010 when a PSA was not performed. When he did have an out-of-range PSA in 2011, it was repeated in 6 months, and a DRE was performed. Based on the abnormal DRE, PCP B referred the patient to a urologist. A biopsy was obtained, prostate cancer was diagnosed, and appropriate treatment was provided.

We found that during the time that the patient has been receiving care at VHA, prostate screening guidelines have differed. PSA testing without a DRE for prostate cancer screening of an asymptomatic patient from 2010 to present was, and is, consistent with current guidelines from several organizations such as USPSTF, VHA, and 2013 AUA guidelines. Past guidelines such as the 2009 AUA Best Practice Statement differ from recent publications. Given this, we would expect that practicing clinicians during this time would reasonably differ in their expectations for prostate cancer screening.

While we found that accepted guidelines for prostate cancer screening vary and are evolving, the most recent guidelines are in greater agreement than the past and acknowledge the concerns of overdiagnosis and overtreatment.

## Conclusions

We did not substantiate that the patient received substandard prostate cancer screening.

We found that accepted guidelines for prostate cancer screening vary. PSA testing without a DRE for prostate cancer screening of an asymptomatic patient from 2007 to present was consistent with USPSTF guidelines, VA guidance, and 2013 AUA guidelines. Past guidelines such as the 2009 AUA Best Practice Statement differ from recent publications.

<sup>18</sup> American Urological Association. Early Detection of Prostate Cancer: AUA Guideline, April 2013. <https://www.auanet.org/education/guidelines/prostate-cancer-detection.cfm>. Accessed August 25, 2014.

<sup>19</sup> Ibid

In September 2011, the patient had an elevated PSA. The patient's PCP performed a DRE in March 2012, which revealed an enlarged prostate. However, testing later in March 2012 showed the patient's PSA returned to normal. The patient had a urology visit in April, a prostate biopsy in May, and a referral to radiation oncology in June 2012. The patient was reportedly cancer free at the time of this review.

We made no recommendations.

## VISN Director Comments

**Department of  
Veterans Affairs**

## Memorandum

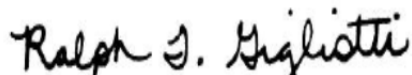
**Date:** April 1, 2015

**From:** Director, VA Rocky Mountain Network (10N19)

**Subj:** Healthcare Inspection—Alleged Substandard Prostate Cancer Screening, VA Eastern Colorado Health Care System, Denver, Colorado

**To:** Director, Denver Office of Healthcare Inspections (54DV)  
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. I have reviewed and concur on the comments from VA Eastern Colorado HCS and the findings of no substantiation and no recommendations for this report of Alleged Substandard Prostate Cancer Screening.
2. If you have any additional questions, please contact Ms. Susan Curtis, VISN 19 HSS at (303) 639-6995.



Ralph T. Gigliotti, FACHE

## System Director Comments

**Department of  
Veterans Affairs**

## Memorandum

**Date:** March 23, 2015

**From:** Acting Director, VA Eastern Colorado Health Care System (554/00)

**Subj:** Healthcare Inspection—Alleged Substandard Prostate Cancer Screening, VA Eastern Colorado Health Care System, Denver, Colorado

**To:** Director, Rocky Mountain Network (10N19)

1. VA ECHCS primary care providers continue to use a combination of clinical reminders to screen for prostate health risks and utilize approved clinical practice guidelines to adhere to current and appropriate treatment techniques in collaboration with our Veteran patients. This investigation found no evidence to indicate the care provided to this Veteran was sub-standard.
2. VA ECHCS embraces a culture of transparency and is open to audits regarding the care provided to our Veterans. We continue to partner with our Veterans to achieve their health care goals.



Natalie A. Merckens

## Office of Inspector General Contact and Staff Acknowledgments

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