

#### Office of Healthcare Inspections

Report No. 15-05123-254

# **Healthcare Inspection**

# Alleged Misdiagnosis and Delay in Treatment Providence VA Medical Center Providence, Rhode Island

June 15, 2017

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## **Executive Summary**

The VA Office of Inspector General conducted a healthcare inspection to evaluate allegations that a provider at the Providence VA Medical Center (facility), Providence, RI, misdiagnosed a patient's Achilles tendon rupture (ATR) in 2014 leading to a delay in treatment and further injury to the Achilles tendon. Specifically, the complainant alleged that:

- On two occasions, an Emergency Department (ED) provider ignored (did not respond to) a patient's complaint that he may have a torn Achilles tendon and misdiagnosed him with a sprained ankle.
- The ED provider's misdiagnosis delayed the treatment for the patient's ATR.
- The misdiagnosis, delay in treatment for ATR, and the initial treatment provided for a sprained ankle versus an ATR worsened the patient's injury.

We substantiated that on two occasions an ED provider did not respond to a patient's complaint that he may have an ATR and misdiagnosed him with a sprained ankle. We also substantiated that the provider did not fully assess the patient's injury and misdiagnosed the injury as a sprained ankle on both ED visits in 2014. A review of the patient's electronic health record indicated that the provider did not conduct a Thompson (calf squeeze) test<sup>1</sup> to elicit foot movement, a common, definitive diagnostic test used to identify a potential ATR.

We substantiated that the sprained ankle misdiagnosis caused a delay in treatment of the patient's ATR. Sixteen days elapsed from the patient's initial presentation to the ED with complaints of Achilles tendon pain to the diagnosis of ATR.

We could not substantiate that the misdiagnosis, delay in treatment for the ATR, and the treatment prescribed for a sprained ankle versus an ATR in the ED worsened the injury. A delay in ATR diagnosis or treatment may result in a worse outcome. Providers utilize a combination of ATR-specific clinical assessments and tests to diagnose and determine the extent of an ATR. However, because the ED provider did not document the proper assessments, which would have provided a clinical baseline of the ATR, we could not discern whether the injury became worse during the 16 days the patient followed the treatment plan for a sprained ankle.

Besides the 16 day delay, we identified other timeframes when different treatments affecting optimal outcomes could have occurred. The initial assessment occurred 3 days after the injury. The patient was given options for conservative or surgical treatments within 4 weeks of injury and decided to pursue conservative treatment. The patient had complaints of persistent pain after 6 months of conservative treatment with serial casting and sought options for possible surgical interventions. The orthopedic

<sup>&</sup>lt;sup>1</sup> To administer the Thompson test, the patient lies face down while the examiner squeezes the patient's calf muscle to assess whether the foot flexes forward. The test is positive for ATR if there is little or no movement of the foot and ankle compared with the unaffected side.

surgeon documented in the patient's electronic health record, that during the discussion of surgical options, he advised the patient recovery of the full use of the ankle was unlikely and at a subsequent visit documented that the Achilles tendon had healed in a lengthened state. The following month the patient decided to undergo Achilles tendon surgery.

We could not determine the extent to which the 3-day delay in seeking treatment, the 16-day delay in diagnosis, and/or the 6-month delay occasioned by the patient's initial choice of non-operative treatment contributed to the unfavorable healing of the Achilles tendon.

We found a peer review was done but documentation of the peer review process was incomplete.

We identified that the Chief of Emergency Medicine did not follow up on the patient's complaint about his first ED visit. The Chief of Emergency Medicine attempted to contact the patient, left a voice mail message, and did not follow up when he did not hear back from the patient.

We recommended that the Facility Director (a) ensure that peer reviews are completed and reported as required by the Veterans Health Administration and (b) strengthen processes to ensure that patient complaints are resolved in accordance with facility policy.

#### Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 12–14 for the Directors' comments.) We consider Recommendation 1 closed. We will follow up on the planned actions for Recommendation 2 until they are completed.

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

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## **Purpose**

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate allegations that, in 2014, a provider at the Providence VA Medical Center (facility), Providence, RI, misdiagnosed a patient's Achilles tendon rupture (ATR) leading to a delay in treatment and further injury to the Achilles tendon.

#### **Background**

The facility operates 73 inpatient beds and provides medicine, surgery, and psychiatry services. It delivers primary and secondary health care services at the main campus in Providence and at community based outpatient clinics in New Bedford and Hyannis, MA, and Middletown, RI. The facility is part of Veterans Integrated Service Network (VISN) 1.

**ATR.** The Achilles tendon is a strong cord of dense tissue fibers that connects the calf muscles to the heel bone<sup>2</sup> and facilitates walking, running, and jumping.<sup>3</sup> While it is the strongest tendon in the human body, the Achilles tendon endures frequent use and stress making it prone to injury.<sup>4</sup> An ATR is a tearing or separation of the tendon fibers making its normal functions difficult to perform.<sup>5</sup> It is one of the most common sports related injuries, most often the result of repetitive overuse, and frequently seen in athletes.<sup>6</sup> Typically, an ATR occurs in men between the ages of 30 and 50 years who have had no prior injury in the affected leg.<sup>7</sup>

*Symptoms.* Patients with an ATR generally complain of pain and swelling near the heel and the inability to "push off" from the leg when walking, stand on their toes, or flex the foot downward. Some patients may recall hearing a popping or snapping sound at the time of the rupture and be unable to walk.<sup>8</sup>

*Diagnosis*. Providers must make a prompt and accurate diagnosis of an ATR to provide patients with timely and effective care. Without appropriate assessment by a physician

0598/Work%20Papers/American%20Journal%20of%20Emergency%20Medicine.pdf. Accessed

VA Office of Inspector General

<sup>&</sup>lt;sup>2</sup> Mayo Clinic. Achilles Tendon Rupture: Definition. <a href="http://www.mayoclinic.org/diseases-conditions/achilles-tendon-rupture/basics/definition/con-20020370">http://www.mayoclinic.org/diseases-conditions/achilles-tendon-rupture/basics/definition/con-20020370</a>. Accessed September 2, 2016.

<sup>&</sup>lt;sup>3</sup> American Academy of Orthopaedic Surgeons. Achilles Tendon Rupture (Tear). http://orthoinfo.aaos.org/topic.cfm?topic=AV0003. Accessed September 2, 2016.

<sup>&</sup>lt;sup>4</sup> Metzl, J. A., Ahmad, C. S., Levine, W. N. The ruptured Achilles tendon: operative and non-operative treatment options. *Current Reviews in Musculoskeletal Medicine*, 1(2), 161–164. http://doi.org/10.1007/s12178-008-9025-4.

<sup>&</sup>lt;sup>5</sup> American Academy of Orthopaedic Surgeons. Achilles Tendon Rupture (Tear). http://orthoinfo.aaos.org/topic.cfm?topic=AV0003. Accessed September 2, 2016.

<sup>&</sup>lt;sup>6</sup> Adhikari, S, Marx, J., Crum, T. Point of care ultrasound diagnosis of acute Achilles tendon rupture in the ED. *The American Journal of Emergency Medicine*. 2012: 30.634.e3-634.e4. https://vaww.portal.oig.va.gov/directorates/54/Hotlines/2015-05123-HI-

September 2, 2016.

<sup>&</sup>lt;sup>7</sup> Ibid.

<sup>&</sup>lt;sup>8</sup> Mayo Clinic. Achilles Tendon Rupture: Symptoms. <a href="http://www.mayoclinic.org/diseases-conditions/achilles-tendon-rupture/basics/symptoms/con-20020370">http://www.mayoclinic.org/diseases-conditions/achilles-tendon-rupture/basics/symptoms/con-20020370</a>. Accessed September 6, 2016.

or other provider, the condition can often be mistaken for a sprain.9 According to the American Academy of Orthopaedic Surgeons clinical practice guideline on the Diagnosis and Treatment of Acute Achilles Tendon Rupture, 10,11 healthcare providers may diagnose an ATR with a detailed patient history and physical examination. The diagnosis of an ATR should include two or more of the following clinical findings:

- Positive Thompson (calf squeeze) test 12
- Positive Matles (knee flexion) test<sup>13</sup>
- Evidence of a tendon gap, defect, or loss of contour upon palpation <sup>14,15</sup>
- Inability to flex foot downward or away from body (ankle plantar flexion)<sup>16</sup>

Utilizing the above clinical assessments to diagnose an ATR has the advantage of being inexpensive and noninvasive. The Thompson test is the most reliable, the even when used as the sole method to determine whether an ATR has occurred. 19 In addition to these assessments, providers can use magnetic resonance imaging or ultrasound to help confirm diagnosis and determine the extent of the injury such as a complete or partial tear.<sup>20</sup> Basic x-rays generally do not identify specific tendon damage and may be more useful in ruling out injuries such as bone fractures and dislocation of ioints.<sup>21</sup> Tendons are soft tissue and may be seen as shadows on a basic x-ray.

<sup>&</sup>lt;sup>9</sup> A sprain, commonly in the ankle, is the stretching or tearing of ligaments that connect bones together in joints. <sup>10</sup> The Clinical Practice Guidelines are not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis.

<sup>&</sup>lt;sup>11</sup> American Academy of Orthopaedic Surgeons. The Diagnosis and Treatment of Acute Achilles Tendon Rupture Guideline and Evidence Report. Adopted by the American Academy of Orthopaedic Surgeons Board of Directors December 4, 2009. http://www.aaos.org/research/guidelines/atrguideline.pdf. Accessed March 10, 2017.

<sup>&</sup>lt;sup>12</sup> To administer the Thompson test, the patient lies face down while the examiner squeezes the patient's calf muscle to assess whether the foot flexes forward. The test is positive for ATR if there is little or no movement of the foot and ankle compared with the unaffected side.

<sup>&</sup>lt;sup>13</sup> The exam is considered positive when the patient lies in the prone position with knees bent at 90 degrees and is unable to flex his/her foot upward and toward the body.

<sup>&</sup>lt;sup>14</sup> Palpation involves examination by applying the hands or fingers to the external surface of the body to detect evidence of disease or abnormalities to internal organs or structures

<sup>&</sup>lt;sup>15</sup> Hodgson, R. J., O'Connor, P. J., Grainger, A. J. Tendon and ligament imaging. The British Journal of Radiology, 2012: 85(1016), 1157–1172.

<sup>&</sup>lt;sup>16</sup> Ankle plantar flexion refers to the ability to flex the foot downward and away from the body.

<sup>&</sup>lt;sup>17</sup> Adhikari, S, Marx, J., Crum, T. Achilles tendon rupture: a challenging diagnosis. *Journal of the American Board* of Family Medicine. 2000: (13), 5.

<sup>&</sup>lt;sup>18</sup> Of the clinical tests, the Thompson test has the highest sensitivity and specificity, 96 and 93 percent, respectively. Douglas, J., Kelly, M., Blachut, P. Clarification of the Simmonds-Thompson test for rupture of an Achilles tendon. Canadian Journal of Surgery, 2009: 52(3), E40-E41.

<sup>&</sup>lt;sup>19</sup> Douglas, J., Kelly, M., Blachut, P. Clarification of the Simmonds–Thompson test for rupture of an Achilles tendon. Canadian Journal of Surgery, 2009: 52(3), E40-E41.

<sup>&</sup>lt;sup>20</sup> Adhikari, S, Marx, J., Crum, T. Achilles tendon rupture: a challenging diagnosis. *Journal of the American Board* of Family Medicine. 2000: (13), 5.

http://emedicine.medscape.com/article/309393-workup, Accessed June 7, 2016.

Therefore, unless a radiologist identifies a gap where the tendon should be, the x-ray may not show any visible changes that can be used for diagnosis.<sup>22</sup>

Treatment—Non-Surgical versus Surgical. Although overall healing rates are similar, the choice of non-surgical versus surgical treatment for acute ATR is controversial and focuses on re-rupture rates and wound complications related to surgery.

Non-surgical repair utilizes a heel wedged cast or walking boot that elevates the heel, thus approximating the ends of the torn tendon and allowing the torn tendon to heal. Recovery may take longer, and the risk of re-rupture may be higher with a non-surgical approach, as opposed to the surgical approach, and may cause a future surgical repair to be more difficult. Failure to closely approximate the ends of the torn tendon may affect the healing process. Scar tissue can form in the gap and result in unfavorable lengthening of the tendon. Lengthening can cause decreased ankle function, stability, and strength, and reduce the likelihood of obtaining optimal results.<sup>23</sup>

Surgical repair connects the two ends of the torn tendon with sutures and, depending on the extent of damage to the torn tendon, may require reinforcement with other tendons. Complications may include tendon scarring, infection, or nerve damage. Following tendon repair, rehabilitation can take 4–6 months and includes physical therapy (PT) to strengthen the tendon and leg muscles.

**Peer Review.** According to Veterans Health Administration (VHA) policy, peer review is an organized process used to improve quality of care and is performed by health care professionals<sup>25</sup> acting as individual case reviewers and a Peer Review Committee (PRC).<sup>26,27</sup> Peer reviewers primarily evaluate the performance of other providers or professionals, and secondarily, identify "problems with systems at the facility that are independent of provider practices." The PRC discusses the peer reviewer findings and, if necessary, develops an education or other action plan for the provider's supervisor to

www.podiatrytoday.com. 2013 (26)11Accessed April 19, 2017.

<sup>&</sup>lt;sup>22</sup> Jun, L., Zhong, Z., Lidtke, R. et al. Radiology of soft tissue of the foot and ankle with diffraction enhance imaging. *Journal of Anatomy*. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1571096/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1571096/</a>. Accessed March 10, 2017.

<sup>&</sup>lt;sup>23</sup> Grove J, Hardy M, Autograft, Allograft and Xenograft Options in the Treatment of Neglected Achilles Tendon Ruptures: A Historical Review with Illustrations of Surgical Repair, *The Foot & Ankle Journal*. 2008 1(5)
<sup>24</sup> Bevilacqua, N, A Closer Look at Treatment Options for Neglected Achilles Tendon Ruptures,

Professionals can include providers such as physicians, nursing staff, or social workers.

<sup>&</sup>lt;sup>26</sup> Federal law provides confidentiality for records and documents created as part of VHA's medical quality assurance program in 38 U.S.C. § 5705 *Confidentiality of Medical Quality-Assurance Records* and its implementing regulations 38 C.F.R. §§ 17.500-17.511. VHA's medical quality assurance program includes systematic health care reviews carried out by or for VHA for the purposes of improving the quality of medical care. The protected peer review process is part of VHA's medical quality assurance program and, as such, documents generated through its processes are confidential and privileged.

<sup>&</sup>lt;sup>27</sup> VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. This policy was in effect during the timeframe of the events described in this report. This Directive expired June 30, 2015 and has not been updated.

follow with the provider. The supervisor reports to the PRC when the provider's action plan is completed. <sup>28,29</sup>

**Allegations.** In 2015, the OIG Hotline Division received an e-mail from a complainant with the following allegations:

- On two occasions, a facility Emergency Department (ED) provider ignored (did not respond to) a patient's complaint that he may have a torn Achilles tendon and misdiagnosed the patient with a sprained ankle.
- The ED provider's misdiagnosis delayed the treatment for the patient's ATR.
- The misdiagnosis, delay in treatment for ATR, and the initial treatment provided for a sprained ankle versus ATR, worsened the patient's injury.

Initially, the OIG Hotline Division requested that the VISN conduct a review of the complainant's allegations and submit a response. We reviewed the response, determined it to be insufficient and subsequently initiated this inspection. Additionally, we found issues with the peer review and patient complaint processes.

## **Scope and Methodology**

We initiated our review in November 2015 and completed our work in June 2016. We conducted a site visit December 17, 2015.

We interviewed the complainant to clarify the allegations. We interviewed the Facility Director, Chief of Staff, Chief of Emergency Medicine, Risk Manager, and the ED provider who treated the patient. We reviewed the patient's electronic health record (EHR), facility quality management information, peer reviews, and other relevant documents. We also reviewed relevant literature, facility and VHA policies, Joint Commission standards, and the American Academy of Orthopaedic Surgeons clinical practice guideline, *The Diagnosis and Treatment of Acute Achilles Tendon Rupture*.

VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010 cited in this report expired June 30, 2015. We considered the policy to be in effect, as it had not been superseded by more recent policy or guidance. In a June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),<sup>30</sup> 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." The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with

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<sup>&</sup>lt;sup>28</sup> Peer review is a non-punitive, confidential process used to evaluate care provided to patients by individual providers.

<sup>&</sup>lt;sup>29</sup> VHA Directive 2010-025.

<sup>&</sup>lt;sup>30</sup> VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 11, 2017.

<sup>&</sup>lt;sup>31</sup> VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.

ensuring "...the timely rescission or recertification of policy documents over which their program offices have primary responsibility." <sup>32</sup>

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.

<sup>&</sup>lt;sup>32</sup> VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.

## **Case Summary**

In 2014, a male in his late 30s presented to the facility's ED with a complaint of moderate left Achilles pain. He told the ED triage nurse that he had been playing football 3 days prior when he felt a pop in the back of his left leg. According to the EHR, the ED provider documented a brief focused patient history and brief physical examination, including palpation of the patient's left ankle noting that the patient had tenderness on the Achilles tendon, a decreased range of motion in the ankle, mild edema (swelling), and no erythema (reddening of the skin) or ecchymosis (bruising).

The ED provider ordered basic x-rays of the left ankle and the soft tissue on the Achilles tendon. A facility radiologist reported that no fractures were seen and the soft tissue was normal. He/she interpreted the x-rays as unremarkable. The ED provider reviewed the radiology report and assessed the patient as having "ankle pain/sprain," administered an injection of a non-narcotic pain reliever, and prescribed an oral anti-inflammatory medication. The ED provider instructed the patient to limit activities to light duty for about 1 week and to follow up with his primary care provider (PCP). ED staff wrapped the patient's ankle in an ace bandage, fitted him with a lace-up soft ankle bootie, and discharged him from the ED.

Approximately 12 days later, the patient returned to the ED complaining of left heel/Achilles pain. The ED triage nurse documented the patient's belief that his Achilles tendon was torn. The patient was unable to flex the toes of the affected foot without pain. He reported that he had fallen twice since the injury. The ED provider, who had treated the patient during the first ED visit documented a brief physical examination, which revealed that the patient's left ankle was tender to palpation with a slightly decreased range of motion and mild swelling, but no redness or bruising. The ED provider again ordered basic x-rays of the left ankle. A VHA National Teleradiology Program<sup>33</sup> radiologist interpreted the x-rays as unremarkable. After reviewing the radiology report, the ED provider assessed the patient as having left ankle pain. The ED provider discharged the patient with instructions to follow up with a PCP, continue with anti-inflammatory medication, wrap the ankle with an ace bandage, use an ankle brace, and apply sport cream three times daily.

The patient did not have a VA PCP. The ED provider initiated a consult for the patient to be enrolled and assigned a PCP at the facility. Four days later, the patient saw a PCP for evaluation of severe pain and swelling in the Achilles tendon area. The PCP documented a patient history and conducted a physical examination, which revealed marked tenderness over the left Achilles tendon and an abnormal Thompson test. Based on the physical findings, the PCP discussed the case with an orthopedic surgeon who agreed to see the patient in the orthopedic clinic later that day. The orthopedic surgeon assessed the patient's left ankle and Achilles tendon and arranged for STAT<sup>34</sup>

<sup>&</sup>lt;sup>33</sup> The VHA National Teleradiology Program provides radiologists who remotely review and interpret images for VA facilities.

<sup>&</sup>lt;sup>34</sup> STAT is derived from the Latin word *statim*, meaning immediately and without delay.

magnetic resonance imaging (MRI) studies. The MRI results revealed a full-thickness tear of the left Achilles tendon. A preoperative evaluation was scheduled for 10 days later with possible surgery the following day. In the interim, an orthopedic surgery team recommended a controlled ankle movement boot<sup>35</sup> and partial weight bearing on the affected foot. During the preoperative evaluation on the day before surgery was scheduled to take place, an orthopedist documented that after an extensive discussion with the patient regarding surgical versus non-surgical options, the patient elected to forgo surgery and proceed with casting and PT.

Approximately 6 months later, when he was again seen in the orthopedic surgery clinic, the patient inquired about the possibility of surgical intervention after expressing unhappiness with his clinical outcome, including weakness, ongoing pain, and the inability to climb stairs effectively. The orthopedic surgeon informed the patient that recovering full use of the left ankle even with surgery was unlikely and noted that the patient indicated his understanding.

Approximately 2 weeks later, orthopedic surgery clinic staff noted that the patient's injury had healed in an unfavorable lengthened state and that the patient was dissatisfied with the non-surgical treatment outcome and continued to experience weakness in the affected leg and ankle as well as persistent pain. The orthopedic clinic resident presented the patient with two treatment options—continue non-surgical management with PT or proceed with a surgical reconstruction of the torn Achilles tendon with a tendon transfer.<sup>36</sup> The patient elected surgery and was referred to a podiatry clinic at another VA facility. At the visit with the surgical podiatrist, the patient complained of walking with a limp and having a difficult time climbing stairs. The patient underwent surgical repair of the left Achilles tendon with tendon debridement<sup>37</sup> and graft augmentation<sup>38</sup> in 2015, approximately 10 months post-injury. In the month following surgery, the patient was non-weight bearing and used crutches. Over this period the patient's pain continued to decrease.

Approximately 3 months after surgery, a physical therapist evaluated the patient, and over the following 4 weeks, the patient attended PT sessions. In late 2015, the patient requested to see his PCP for swelling and constant pain over the left Achilles area, an inability to flex the left ankle fully, and frequent awakening due to pain. The PCP documented that, after a delayed diagnosis of a left ATR and with unsatisfactory delayed surgical repair, the patient was complaining of swelling and constant pain over the Achilles tendon and the inability to flex the ankle fully. The PCP recommended non-narcotic analgesic medication, PT, and a referral to a behavioral health pain self-management program.

<sup>&</sup>lt;sup>35</sup> A controlled ankle movement boot is an adjustable orthopedic apparatus that allows the foot to be held in plantar flexion of varying degrees to promote anatomical healing of the two ends of a ruptured Achilles tendon.

<sup>&</sup>lt;sup>36</sup> Tendon transfer is a surgical technique where tendons are transferred from an alternate muscle in place of the injured muscle to help restore strength in a joint.

<sup>&</sup>lt;sup>37</sup> Debridement is the removal of dead tissue to promote healing.

<sup>&</sup>lt;sup>38</sup> Graft augmentation is a technique that uses biomaterials (natural or synthetic) to bridge together or reinforce the damaged tendon(s) for a stronger repair.

## **Inspection Results**

#### Issue 1: Alleged Misdiagnosis of ATR

We substantiated that on two occasions an ED provider did not respond to the patient's complaint that he may have had a torn Achilles tendon, and the provider misdiagnosed<sup>39,40</sup> him with a sprained ankle.

During the initial visit to the ED, the nurse documented in the patient's EHR that the patient reported Achilles tendon pain and that he "felt a pop" when the injury occurred. The provider told us that he read the nurse's comments in the patient's EHR. The provider documented a brief assessment and reviewed soft tissue results from a basic x-ray regarding the patient's ankle, which were unremarkable, showing no definitive injury. However, the provider did not perform a Thompson test, one of the most definitive clinical assessments of an ATR, or order any additional diagnostic tests, and diagnosed the patient with a sprained ankle.

When the patient returned for a second visit because of worsening symptoms, he indicated his concern about a possible ATR to the ED nurse. The provider assessed the ankle and reviewed a second basic x-ray with unremarkable soft tissue results but did not acknowledge or document the patient's complaint of a potential ATR. The second assessment by the provider also did not include a Thompson test or additional diagnostic tests, and the provider again diagnosed the patient with a sprained ankle. During a PCP visit 16 days after the initial ED visit, the PCP performed a Thompson test and found that the patient had an ATR, which upon further testing, proved to be a full-thickness Achilles tendon tear.

The Chief of Emergency Medicine and the Chief of Staff told us that when a patient presents with classic symptoms of a possible ATR, including a history that the injury occurred while playing football and that the patient heard a popping sound in the back of his leg, with pain and swelling in the Achilles tendon, the expectation for ED providers is to administer the Thompson test as part of the patient's physical examination. In 2015, the Chief of Staff made an institutional disclosure of an adverse event<sup>41</sup> to the patient citing a delay in the diagnosis of an ATR secondary to the provider's inadequate assessment of the injury on the first and second visits to the ED.

<sup>&</sup>lt;sup>39</sup> Misdiagnosis is the result of a diagnostic error or failure in the diagnostic process. The Joint Commission defines delayed diagnosis as a form of diagnostic error, and as a non-optimal interval of time between the onset of symptoms, identification of the injury or illness, and the initiation of treatment.

<sup>&</sup>lt;sup>40</sup> The Joint Commission. Preventing delays in treatment. *Quick Safety*. January 2015: Issue Nine. <a href="https://www.jointcommission.org/assets/1/23/Quick\_Safety\_Issue\_Nine\_Jan\_2015\_FINAL.pdf">https://www.jointcommission.org/assets/1/23/Quick\_Safety\_Issue\_Nine\_Jan\_2015\_FINAL.pdf</a>. Accessed March 10, 2017.

<sup>&</sup>lt;sup>41</sup> According to VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012 (corrected copy October 12, 2012), an institutional disclosure is a formal process by which facility leader(s) and/or clinicians inform the patient that an adverse event—an untoward incident of harm or potential harm directly associated with care or services provided within the jurisdiction of VHA—has occurred during the patient's care that resulted in, or is reasonably expected to result in death or serious injury.

#### **Issue 2: Alleged Delay in Treatment**

We substantiated that the ED provider's misdiagnosis delayed the treatment for the patient's ATR. We found that 16 days had lapsed from the time the patient initially presented to the ED with Achilles tendon pain and functional impairment to the diagnosis of ATR. Although the provider diagnosed and treated the patient for a sprained ankle, the treatment was not appropriate for an ATR

Once diagnosed and referred by the PCP, the patient was evaluated by an orthopedic surgeon who presented the patient with the options of surgical versus non-surgical treatment. The patient chose non-surgical treatment, and the ATR was treated with a controlled ankle movement boot and PT.

#### Issue 3: Alleged Worsening of the Patient's Injury Due to Misdiagnosis

We could not substantiate that the 16-day delay in diagnosis and treatment worsened the Achilles injury. We were unable to determine if the patient initially suffered a partial tear that progressed to a full-thickness tear during this time-period because the ED provider did not document the proper assessments, which would have provided a clinical baseline of the ATR, and the radiologist interpreted the initial x-ray of the left ankle soft tissue to be normal.

Besides the 16 day delay, we identified other timeframes when different treatments affecting optimal outcomes could have occurred. The injury happened in 2014 and initial assessment occurred 3 days later. The patient was given options for conservative or surgical treatments within 4 weeks of injury and decided to pursue conservative treatment. The patient had complaints of persistent pain after 6 months of conservative treatment with serial casting and sought options for possible surgical interventions. The orthopedic surgeon documented in the patient's EHR that during the discussion of surgical options, he advised the patient recovery of the full use of the ankle was unlikely and at a subsequent visit documented that the Achilles tendon had healed in a lengthened state. The following month, the patient decided to undergo Achilles tendon surgery.

We could not determine the extent to which the 3-day delay in seeking treatment, the 16-day delay in diagnosis, and/or the 6-month delay occasioned by the patient's initial choice of non-operative treatment contributed to the unfavorable healing of the Achilles tendon.

#### Issue 4: Other Issues

**Peer Review.** Prior to the initiation of our hotline inspection, the facility PRC requested an internal peer review. According to VHA, certain peer review documentation must take place. We found documentation was incomplete.<sup>42</sup> We are unable to publish the specifics of our review of the facility's peer review documentation as disclosure of

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<sup>&</sup>lt;sup>42</sup> VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010.

confidential information in VHA protected quality assurance documents is prohibited by 38 U.S.C. § 5705. 43

**Patient Complaint.** We identified a process deficiency that may have contributed to a delay in diagnosis and treatment of the patient's ATR.

According to facility policy, the first recourse for resolving a patient complaint is the responsibility of a provider's service chief or staff supervisor. Prior to going to the ED for a second visit, the patient left a phone message for the Chief of Emergency Medicine regarding concerns related to the patient's first ED visit. The Chief of Emergency Medicine returned the patient's call, left a message, and documented the attempt to reach the patient as an addendum to the ED provider's summary note of the patient's initial ED visit. However, we found no further documentation by the Chief of Emergency Medicine to follow up, review the patient's ED visit, or resolve the patient's complaint. The Chief of Emergency Medicine told us that he did not follow up on the patient's case after leaving a message. Four days later, the patient had his first appointment with a PCP who diagnosed him as having a left ATR.

#### **Conclusions**

We substantiated that an ED provider ignored a patient's complaint of a possible ATR and misdiagnosed him with a sprained ankle on two occasions in 2014. Interviews with ED managers indicated that a Thompson test would have been a reasonable and appropriate test to conduct on the patient as part of a full assessment.

We substantiated that because the injury was misdiagnosed, treatment of the patient's ATR was delayed for 16 days. However, we could not substantiate that the misdiagnosis, delay in treatment for the ATR, and the treatment prescribed for a sprained ankle versus an ATR worsened the injury. A delay in ATR diagnosis or treatment may result in a worse outcome. Because the ED provider did not document the proper assessments, which would have provided a clinical baseline of the ATR, we could not discern whether the injury became worse when the patient followed the treatment plan for a sprained ankle.

We found that although the facility completed an internal peer review, certain required documentation was not completed. We also identified that the patient's complaint to the Chief of Emergency Medicine regarding the first ED visit was not resolved in accordance with facility policy.

<sup>&</sup>lt;sup>43</sup> VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. The peer review for quality management process is part of VHA's medical quality assurance program and, as such, documents generated through its processes are confidential and privileged.

<sup>&</sup>lt;sup>44</sup> Facility Policy Memorandum 00-13, *Patient Advocacy Program*, November 14, 2013.

# Recommendations

- 1. We recommended that the Facility Director ensure that peer reviews are completed and reported as required by Veterans Health Administration policy.
- 2. We recommended that the Facility Director ensure that processes are strengthened to ensure that patient complaints are resolved in accordance with facility policy.

# **VISN Director Comments**

# **Department of Veterans Affairs**

# **Memorandum**

Date: February 7, 2017

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

Healthcare Inspection—Alleged Misdiagnosis and Delay in Treatment, Providence VA Medical Center, Providence, Rhode Island

Acting Director, Bedford Office of Healthcare Inspections (54BN)
Director, Management Review Service (VHA 10E1D MRS Action)

VISN 1 concurs with the OIG's Report and with the recommendations listed below.

Sincerely,

(original signed by Barrett Franklin, Deputy Network Director, for:)

Michael F. Mayo-Smith, MD, MPH

Network Director, VISN 1

# **Facility Director Comments**

# Department of Veterans Affairs

# **Memorandum**

Date: February 7, 2017

From: Director, Providence VA Medical Center, Providence, Rhode Island (650/00)

Healthcare Inspection—Alleged Misdiagnosis and Delay in Treatment, Providence VA Medical Center, Providence, Rhode Island

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

Providence VAMC concurs with the OIG's Report on the following page.

Susan A MacKenzie 182813

Digitally signed by Susan A Mackenzle 182813 DN: do-gov, do-va, o-Internal, ou-people, 0.9 2342.19200300.100.1.1-susan.mackenzl egiva.gov, on-Susan A Mackenzle 182813 Date: 2017.02.07 13:03:43 -0500

# **Comments to OIG's Report**

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

#### **OIG Recommendation**

**Recommendation 1.** We recommended that the Facility Director ensure that peer reviews are completed and reported as required by Veterans Health Administration policy.

#### Concur

Target date for completion: February 15, 2017

Facility response: [Redacted pursuant to 38 U.S.C. § 5705]. 45

**OIG Comment**. Based on information provided to us by the facility, we consider this recommendation closed.

**Recommendation 2.** We recommended that the Facility Director ensure that processes are strengthened to ensure that patient complaints are resolved in accordance with facility policy.

#### Concur

Target date for completion: March 1, 2017

Facility response: The process for handling patient complaints was reviewed with the Chief of Emergency Medicine and the Emergency Department Provider who was involved at the time of discovery. The exiting policy identifies the steps to be followed with a patient complaint and has been circulated to all clinicians. With the implementation of the retooled Patient Advocate/Experience Program, this process will be covered more extensively in the policy and then this will be covered with all members of the healthcare tea to ensure compliance.

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<sup>&</sup>lt;sup>45</sup> 38 U.S.C §5705 prohibits the unauthorized disclosure of VA medical quality assurance records.

#### Appendix C

# **OIG Contact and Staff Acknowledgments**

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Inspection Team	Clarissa Reynolds, CNHA, MBA, Team Leader Thomas Jamieson, MD Valerie Zaleski, RN, BSN
Other	Roneisha Charles, BS
Contributors	Elaine Kahigian, RN, JD

Appendix D

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