Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 15-02456-396

Healthcare Inspection

Care of an Urgent Care Clinic Patient Tomah VA Medical Center Tomah, Wisconsin

June 18, 2015

Washington, DC 20420

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Executive Summary

VA's Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection at the request of Senator Tammy Baldwin and Senator Ron Johnson to assess the merit of allegations of poor care and delayed care of a patient in the Urgent Care Clinic (UCC) at the Tomah VA Medical Center (VAMC) in Tomah, WI.

We did not substantiate the general allegations of poor care and delayed care. With respect to the specific allegations made by the patient's family, we found the following.

We did not substantiate that the case patient waited for 3 hours before being seen at the UCC or that other patients arrived and were treated and released before the case patient was seen. We did not substantiate that the physician who treated the patient was unaware of stroke symptoms. We substantiated the allegation that the physician did not affirmatively diagnose the first neurologic event the patient experienced as a transient ischemic attack or acute ischemic stroke; however, the physician properly considered broad diagnostic possibilities for the syncopal episode, which occurred while the patient was in the Tomah VAMC UCC waiting room awaiting a mental health evaluation. We did not substantiate that the physician failed to treat the patient's second neurologic event, an acute ischemic stroke, with sufficient urgency.

We did not substantiate that UCC staff were dismissive of the signs and symptoms that the patient exhibited. We did not substantiate that the Tomah VAMC's computerized tomography (CT) scan was broken; however, we determined it was not available due to scheduled, routine maintenance when the patient was treated in the UCC. We substantiated that the physician ordered a CT after the patient's second neurologic event. We did not substantiate that the electrocardiogram (ECG) machine was broken.

We substantiated that the patient was not transferred to Tomah Memorial Hospital, located 2 miles from the Tomah VAMC; however, we determined that transferring the patient to Gundersen Health System was the appropriate action because it was the closest Joint Commission-certified Primary Stroke Center and was in accordance with the Tomah VAMC's local transfer policy. We could not substantiate that the patient's electronic health record was inappropriately accessed prior to February 25, 2015; however, we determined it was not accessed inappropriately on or after that date. We could not determine exactly what the family was told about air ambulance (helicopter) availability on January 12, 2015, but found that the Tomah VAMC does not own or operate an air ambulance and that one was not available to transfer the patient. We could not substantiate the allegation that Gundersen Health System staff commented negatively about the patient's care at the Tomah VAMC UCC.

We concluded that, overall, the UCC staff acted appropriately in the face of a patient experiencing a sudden and unexpected acute ischemic stroke while waiting for a mental health evaluation in a rural hospital that is not equipped to treat a health problem of this magnitude. Nevertheless, we identified opportunities for improvement, none of which impacted the care of this patient.

We made three recommendations to the Interim Under Secretary for Health and six recommendations to the Facility Director.

Comments

The Interim Under Secretary for Health, Veterans Integrated Service Network Acting Director, and Facility Director concurred with our recommendations and provided an acceptable action plan. (See Appendixes B–D, pages 28–36 for the Interim Under Secretary for Health and Directors' comments.) We will follow up on the planned actions until they are completed.

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Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) conducted an inspection at the request of Senator Tammy Baldwin and Senator Ron Johnson to assess the merit of allegations of poor care and delayed care to a patient in the Urgent Care Clinic (UCC) at the Tomah VA Medical Center (VAMC) in Tomah, WI.

Background

Stroke—Overview

A stroke, also known as a cerebrovascular accident or CVA,[1] occurs when the blood supply to the brain is interrupted, which causes brain cells to die. Symptoms of acute stroke include new onset numbness or weakness of the leg, arm, or face; confusion or trouble understanding; trouble seeing in one or both eyes; trouble walking, dizziness, loss of balance or coordination; and severe headache.[2] Fleeting signs and symptoms of stroke known as a transient ischemic attack (TIA) may occur.[3] In the United States over 795,000 people yearly suffer a stroke and it is the fifth leading cause of death and a major cause of disability.

Neurologists (brain and stroke specialists) generally divide strokes into two categories: ischemic and hemorrhagic. In an ischemic stroke, the blood supply to the brain is cut off because of blockage of an artery(ies) supplying blood and oxygen to the brain. This blockage is typically caused by a blood clot occurring in a brain vessel, with the clot severely reducing or preventing blood flow to tissue beyond it.[4] This type of stroke is often referred to as an acute ischemic stroke (AIS) and accounts for 85 percent of all strokes.[5] In contrast, an acute hemorrhagic stroke is caused by bleeding into the brain and may be referred to as an intracerebral hemorrhage.[6]

Whether a stroke is of the ischemic or hemorrhagic type has important treatment and prognostic implications. The "clot-busting" drug, tissue plasminogen activator (tPA), may be infused in the case of AIS in an attempt to dissolve the blood clot(s) causing the stroke and to prevent existing clots from expanding. Currently, tPA is the only such drug approved by the Food and Drug Administration for an acute stroke.

[1] "Cerebrovascular disease refers to a group of conditions that affect the circulation of blood to the brain, causing limited or no blood flow to affected areas of the brain." http://www.medicalnewstoday.com/articles/184601.php (accessed 3/20/2015).
[2] http://www.strokeassociation.org/STROKEORG/WarningSigns/Learn-More-Stroke-Warning-Signs-and-Symptoms_UCM_451207_Article.jsp.
[3] "A transient ischemic attack (TIA) occurs when blood flow to a part of the brain stops for a brief time. A person will have stroke-like symptoms for up to 24 hours. In most cases, the symptoms last for 1 to 2 hours. A TIA is felt to be a warning sign that a true stroke may happen in the future if something is not done to prevent it." http://www.nlm.nih.gov/medlineplus/ency/article/000730.htm. (accessed 4/20/2015).
[4] http://www.cedars-sinai.edu/Patients/Programs-and-Services/Stroke-Program/Stroke-Resources/Acute-Ischemic-Stroke.aspx (accessed 3/11/2015).
[5] http://www.mayoclinic.org/diseases-conditions/stroke/symptoms-causes/dxc-20117265 (accessed 2/21/2015).
[6] http://emedicine.medscape.com/article/1916662-overview (accessed 3/11/2015).

Since the very mechanism of action of tPA is to break up clots and impair further clot formation, this drug cannot be used in treating a hemorrhagic stroke.

Because tPA can worsen bleeding, the clinician must know if the stroke is ischemic (clot) or hemorrhagic (bleeding). In addition, the stroke must be severe enough to justify the risk implicit with the use of tPA. A head computerized tomography (CT) scan can reveal blood in or on the brain if the stroke is hemorrhagic, and in that situation, tPA is to be avoided. Conversely, if the patient is suffering from an AIS, tPA must be started rapidly.

The term "the golden hour," a phrase adopted from the practice of rapid emergency treatment of trauma, has been applied to the window for starting tPA in a patient with an AIS in order to maximize the chances for the best possible outcome. In an article from *Stroke*, a leading neurology journal, Jeffrey Saver, MD, of the UCLA Stroke Center, UCLA School of Medicine, wrote:

> *The benefit of intravenous (IV) thrombolytic therapy [tPA] in acute brain ischemia [diminished blood flow] is strongly time dependent. Therapeutic yield is maximal in the first minutes after symptom onset and declines rapidly during the next 4.5 hours.*[7]

However, as recently as March 2015, it was reported:

> *Even under an optimistic scenario, as many as 114 million people in the U.S. would be unable to reach a comprehensive stroke center (CSC)*[8] *using ground transportation within the critical treatment "golden hour.*[9]

Specialized stroke care is best provided at Joint Commission (JC)-certified Primary Stroke Centers (PSC), of which more than 1,000 exist in the U.S. (including Puerto Rico), or a Comprehensive Stroke Center (CSC). The U.S. Centers for Disease Control and Prevention notes:

> *…for a hospital to be designated as a primary stroke center, it must meet specific policy criteria established in one of two ways: 1. States adopt The Joint Commission certification criteria. 2. A state agency is given the authority to develop a distinct process and criteria.*[10]

JC certification requires that PSCs utilize JC's *Specifications Manual for National Hospital Inpatient Quality Measures*, and collect and report data on multiple quality

[7] Saver, JL, et. al., "The 'Golden Hour' and Acute Brain Ischemia Presenting Features and Lytic Therapy in >30 000 Patients Arriving Within 60 Minutes of Stroke Onset," *Stroke* July 2010, p. 1431, http://stroke.ahajournals.org/content/41/7/1431.full.pdf (accessed 3/11/2015)

[8] A Comprehensive Stroke Center (CSC) meets certain standards to treat the most complex stroke cases. See: http://www.heart.org/HEARTORG/HealthcareResearch/HospitalAccreditationCertification/ComprehensiveStrokeCenterCertification/Comprehensive-Stroke-Center-Certification_UCM_455446_SubHomePage.jsp (accessed 5/4/2015)

[9] http://www.medpagetoday.com/Cardiology/Strokes/50328 (accessed 3/11/2015)

[10] A Summary of Primary Stroke Center Policy in the United States http://www.cdc.gov/dhdsp/pubs/docs/primary_stroke_center_report.pdf (accessed 5/4/2015)

assurance measures related to stroke.[11] An even higher level of stroke care may be provided by a CSC, which is a Primary Stroke Center with additional stroke care qualifications.[12]

Stroke in Wisconsin

The most recent stroke data from the State of Wisconsin was published in March 2015 by the Wisconsin Department of Health Services' Division of Public Health, Office of Health Informatics. This data revealed that in 2013, 2,523 people in Wisconsin were recorded as having an underlying cause of death of cerebrovascular disease. "All mention" cause of death, which includes all conditions listed on the death record, showed 4,106 people in Wisconsin with cerebrovascular disease as part of the mortality chain of events.[13]

Wisconsin currently has 26 JC-certified PSCs.[14] Within a 50-mile radius of Tomah, WI, two JC-certified PSCs are located in La Crosse, WI, at the Gundersen Health System (GHS) and at the Mayo Clinic Health System/Franciscan Healthcare.[15]

Stroke Care in VA

Clinical management of stroke depends upon a facility having a stroke protocol in place, practiced, and understood. Veterans Health Administration (VHA) Directive 2011-038, *Treatment of Acute Ischemic Stroke (AIS)*, describes VHA's policy regarding the management of acute cerebrovascular accidents (strokes).[16] Under this policy, Veterans Integrated Service Network (VISN) directors are responsible for classifying facilities as either VHA PSCs, VHA limited hours stroke facilities (LHSFs), or VHA supportive stroke facility (SSFs).

Facilities designated as a PSC or LHSF must have an in-house radiologist available to read a non-contrast CT within 45 minutes of a patient's presentation to the Emergency

[11] Quality measures include (1) venous thromboembolism prophylaxis, (2) discharged on antithrombotic therapy, (3) anticoagulation therapy for atrial fibrillation/flutter, (4) thrombolytic therapy, (5) antithrombotic therapy by end of hospital day two, (6) discharged on statin medication, (7) stroke education, and (8) assessed for rehabilitation.

[12] The American Heart Association notes: "Comprehensive Stroke Center Certification recognizes hospitals that meet standards to treat the most complex stroke cases. Eligibility standards include all components of a Primary Stroke Center plus:

- availability of advanced imaging techniques, including MRI/MRA, CTA, DSA and TCD
- availability of personnel trained in vascular neurology, neurosurgery and endovascular procedures
- 24/7 availability of personnel, imaging, operating room and endovascular facilities
- ICU/neuroscience ICU facilities and capabilities
- experience and expertise treating patients with large ischemic strokes, intracerebral hemorrhage and subarachnoid hemorrhage"

[13] 2013 Wisconsin Deaths. State Vital Records Office. Office of Health Informatics. Division of Public Health. Wisconsin Department of Health Services. Published March 2015. Page 21.

[14] Primary Stroke Centers are facilities certified by the Joint Commission in collaboration with the American Heart Association/American Stroke Association (AHA/ASA).

[15] http://www.strokecenter.org/trials/centers?utf8=%E2%9C%93&search=54660&radius=50 (accessed May 6, 2015).

[16] VHA Directive 2011-038, *Treatment of Acute Ischemic Stroke (AIS)*, November 2, 2011. (This VHA Directive expires November 30, 2016.)

Department (ED). An LHSF, however, is only required to have these services available during regular business hours. Patients presenting outside these hours must be referred or diverted.

An SSF (which is the Tomah VAMC's designation by VISN 12[17]) is a facility without the appropriate resources to care for acute stroke patients, and is required to have robust transfer agreements in place to address the needs of stroke patients. These agreements must cover emergency transfers. Specifically, VHA Directive 2011-038 states, "Plans for emergent transfer on a 24/7 basis to the nearest VA or non-VA Primary Stroke Center capable of providing AIS care must be in place at VHA LHSF and VHA SSF."[18]

VHA Directive 2011-038 also requires local facilities to have clinical protocols in place by June 1, 2012, for rapidly identifying, evaluating, and treating patients with strokes. These protocols must include plans for managing patients who present before and after the expiration of the 3-hour window for administration of tPA. While VHA policy acknowledges that some studies have supported the use of tPA up to 4.5 hours after symptom onset, VHA policy supports a 3-hour window.[19]

VHA Directive 2011-038 also requires facility directors to collect quality data regarding stroke evaluation, treatment, and outcomes; to provide an extensive education program for patients and staff; and to post guidelines for the management of stroke in the ED, Urgent Care Clinic (UCC), and at the nursing stations on the units in all VHA facilities.

Tomah VAMC

The Tomah VAMC is located in Tomah, WI, a community of approximately 10,000 in Central Wisconsin. It is one of seven VAMCs in VISN 12, the VA Great Lakes Health Care System. Approximately 57,000 veterans reside in the Tomah VAMC's primary service area.

There are five levels of facility complexity—1a, 1b, 1c, 2, and 3 in descending order of complexity based partly on the clinical services a facility offers. The Tomah VAMC is a Level 3 complexity facility and does not offer emergency, intensive care, or surgical services.[20] William S. Middleton Memorial Veterans Hospital (Madison VAMC),[21] a Level 1b complexity facility, serves as the Tomah VAMC's VA specialty care referral center. Madison VAMC is located approximately 100 miles southeast of the Tomah VAMC in Madison, WI. Pertinent to this case, Madison VAMC offers services that include emergency, intensive care, and neurosurgery.

[17] MCM No. MS-21, *Treatment of Acute Ischemic Stroke,* March 7, 2012.
[18] VHA Directive 2011-038, *Treatment of Acute Ischemic Stroke (AIS*), November 2, 2011. (This VHA Directive expires November 30, 2016.)
[19] Ibid, p. 3.
[20] VA categorizes all VA medical centers by complexity levels every 3 years.
[21] The William S. Middleton Memorial Veterans Hospital in Madison, WI, is a tertiary care facility affiliated with the University of Wisconsin School of Medicine and Public Health.

The Tomah VAMC provides primary care, acute medicine, acute and long-term psychiatry, mental health, and long-term care services. It has 180 Community Living Center long-term care beds, 35 Residential Rehabilitation Treatment Program beds, 21 acute care medical beds, and 10 vocational and social rehabilitation beds. Outpatient care services are also provided at community based outpatient clinics in La Crosse, Loyal, Wausau, and Wisconsin Rapids, WI.

On January 12, 2015, the Tomah VAMC also operated a four-bed UCC that was open 24 hours a day, 7 days a week. From January 1, 2014, through March 3, 2015, there were 7,240 UCC visits for an approximate average daily census of 17 patients.

The Tomah VAMC does not operate a land or air ambulance service. Air ambulance services are available in Madison and La Crosse, WI. Basic life support equipped ground ambulance service is available locally. Advanced life support transportation can take 30 minutes or more for air transportation, and up to 2 hours for ground transportation to arrive to transport patients to higher level of care facilities.

Pertinent to this review, the Tomah VAMC operates an on-site CT scanner, but is not a PCS or LHSF. According to VHA policy, as an SSF, providers at the Tomah VAMC cannot administer tPA for the immediate treatment of strokes.

Tomah Memorial Hospital

Tomah Memorial Hospital (TMH) is a non-VA community hospital located just over 2 miles from the Tomah VAMC. It has a cardiac monitoring unit, neurology services, surgical services, and a CT scanner. At the time of the events giving rise to the allegations reviewed in this inspection, TMH was not a JC-designated PSC.

Gundersen Health System

GHS, located in La Crosse, WI, is a multi-specialty tertiary referral center and teaching hospital. It is a JC-certified PSC. A neurovascular surgeon and necessary vascular imaging for treatment of an AIS are available, and surgical clot removal, when indicated, may be performed at GHS.

Urgent Care Clinic

The Tomah VAMC UCC was established for minor emergencies and medical issues. It is specifically not an ED. According to VA policy:[22]

> *An urgent care clinic (UCC) provides ambulatory medical care for patients without a scheduled appointment who are in need of immediate attention for an acute medical or mental health illness and/or minor injuries. UCCs can exist in facilities with or without an ED. In either case, UCCs are not designed to provide the full spectrum of emergency medical care*.

[22] VHA Directive 1079, *Standards for Nomenclature and Operations for Urgent Care Clinics in VA Medical Facilities*, February 3, 2014. (This VHA Directive is scheduled for recertification on or before last working day of February, 2019.)

VHA Directive 1079 states, in part, that UCCs must:

- Provide services that are congruent with the capabilities and capacity of the facility.
- Have the capability to treat simple fractures, minor trauma and lacerations, or have a referral process to obtain these services.
- Have appropriate radiology, laboratory, and pharmacy services available.
- Have mental health coverage available on-site or on-call if the UCC operates 24 hours a day, 7 days a week.
- Have policies for the stabilization and transfer to an appropriate higher-level facility for patients whose needs exceed the facility's capability.
- Have transfer agreements developed in advance with local and regional health care partners.

Emergency Severity Index

At the Tomah VAMC, a registered nurse (RN) triages all patients who present to the UCC and assigns acuity levels based on the Emergency Severity Index (ESI). The ESI is a five-level algorithm that categorizes acuity and expected resource needs into priority groups from 1 and 2 (requires or may require immediate, life-saving intervention) to 3 through 5 (non-urgent). ESI level 1 and 2 decisions are based on patient acuity.[23]

The RN considers resource needs when assigning levels 3 through 5 to assist with sorting the order of when patients need to be seen by a provider. Clinically, ESI level 4 and 5 patients are stable, require one resource such as a specialty consultation in the present case, and "can wait several hours to be seen by a provider."[24]

Allegations

The general allegations are of poor care and delayed care while the patient was at the Tomah VAMC UCC. The patient's family raised the following specific allegations:

- The patient waited 3 hours to be seen.
- Other patients came and went before the case patient was seen.
- The physician was unaware of the symptoms of a stroke.
- The physician did not diagnose the first neurologic event as a TIA [transient ischemic attack], nor did he treat the patient's second neurologic event, an acute stroke, with sufficient urgency.

[23] Gilboy N, Tanabe T, Travers D, Rosenau AM, *Emergency Severity Index (ESI): A Triage Tool for Emergency Department Care, Version 4: Implementation Handbook 2012 Edition*, AHRQ Publication No. 12-0014, Rockville, MD, Agency for Healthcare Research and Quality, November 2011.
[24] *Ibid*.

- Family concerns that the patient was experiencing stroke symptoms were dismissed.
- The physician waited until after a second stroke occurred before suggesting a CT scan.
- The physician wanted to obtain a CT scan, but the CT machine was broken. Without a CT scan, the staff informed the patient's daughter, they could not administer the anticoagulant medication that is commonly used to treat a stroke victim.
- The complainant had to help fix the electrocardiogram (ECG) machine.
- The patient should have been transferred to nearby Tomah Memorial Hospital.
- Unauthorized parties accessed and/or disseminated the patient's electronic health record (EHR) inappropriately.
- UCC staff told the patient's daughter that her father would be transported to GHS via helicopter, but a short time later, and without further explanation, staff told her that helicopters were not flying that day even though the weather was clear and the winds calm.
- GHS doctors "could not understand" why the patient was not administered the anticoagulant medication at the Tomah VAMC or why he was not transported to La Crosse via helicopter.

Scope and Methodology

This review focuses on care provided by the Tomah VAMC to the case patient on January 12, 2015. Non-VA facilities do not fall under the jurisdiction of VA OIG oversight. Therefore, relevant antecedent history leading to the patient presenting to the Tomah VAMC UCC on January 12, as well as events after transfer to GHS on January 12, are noted; however, care at those institutions is not reviewed.

The period of review was February 11–June 2, 2015. We conducted site visits February 11–12, and February 18–20. We interviewed the patient's surviving spouse and daughter. We interviewed Tomah VAMC leadership, managers, clinical, clerical, and administrative staff and the Tomah VAMC Information Security Officer. We also interviewed VHA's National Program Director for Emergency Medicine and National Stroke Program Director.

We reviewed the case patient's VA electronic health record (EHR) and VA archived medical records, non-VA medical records, and January 12 ambulance transfer records. We reviewed the EHRs of other patients who received care in the Tomah VAMC UCC on January 12. We reviewed relevant VA handbooks and directives. We reviewed the credentials, privileges, and select training records of the patient's UCC primary physician provider and other UCC staff. We reviewed clinical quality assurance (QA) documents generated by this patient's care at the Tomah VAMC, including a Root Cause Analysis. We reviewed CT scan and ECG machine maintenance records. We also reviewed selected stroke literature.

We created a timeline of events, which is found in Appendix A of 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.

Case Summary

The patient was a 74-year-old U.S. Army veteran who was service-connected for a mental health disorder. According to the family, since the 1970s, he had received his routine medical and psychiatric care at the Marshfield Clinic, a non-VA tertiary care health care system located 60 miles northeast of Tomah, in Marshfield, WI. His medical history included hypertension (high blood pressure), chronic obstructive pulmonary disease (COPD),[25] and bipolar disorder. His regular medications included metoprolol, Advair® (fluticasone and salmeterol), Combivent® (ipratropium and albuterol), lithium, zolpidem, Vitamin C, and Vitamin D with calcium.

The patient received extensive VA inpatient care in the 1960s, 1970s, and early 1980s. According to archived records, prior to the events discussed in this report, the patient's last VA hospitalization was at the Tomah VAMC from May 25, 1982, to August 13, 1982.

Although followed for several chronic conditions at the Marshfield Clinic, the patient had no past history of cerebrovascular disease, including TIA or stroke. The medical records we reviewed do not document a history of stroke-like symptoms such as unexplained loss of consciousness, blindness, speech difficulties, unexplained limb weakness, or unexplained balance problems. Other than hypertension, the patient had no underlying medical conditions or clinical findings on examination portending a TIA or stroke, such as atrial fibrillation (abnormal heart rhythm), blood clots, or carotid bruits.[26] Overall, the patient's Marshfield Clinic medical records reflect that he was in stable condition, both medically and psychiatrically.

Events Immediately Preceding January 12, 2015

According to Marshfield Clinic records, the patient entered the new year of 2015 in stable condition. However, shortly after New Year's Day, he developed a cough. On January 3, the patient's wife called the Marshfield Clinic and described "coughing for [the] past 12 hours when laying down, or sits." A Marshfield Clinic note written in response to that call notes, "Pharmacist cannot find anything that is suitable for him due to [his] many prescriptions." The plan was "Caller [the patient's wife] will continue to monitor, try additional homecare measures as discussed, and call back or seek medical care [for her husband] if symptoms do not improve or symptoms worsen."

A second call, again by the patient's wife, was made the next day, January 4. In this call, reference was made to "flu symptoms" that her husband was experiencing. The Clinic's assessment was "influenza suspected: Rapid onset fever and respiratory symptoms (cough)" and the plan was "Call placed to Dr. [physician named], on call for

[25] Chronic bronchitis or emphysema.
[26] "A bruit is an audible vascular sound associated with turbulent blood flow," and "is usually heard with the stethoscope." http://www.ncbi.nlm.nih.gov/books/NBK289/ (accessed 5/4/2015)

Dr. [the patient's primary care physician], to discuss Tamiflu.[27] Orders received." Tamiflu® was started.

A third call was placed on January 9. In addition to respiratory problems, the patient was now experiencing "waking at 0300 [3 a.m.] in the morning the last few nights. [The patient's wife] feels he is delusional at night." The patient was advised to go to an ED.

The patient was seen in the ED of Ministry Saint Joseph's Hospital in Marshfield. An extensive note documents the patient's evaluation which included blood work, a chest x-ray, and an ECG. The final disposition notes, "Impression: Dyspnea [shortness of breath], COPD, Bronchitis Acute, Bipolar Disorder." The patient was felt to be stable and he was discharged to home with prescriptions for albuterol, prednisone,[28] Tessalon Perles®,[29] and azithromycin (an antibiotic drug), with instructions to follow up with his private physician in 3 to 4 days if he was not improving.

The patient's family members reported to OIG that the patient's respiratory condition appeared to improve; however, he began to experience problems with excess restlessness, racing thoughts, and further insomnia. The family members told us that they were concerned about the recent prescription of prednisone in the context of his history of bipolar disorder and contacted the patient's Marshfield Clinic mental health provider.

In January 2015, the patient had, on his own, increased his lithium dosage in response to worsening psychiatric symptoms, and was also taking zolpidem (a sedative often prescribed for insomnia) in the daytime. On January 11, a Marshfield Clinic psychiatrist formally increased the patient's lithium dosage, writing "After reviewing the patient's medical records, [the] patient's wife was instructed to just maintain the patient on 900 milligrams of lithium per day." The patient's Tomah VAMC's EHR also notes that "his [the patient's] non va provder [sic] has increased lithium dose from 300 mg bid [2 times daily] to 300 mg tid [3 times daily] and this past week increased med to 300 mg QID [4 time daily]." The patient's regular mental health caregiver was to be informed of the above and a lithium level was to be checked.

Despite the prescription of several new medications—albuterol, azithromycin, prednisone, and Tamiflu®—and the adjustment of an already prescribed medicine—lithium—the family members told us that the patient continued to not feel well.

According to the family, on the morning of January 12, a family member called Marshfield Clinic and was informed that if the patient could get to the clinic before 8:45 a.m. the patient could be seen. The Marshfield Clinic record documents that the patient did not check in at the Marshfield Clinic until 8:57 a.m. and the family was told to

[27] Tamiflu® (oseltamivir) is an antiviral drug prescribed for the treatment of influenza A and B.
[28] A corticosteroid drug, which is sometimes prescribed for patients who experience a COPD flare-up.
[29] Tessalon Perles® are benzonatate gelcaps. Benzonatate is a non-narcotic, cough medication that attempts to control cough by numbing and suppressing airway and lung cough reflexes. See: http://www.everydayhealth.com/drugs/benzonatate (accessed 4/20/2015).

wait and the patient would be "worked in." The Marshfield Clinic record also notes that at 9:16 a.m. the family dropped off forms at the reception desk, informed staff "he's leaving, he's sick," and left.

Morning and Initial Tomah VAMC Events, January 12, 2015

The family member told OHI that she called the Tomah VAMC after leaving the Marshfield clinic because she believed the patient's symptoms seemed to be of a mental health nature and would require a mental health hospitalization; the patient had been seen at the Tomah VAMC before, and she believed that the patient should and would be admitted to the hospital. The patient's family member further described to OHI that in the 1990s the patient had experienced an urgent psychiatric episode requiring inpatient psychiatric admission at the Marshfield Clinic; the VA did not subsequently reimburse the patient for this hospitalization, and, in anticipation of a psychiatric hospitalization for the patient, did not want to go through this experience again.

The family member told OHI that, after leaving the Marshfield Clinic, she called the Tomah VAMC, spoke to an operator, asked to be transferred to the Mental Health Outpatient Clinic, and left a voice message. The family member received a call back from the Tomah VAMC Mental Health Nurse Practitioner (MHNP) in approximately 15 minutes. According to the family member, she told the MHNP that the patient generally was not feeling or sleeping well, had balance problems, shortness of breath, and disorientation. During an interview with OHI, the MHNP had no recollection of being told of respiratory distress, and stated that had she been so informed, she would not have directed the family to take the patient to Tomah VAMC.

The MHNP's recollection is consistent with the Tomah VAMC EHR, which documents in a 9:20 a.m. January 12, MHNP note:

> *Daughter [of the patient] calling seeking information about where to get help for her father. States he was seen at Tomah in the 1980s and has been followed in the private sector since. Daughter states patient is Bipolar and has been ill. He's got the flu about 1.5 weeks ago. Was taken to the local ER and given prednisone this past Friday for exacerbation for COPD. He hasn't slept since Friday. He is willing to come into the hospital if needed...Encouraged [the] daughter to bring all meds with them should they come to Urgent Care [at the Tomah VAMC]. No admission is promised but will be assessed.*

According to the patient's family, after packing a bag for the patient, the family drove to the Tomah VAMC and arrived at approximately 11:00 a.m. The family told us that, in the 90-minute drive from Marshfield to Tomah, the patient's condition deteriorated. Specifically, the patient's dyspnea (difficulty breathing) increased.

According to the patient's family, when the patient and his family arrived at the Tomah VAMC, the patient's daughter brought a wheelchair to the parking lot to transport him to the UCC. The family told OHI that, upon checking in at the UCC, the family informed a UCC clerical employee that the patient was experiencing the symptoms of generally not feeling well, balance problems, shortness of breath, disorientation, and insomnia.

Documents reviewed by OHI indicate that the patient checked in at the UCC's front desk at 11:09 a.m.

According to the patient's family, at approximately 12:15–12:30 p.m., a nurse came out, apparently from the 4-bed UCC treatment area, and took the patient's vital signs. The family told this nurse that the patient had a history of bipolar disorder and they were concerned that he was having mental health related problems. Nevertheless, they were not 100 percent sure that the patient's symptoms were solely of a mental health nature. This is largely in accord with a facility EHR note, signed at 12:21 p.m. by the UCC triage nurse, which states that the patient presented:

> *with manic episodes resulting from bi-polar disorder. [The patient] states he has been taking steroids since Friday for bronchitis and wife has noticed him becoming 'manic.*' *[MHNP] has been notified and will be coming to get patient from UC waiting room.*

At that time, the patient's vital signs were not a cause for alarm. The patient was assigned an Emergency Severity Index (ESI) triage category of Level 4. The triage nurse noted that there would be an evaluation for admission, and the UCC disposition would be made by the MHNP, the same MHNP who had spoken with the family earlier by phone.

According to the patient's family, the UCC nurse who took the vital signs stated that it would probably be at least another hour before the patient was seen. The family stated that a family member checked at the UCC front desk approximately every 20 minutes to inquire as to when the patient would be further evaluated.

<u>Early Afternoon, January 12, 2015, Tomah VAMC UCC, Event #1</u>

At approximately 1:25 p.m., the patient suddenly slumped over while sitting in his wheelchair in the waiting area (Event #1). The patient's family told OHI that the patient stopped talking, his head slumped to the left, and he started to fall to his left side. Further, according to the patient's family, the patient's left arm was hanging down, his dentures fell out of his mouth, and he became unresponsive. The patient's eyes were said to be only half open, and he was drooling. He did not seem to be in pain, and there were no changes in his respirations. Further, according to the patient's family, the patient's wife screamed, "Oh my God, somebody help him." The family recounted that nobody came to help, despite this dramatic change in condition occurring just 5 feet from the UCC waiting room desk.

According to a clerk present at the time, the patient's daughter approached the information desk, and said words to the effect of "I think he's [her father] having a stroke." The clerk told OHI that she immediately called a nurse (RN 1) from the UCC and RN 1 went to the patient in the waiting area. While staff describe the response as immediate, according to the patient's family, there was delay in taking action. A note in the EHR indicated that the patient was brought to Triage at 1:25 p.m. and that the physician (Physician 1) arrived within 5 minutes.

A UCC triage nurse documented the following in the EHR:

> *1325 [The] Veteran [was] brought to triage via wc [wheelchair] by staff as there were no available beds in UC and he had a change of behavior in the waiting room…Veteran is awake, his head is slumped…He is pink and appears to be looking around. Veteran's wife states he just stopped talking and he is not talking to us. Veteran responded verbally to nurse and he asked for his daughter.*

OHI ascertained that, with the onset of Event #1, all four UCC beds were occupied and the patient was brought to the triage room, where he was first seen by Physician 1. He was then taken into a UCC room after a bed was cleared. Overall, the exact time intervals among the events of the patient's change in status, being transported to the UCC to the triage room, and then being transported to a UCC treatment room bed cannot be exactly determined with available documentation, but approximately occupies the 1:25-1:30 p.m. time interval. There is no videotape available to clarify exact times.

According to the patient's family, when in the triage room the patient started to speak a little and Physician 1 arrived. Also according to the patient's family, the elapsed time from the patient slumping over to Physician 1 seeing the patient was 15 minutes. Physician 1 stated that the time was more in the 5 minute range.

RN 1, who provided the patient's care from Event #1 until approximately 2:15 p.m., documented:

> *Vet was apparently here for MH appoint [appointment] and family stated he became unresponsive in WC in waiting room. Admissions called staff to vet and found to be able to respond, all 4 extremeties [sic] moving, left appears weaker than right but no prior baseline noted. Vet was brought to UC room. ambulated to bed. VSS [vital signs stable], he asked and performs MDI [metered-dose inhaler] WNL [within normal limits]. Lungs clear. Follows simple instructions. Lab called, MD in room.*

The patient's ESI "Triage Category" was changed to "Level 3 (Yellow)–Urgent" due to "Decreased mentation." Physician 1 who evaluated the patient at this time concluded that the patient had experienced a syncopal (loss of consciousness) episode of unknown etiology (cause). He ordered blood tests,[30] chest x-ray, and ECG.

A UCC RN (RN 2) who took over the care of the patient from RN 1 at approximately 2:15 p.m. documented: "Pt's [patient's] speech is clear and MAE's [moves all extremities] at this time. Left hand grasp is weaker than right and pt [patient] moving lower extremities equally."

Following Physician 1's initial evaluation, the MHNP spent approximately 30 minutes (1:45–2:15 p.m.) with the patient. The MHNP documented in the EHR that, according to his wife, the patient had been experiencing symptoms of his mood being

[30] Ordered tests included: NT-proBNP, CPK, troponin-1, lipase, amylase, ALT (SGPT), AST (SGOT), magnesium, basic metabolic, CBC with differential, prothrombin time & INR, lithium level, TSH, plasma drug screen, 5 Panel Urine Drug Test, urinalysis, acetaminophen, salicylate, ethanol, vitamin D 25-hydroxy test (total), vitamin B_{12} assay, and folate.

"down," irritability, impatience, insomnia, loss of energy, poor concentration, apathy, poor appetite, anxiety, and pressured speech. The MHNP noted that the patient was not psychotic and that the patient's wife and daughter believed he was hypomanic and needed his psychotropic medications reviewed and/or changed. The MHNP also documented:

> *74 y/o male with no previous VA records brought in by his wife and daughter for further assessment. They believe he is hypomanic and needs his psychotropic medications reviewed/changed. Much of the most recent history is provided by his wife. Patient is physically not feeling well and is trying to rest on gurnee [*sic*] and prefers wife to answer the questions. Discussed with [UCC physician] and need for lithium level. Will wait for lab results before making further decisions.*

The MHNP described the patient's speech as "acceptable." She noted that he was oriented to person, place, and time. His "Attitude/Cooperation" was described as "cooperative" and "willing to participate in evaluation," and the patient's "thought organization" was described as "fairly logical defers many questions to wife." The MHNP also noted: "Patient was able to maintain a conversation for 30 minutes." His peripheral motor activity was described as within normal limits.

The MHNP documented that she discussed the case and the need to obtain a lithium level with a UCC physician. This was agreed upon and the MNHP wrote "Will wait for lab results [e.g., lithium level] before making further decisions." The MHNP note did not document awareness of Event #1.

RN 2 documented that, at 2:15 p.m., the patient's speech was clear and that he was moving all his extremities. The RN also documented the following: "Left hand grasp is weaker than right and pt [patient] moving lower extremities equally."

The patient's blood was drawn at 2:21 p.m., a 12-Lead ECG was performed at 2:27 p.m., a portable chest x-ray was performed at or around 2:37 p.m., a urine sample for urinalysis and drug screen was obtained at approximately 3:05 p.m.

Blood tests revealed the patient had an elevated blood glucose level, impaired renal function, and a lithium level that was above the therapeutic range. The ECG showed no signs of acute cardiac abnormalities, and the chest x-ray showed no signs of acute pulmonary or cardiac abnormalities.

Mid-Afternoon, January 12, 2015, Tomah VAMC UCC, Event #2

A second event (Event #2) occurred at approximately 3:05 p.m. In the course of obtaining the urine sample, as noted by RN 2:

> *Pt [the patient] states he is feeling weak and upon attempting to sit in the chair next to the stretcher pt sat on left side losing mobility of left arm and left leg and unable to answer questions, speech is unclear and mumbled and pt is drooling, pt does not focus upon verbal stimuli or follow commands.*

According to the patient's family, family members heard a nurse yelling for help, saw the patient half in a chair and half on the floor with a nurse underneath him, and a nurse told the family to summon help. Together, the Tomah VAMC staff and the family got the patient back into bed. He was, at this time, completely paralyzed on his left side, his head was drooping to the left, and he appeared to want to speak but his speech was garbled.

Another UCC physician [Physician 2] started examining the patient and performing an NIH Stroke Scale evaluation,[31] a #20 intravenous (IV) catheter was placed into the patient's right arm, a #18 IV catheter was inserted into the patient's left arm, and the patient was administered oxygen via nasal cannula. At 3:13 p.m., the patient's Triage Level was upgraded to Level 2 "due to Acute CVA," and a CT scan of the head was ordered. At 4:05 p.m., the patient's blood pressure and heart rate remained stable.

At or around 3:19 p.m., Physician 1 contacted the Madison VAMC. He learned that it had no available beds. He contacted GHS and was informed that its helicopter was "down for maintenance." He thereupon "commandeer[ed] the ambulance already en route" for another UCC patient. This patient had arrived at the UCC before the case patient and was diagnosed with acute coronary syndrome and also required transfer to GHS.[32] Transfer to TMH was not considered a viable option in Physician 1's opinion because TMH was not a certified PSC.

The ambulance arrived at the Tomah VAMC at 3:57 p.m. and left at 4:15 p.m. At the time of transfer to GHS via ambulance, the patient was assessed as medically and behaviorally stable for transfer, although his condition was described as "guarded." Transfer diagnoses included lithium toxicity, acute stroke, and bipolar disorder. A report on the patient and his history was called to a GHS Emergency Department RN. The ambulance record documents:

> *Family reports that they had originally presented to Urgent Care for an unrelated concern-patient has a history of bipolar disorder and they were worried that he was becoming manic. Patient and family were in waiting room for approximately two hours, when patient all of a sudden begin [sic] to exhibit the symptoms of garbled speech and left-sided weakness. Patient was then immediately taken back for further evaluation. Symptoms did resolve for a short time, according to MD, but quickly recurred and have not receded since then. Patient is receiving O2 [*oxygen*] by NC [*nasal cannula*] at 2LPM [2 liters per minute], has bilateral IV [intravenous] access as noted, and has received no other interventions. He is to be transferred to Gundersen for stroke alert protocol. Physician reports that he has already spoken with neurologist [at GHS].*

The ambulance arrived at GHS at 5:01 p.m.

[31] "The National Institutes of Health Stroke Scale (NIHSS) is a systematic assessment tool that provides a quantitative measure of stroke-related neurologic deficit. The NIHSS was originally designed as a research tool to measure baseline data on patients in acute stroke clinical trials. Now, the scale is also widely used as a clinical assessment tool to evaluate acuity of stroke patients, determine appropriate treatment, and predict patient outcome." From: http://www.nihstrokescale.org/ (accessed 4/18/2015).

[32] "Necessary arrangements for a second ambulance" were made for the patient for whom the ambulance was originally called.

As this is not a review of care at non-VA facilities, the patient's GHS course is only briefly summarized:

Providers at GHS performed a CT scan, which revealed findings consistent with a stroke. An angiogram demonstrated clots in the right internal carotid artery and a branch of the middle cerebral artery (the middle cerebral artery is the main blood vessel supplying blood to the frontal, parietal and temporal lobes of the brain). GHS staff administered a thrombolytic ("clot-busting") medication. When this did not dissolve the clot, providers opened the blood vessels through a catheterization procedure. The patient went to the intensive care unit following the procedure. On the second hospital day, providers obtained another CT scan, which revealed a right middle cerebral artery stroke, possible bleeding into the brain, and a new stroke in a different part of the brain.

Based on the patient's continued deterioration and the futility of further aggressive actions, the family "unanimously decided to transition to a comfort based approach to his [the patient's] care forgoing all aggressive measures." Accordingly, the patient was transferred to Palliative Care at GHS.

On January 14, 2015, at 4:20 p.m., the patient died with his family at his bedside. No further laboratory tests were pending at that time and an autopsy was declined.

Inspection Results

Issue 1: Quality of Care Concerns

Allegation 1. The patient waited 3 hours to be seen.

We did not substantiate the allegation that the patient waited for 3 hours before being seen.

The patient checked in at the UCC's front desk at 11:09 a.m. and the UCC triage nurse signed an EHR note describing the patient's history and documenting his 12:11 p.m. vital signs. The elapsed time was approximately 1 hour and 2 minutes (62 minutes).

After the first encounter, the patient was advised the wait to be assessed by the MHNP would be an hour and was asked to wait in the UCC waiting area. The patient was next seen by the triage nurse, RN 1, and Physician 1 at approximately 1:25–1:30 p.m., after the patient experienced Event #1 while in the waiting area, approximately 2 hours and 16 minutes (136 minutes) after being checked in at the UCC.

Allegation 2. Other patients came and went before the case patient was seen.

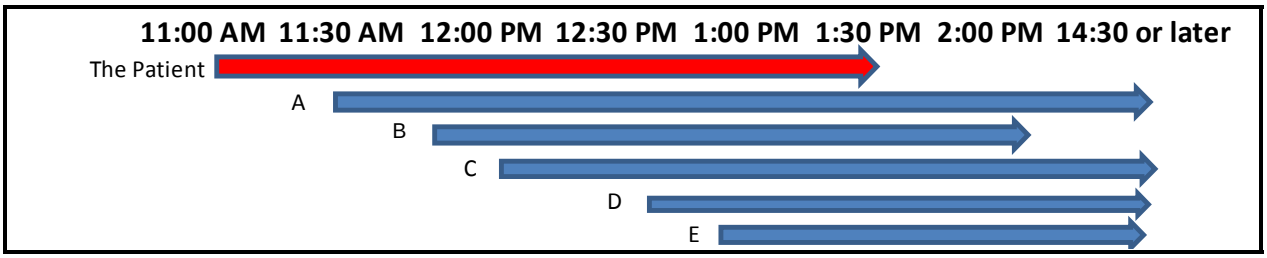
We did not substantiate that other patients arrived and were treated and released before the case patient was seen.

The patient came to the Tomah VAMC for evaluation of recent mental status changes. The possibility of admission for medication adjustments and/or mental health reasons

was to be considered. The triage nurse called the MHNP, who was working in the Mental Health Outpatient Clinic and assigned to assess UCC patients with mental health concerns as needed that day. The triage nurse advised the patient to wait in the waiting area until the MHNP could come to the UCC.

We reviewed the EHRs of all 6 patients (including the case patient) who arrived at the UCC that day between 11:09 a.m., when the patient arrived, and 1:25 p.m., the approximate time the patient experienced Event #1. No patients in that group were treated and discharged during that time period. (See Table 1 below.)

Table 1. UCC Patients (blue arrows) Who Arrived After the Case Patient (red arrow) Arrived on January 12, 2015, and Their Discharge Times in Comparison with the Time of Event #1.



Source: VAOIG

Allegation 3. The UCC physician who treated the patient was unaware of the symptoms of a stroke.

We did not substantiate that Physician 1 was unaware of symptoms of a stroke.

We understood this allegation to mean that the physician did not have the expertise to recognize the signs and symptoms of a stroke. We reviewed the physician's most current credentials and privileges on file and determined they were consistent with this physician having the knowledge and skills to diagnose a stroke. Additionally, in reviewing the physician's Tomah VAMC training records, we found that the physician attended an AIS educational presentation on March 28, 2011.

Allegation 4. The physician did not diagnose the first neurologic event as a TIA, nor did he treat the patient's second neurologic event, an acute stroke, with sufficient urgency.

We substantiated the allegation that the physician did not affirmatively diagnose the first neurologic event as a TIA. However, after Event #1, Physician 1 initiated a work-up to determine the cause of Event #1.

Physician 1, who evaluated the patient at the time of Event #1, told us that he concluded that the patient had experienced a syncopal episode of unknown etiology and acted accordingly. He indicated that he (the physician) was considering multiple causes of syncope. We determined the EHR supports this because Physician 1 ordered extensive blood tests, an ECG, and a chest x-ray after Event #1.

We did not substantiate that Physician 1 failed to treat the patient's second neurologic event, an acute stroke, with sufficient urgency. The Case Summary reflects aggressive and urgent treatment of Event #2 within the limitations of the Tomah VAMC capabilities. Steps taken included:

- Performing an NIH Stroke Scale evaluation
- Starting two intravenous lines
- Contacting Madison VAMC
- Contacting GHS
- "Commandeer[ing] an ambulance already en route" for another patient to take the patient to GHS

Allegation 5. Family concerns that the patient was experiencing stroke symptoms were dismissed.

We did not substantiate that UCC staff were dismissive of the symptoms and signs the patient exhibited. The physician launched an extensive evaluation of syncope, of which TIA is one cause. The evaluation was not initially focused on TIA or stroke after Event #1; rather, it was focused on syncope.

Allegation 6. The UCC physician on duty who treated the patient waited until after a second stroke occurred before suggesting a CT scan.

We substantiated this allegation, but found this was not unreasonable give the patient's clinical presentation and history. Upon evaluating the patient after Event #1, Physician 1 concluded that the patient had experienced a syncopal (loss of consciousness) episode of unknown etiology (cause). He ordered extensive blood tests, an ECG, and a chest x-ray to aid him in diagnosis. He did not order a CT scan until after Event #2.

Allegation 7. The UCC physician wanted to obtain a CT scan, but the CT machine was broken. Without a CT scan, the Tomah VAMC could not administer the anticoagulant medication that is commonly used to treat a stroke victim.

We did not substantiate the allegation that the CT scanner was broken. Nevertheless, the machine was unavailable for use due to routine maintenance at the time the UCC physician wanted to obtain a head CT scan.

We substantiated the allegation that without a CT scan, the Tomah VAMC could not administer tPA. However, the Tomah VAMC providers would not have administered tPA even if its CT scanner had been operational. The Tomah VAMC is a designated VHA SSF and cannot administer tPA to treat an acute ischemic stroke. (See Introduction.)

On January 12, 2015, when Physician 1 wanted to obtain a CT scan of the patient's head, the scanner was unavailable for use due to routine scheduled maintenance. Routine maintenance consists of both preventive maintenance and recalibration, and is performed on a monthly basis by technicians based out of Holmen, WI, 45 miles away. A 4-hour block of time for routine maintenance is scheduled with the Radiology Service, although typically maintenance takes about 2.5 hours.

Obtaining a CT scan on an emergency basis while the CT scan is undergoing routine maintenance is very difficult because the machine may be disassembled. The Tomah VAMC Biomedical Equipment Support Specialist, through whom requests are routed when the scanner is down, was unaware of an emergency CT scan ever having been obtained in the course of a routine maintenance visit.[33]

Allegation 8. The complainant had to help the Tomah VAMC fix the electrocardiogram (ECG) machine.

We did not substantiate the allegation that the ECG machine was broken and had to be fixed by a family member.

The UCC has a dedicated ECG machine. Its last unscheduled maintenance prior to January 12, 2015, occurred on December 16, 2014.

The ECG technician who performed the ECG told OHI that when she arrived by the patient to perform an ECG, the patient was in a fetal position. The technician found it difficult to place the leads, and after being affixed, several fell off. New leads were affixed.

We were told that a paper jam occurred while the technician was obtaining the patient's ECG on January 12, which had to be cleared. The Biomedical Equipment Support Service stated that in this event, the machine's cover is opened, paper is repositioned and/or crumbled sheets of paper in the machine are removed, and the machine is closed.

The ECG technician acknowledged that a family member cleared the paper jam. The ECG technician told OHI, "She [a family member] saw that there was a paper jam in the ECG machine and stood up to help. She stated she worked in the medical field and was able to fix it. Before I was able to troubleshoot the problem she had already opened the paper tray. She did not assist in any way with the ECG procedure. I alone placed the leads and printed the ECG."

Overall, there were no mechanical or software issues that had to be fixed by any party.

[33] Conversely and depending on the issue, with unscheduled maintenance it may be possible to obtain a CT scan on an emergency basis. For example, if a minor issue is being attended to, the machine may possibly be quickly put back on line and an emergency CT scan obtained.

We reviewed this ECG and found that it was of good technical quality. We also reviewed the training record of the ECG technician, and found that all proficiencies were up-to-date and recently certified.

Allegation 9. The patient should have been transferred to nearby Tomah Memorial Hospital.

We did not substantiate the implied inappropriateness of the UCC physician's decision to send the patient to GHS rather than TMH.

As discussed in the Introduction, TMH is located 2 miles from the Tomah VAMC, but it is not a JC-certified PSC. Transferring the patient to TMH would not only have been inconsistent with the Tomah VAMC and VHA policy, but also a temporizing step further delaying transfer to a PSC with resources needed to assess and treat a major stroke.

Allegation 10. Unauthorized parties accessed and/or disseminated the patient's electronic health record information inappropriately.

We did not substantiate this allegation insofar as it pertains to inappropriate EHR access on or after February 25, 2015. We could not substantiate this allegation for the time period before February 25, 2015.

The complainant alleged that "based on public comments we have seen by people claiming to be VA employees, [our concern] is that people/employees have been accessing his records unnecessarily."

The complainant provided several Internet news article "comments" that were felt to be indicative of sensitive EHR information having been accessed and used in an inappropriate manner. In reviewing these comments, we did not identify protected information that could only have been obtained from the patient's VA EHR or other VA privacy protected documents. Nevertheless, we found that it was possible that the patient's EHR could have been accessed inappropriately. If not designated as a "Sensitive" record, an electronic audit trail is not created when an EHR is accessed. The patient's record was not designated "Sensitive" until February 25, 2015.

We found in the time interval of February 25–April 16, 2015, the patient's EHR was accessed 129 times. Entities and/or reasons for accessing the patient's records included OIG, Laboratory Service, Fee Basis, Risk Management, Root Cause Analysis, Coding, Quality Assurance, Release of Information, Patient Safety, the non-VA Care Coordination Team clerk in response to a Congressional inquiry, and Regional Counsel. Overall, in that time period, no employee accessed the record without a legitimate "need to know."

Allegation 11. UCC staff told the patient's daughter that her father would be transported to GHS via helicopter, but a short time later, and without further explanation, staff told her that helicopters were not flying that day.

We could not substantiate exactly what the patient's family was told about helicopter availability on January 12. We verified that the Tomah VAMC does not own a helicopter and does not control the GHS helicopter, which was not flying that day.

Although Physician 1 would have preferred to transport the patient to GHS by helicopter after Event #2, the physician was informed that the GHS helicopter was "down for maintenance." Accordingly, arrangements were made to transfer the patient to GHS via ground ambulance.

Allegation 12. Upon arrival at GHS, doctors there apparently "could not understand" why the patient was not administered the anticoagulant medication in Tomah or why he was not transported to La Crosse via helicopter.

We could not substantiate this allegation because evaluating, and/or analyzing GHS staff reaction to the patient's care at the Tomah VAMC was beyond the scope of our review.

Issue 2: Other Findings

During the course of this review, we found opportunities for improvement that did not affect the outcome of this case.

Memoranda of Understanding

VHA Directive 2011-038, *Treatment of Acute Ischemic Stroke (AIS),* November 2, 2011, provides VHA's policy for the management of acute ischemic stroke (AIS) in VHA medical facilities. The Directive states that medical facilities that do not diagnosis and treat AIS patients must have a plan in place to transfer their care to the nearest Primary Stroke Center. The Tomah VAMC local AIS policy dated March 7, 2012, states "transfer agreements are in place to triage and/or transfer acute stroke patients to facilities offering a higher level of care."[34] Additionally, VHA Directive 1079, *Standards for Nomenclature and Operations for Urgent Care Clinics in VA Medical Facilities*, February 3, 2014, requires that transfer agreements must be developed in advance with local and regional health care partners.

We determined that the Tomah VAMC had appropriate plans in place to transfer patients to the closest PSCs; however, there were no written Memoranda of Understanding. Although, in the current case, transfer of the patient to the closest PSC, a non-VA facility, occurred without incident, a formalized agreement could prevent

[34] MCM No. MS-21. *Treatment of Acute Ischemic Stroke*. March 7, 2012.

potential future transfer delays. We did not conclude that this issue in any way impacted the care provided to this patient.

Web-Based AIS Training

VHA Directive 2011-038 and the Tomah VAMC's local policy requires that its staff receive web-based AIS training. We found that no Tomah VAMC staff have received web-based AIS training as required. We did not conclude that this issue in any way impacted the care provided this patient.

Triage

Triage is the clinical assessment of patients in order to prioritize in what order individuals will be seen by a provider. We determined the UCC registration process, during busy times, has the potential to place patients at risk because patients are not always evaluated by an RN soon after registration. We did not conclude that this issue in any way impacted the care provided this patient.

Patients who present to the Tomah VAMC UCC first encounter a registration clerk. The clerk verifies the patient's name and registers the patient in the UCC system. The patient is then instructed to return to the waiting area and an RN calls each patient in his/her order of arrival to conduct a brief triage assessment. On the day the patient presented to the UCC, patients were not triaged immediately after registering with the clerk. While we did not find that any harm occurred on the day of our review due to the practice, we determined patients presenting with subtle symptoms a clerk might not recognize as serious could be missed and that patients in the waiting area could exhibit more serious symptoms without notice if an RN does not first quickly assess patients as they present to the UCC.

VA's FY15 door-to-triage timeliness target is less than or equal to 15 minutes. We reviewed the EHRs of all the patients who sought UCC care on January 12, 2015, and found 2 of the 20 patient encounters (10 percent) were triaged in less than 15 minutes. Multiple staff told us that Monday, January 12, was a particularly busy day in the Tomah VAMC UCC, and this was validated through review of the Tomah VAMC UCC data with VHA's National Program Director for Emergency Medicine.

Emergency Department Integration Software

Emergency Department Integration Software **(**EDIS) may be used to track and trend UCC and ED data across VHA nationwide. Reliable data for quality assurance and national trending is necessary to assist in making policy to address issues such as the UCC versus ED problem at rural VAMCs (see discussion below). We found that while the Tomah VAMC has EDIS software, it has no trained staff for EDIS and its EDIS processes for gathering UCC data, thereby impeding its ability to capture data such as

"door-to-triage time." We did not conclude that this issue in any way impacted the care provided this patient.

Use of the Tomah VAMC UCC as an Emergency Department

The issue of triage times brought to light another finding. In the course of this inspection we heard extensive testimony and comments from virtually every party involved—from the Tomah VAMC line staff to the Tomah VAMC leadership to VHA National Leadership—that the UCC is being utilized by patients as an ED when, in fact, it is not an ED. The Tomah VAMC has no operating rooms, no intensive care unit, no surgeon on staff, and lacks the infrastructure of an ED. While the UCC was an appropriate destination for the case patient at the time of his departure from Marshfield, the issue of the use of the UCC as an ED surfaced in this inspection.

In performing this inspection, we reviewed the EHRs of other patients seen on January 12, 2015, at the Tomah VAMC's UCC. This review revealed several patients that should have gone to an ED, not a UCC. Nonetheless, we found that the VA providers did not turn them away but rather tried to provide the care needed to stabilize the patient and arranged for transfer when appropriate. For example:

- An 85-year-old patient presented to the UCC on January 6, 2015, and was treated for difficulty breathing. On the evening of January 11, he called the telephone triage with complaints of difficulty breathing and was advised to call 911. On January 12, he instead presented to the UCC at 8:39 a.m. with breathing difficulty which was worsening. The patient soon became unresponsive. The patient was "do-not-resuscitate/do-not-intubate." Providers started IV fluids and oxygen. The patient died at 9:04 a.m.
- At 12:17 p.m., a patient entered the UCC with complaints of heart palpitations after being advised by telephone triage staff at 11:09 a.m. to seek emergency care.
- A 64-year-old patient had been hospitalized in December 2014, for bronchitis. A Tomah UCC note timed 12:09 p.m. documented that he still complained of a cough, but also had new onset sharp intermittent chest pain of 2 weeks duration. His troponin was mildly elevated. Tomah UCC providers completed a transfer note at 2:34 p.m., and an ambulance arrived at 5:37 p.m. to transport the patient to a higher level of care facility. In the interim, the patient received heparin and supportive care.[35]
- A 67-year-old patient presented in follow-up from an evaluation at a non-VA ED 2 days earlier. At that ED, the patient had been diagnosed with influenza A and atrial fibrillation, but declined admission. He also had chronic mild hypokalemia (low blood potassium level) and renal insufficiency. The UCC provider noted that his atrial fibrillation appeared to be rate controlled on metoprolol, and

[35] This was the patient for whom the case patient's ambulance was called.

recommended he continue to take daily aspirin. He also increased the patient's potassium supplementation and ordered follow-up with an echocardiogram and cardiology consultation.

We believe that the instances cited above are all instances of medical and clinical presentation that exceed those envisioned in VHA's UCC Directive VHA Directive 1079, *Standards for Nomenclature and Operations for Urgent Care Clinics in VA Medical Facilities*, February 3, 2014.

Further, we reviewed ambulance records and found that numerous Tomah VAMC UCC patients had to be transferred to higher level facilities. For example, in January 2015, 17 patients had to be transported by ambulance, 16 of whom were transported to either Madison VAMC or GHS, and one of whom was transported to TMH. In discussing this issue with VHA's National Chief of Emergency Services it was acknowledged that this was a VHA system-wide dilemma for VHA's rural facilities.

In a 2014, OIG Combined Assessment Program review of the Tomah VAMC, the Tomah VAMC staff who responded to an EAR survey reported that patients come to the UCC with serious health issues because they are fearful their medical bills will not be paid through the Non-VA Care Coordination program if they go to an ED first. The Tomah VAMC leaders stated it could not control the type or complexity of patients who present to the UCC and that all patients were triaged appropriately. The Tomah VAMC action plan included developing tools to educate patients of the UCC services available with an estimated completion date of March 2015.

Conclusions

We did not substantiate the general allegations of poor care and delayed care. With respect to the specific allegations made by the patient's family, we found the following.

We did not substantiate that the case patient waited for 3 hours before being seen at the UCC, or that other patients arrived and were treated and released before the case patient was seen. We did not substantiate that the physician who treated the patient was unaware of stroke symptoms. We substantiated the allegation that the physician did not affirmatively diagnose the first neurologic event the patient experienced as a transient ischemic attack or acute ischemic stroke; however, the physician properly considered broad diagnostic possibilities for the syncopal episode which occurred while the patient was in the Tomah VAMC UCC waiting room awaiting a mental health evaluation. We did not substantiate that the physician failed to treat the patient's second neurologic event, an acute ischemic stroke, with sufficient urgency.

We did not substantiate that UCC staff were dismissive of the signs and symptoms that the patient exhibited. We did not substantiate that the Tomah VAMC's CT scan was broken; however, we determined it was not available due to scheduled, routine maintenance when the patient was treated in the UCC. We substantiated that the physician ordered a CT after the patient's second neurologic event. We did not substantiate that the ECG machine was broken.

We substantiated that the patient was not transferred to TMH, located 2 miles from the Tomah VAMC; however, we determined that transferring the patient to GHS was the appropriate action because it was the closest JC-certified PSC and was in accordance with the Tomah VAMC's local transfer policy. We could not substantiate that the patient's electronic health record was inappropriately accessed prior to February 25, 2015; however, we determined it was not accessed inappropriately on or after that date. We could not determine exactly what the family was told about air ambulance (helicopter) availability on January 12, 2015, but found that the Tomah VAMC does not own or operate an air ambulance and that one was not available to transfer the patient. We could not substantiate the allegation that GHS staff commented negatively about the patient's care at the Tomah VAMC UCC.

We concluded that, overall, the UCC staff acted appropriately in the face of a patient experiencing a sudden and unexpected acute ischemic stroke while waiting for a mental health evaluation in a rural hospital that is not equipped to treat a health problem of this magnitude. Nevertheless, we identified opportunities for improvement, none of which impacted the care of this patient.

We made three recommendations to the Interim Under Secretary for Health and six recommendations to the Facility Director.

Recommendations

1. We recommended that the Under Secretary for Health review current acute stroke treatment policies, and assess the use of telehealth evaluation and more aggressive local treatment in patients presenting to rural and/or low complexity VHA facilities with signs and symptoms of an acute stroke.

2. We recommended that the Under Secretary for Health review processes to improve the ability to identify unauthorized access to VA medical records.

3. We recommended that the Under Secretary for Health evaluate the complex rules related to reimbursement for a veteran's emergency care at non-VA facilities, and determine if changes in policy or law would make it more likely that veterans would make decisions on where to seek emergency care based upon medical circumstances, rather than fear of adverse financial impact.

4. We recommended that the Facility Director ensure that patients and their families are educated about the services the UCC is equipped to provide.

5. We recommended that the Facility Director ensure that employees who are involved in assessing and treating stroke patients receive the web-based acute ischemic stroke training required by the facility and that facility managers monitor compliance.

6. We recommended that the Facility Director ensure that transfer agreements are established as required.

7. We recommended that the Facility Director review and evaluate computerized tomography scanner routine maintenance schedules to determine if routine maintenance can be conducted during periods of traditionally low utilization.

8. We recommended that the Facility Director ensure Urgent Care Clinic processes are strengthened to reduce door-to-triage timeliness.

9. We recommended that the Facility Director ensure that appropriate staff receive Emergency Department Integration Software training.

Appendix A

Table 2. Timeline of Events, January 12, 2015, Tomah Urgent Care Center

Time	Event
09:16 a.m.	The patient left the Marshfield Clinic.
09:20 a.m.	The patient's daughter spoke to the Tomah VAMC MHNP.
11:09 a.m.	The patient is checked in at the Tomah VAMC UCC.
12:11 p.m.	The patient's vital signs were recorded.
12:17 p.m.	The triage nurse assessed the patient and called the MHNP. ESI 4
1:25 p.m.	Approximate time the patient experienced Event #1.
1:25–1:30 p.m.	Approximate period for events immediately following Event #1.
1:30 p.m.	Approximate time the patient was placed in a UCC bed.
1:45–2:15 p.m.	Approximate time period the MHNP evaluated the patient.
2:21 p.m.	The patient's blood was drawn for ordered laboratory tests.
2:27 p.m.	The patient's electrocardiogram was performed.
2:37 p.m.	The patient's chest x-ray was performed.
3:05 p.m.	The patient's urine for urinalysis was obtained.
3:05 p.m.	Approximate time the patient experienced Event #2 – Diagnosed AIS. ESI 2.
3:57 p.m.	Advanced life support ambulance arrived to transfer the patient to GHS.
5:01 p.m.	Patient arrived at GHS.

Source: VAOIG

Appendix B

Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: June 5, 2015

From: Under Secretary for Health (10)

Subj: Healthcare Inspection—Care Concerns of an Urgent Care Clinic Patient, Tomah VA Medical Center, Tomah, Wisconsin

To: Director, Kansas City Office of Healthcare Inspections (54KC)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. Thank you for the opportunity to review the draft report, Healthcare Inspection - Care of an Urgent Care Clinic Patient, Tomah VA Medical Center (VAMC), Tomah, WI.
2. I reviewed the draft report and concur with the recommendations made to the Interim Under Secretary for Health. Attached is the corrective action plan for recommendations 1 through 3. The Veterans Health Administration considers recommendation 2 fully implemented and requests closure.
3. The Tomah VAMC Director will provide a corrective action plan for recommendations 4 through 9.
4. If you have any questions, please contact Karen M. Rasmussen, MD, Director, Management Review Service (10AR) at VHA10ARMRS2@va.gov.

(*original signed by:*)

Carolyn Clancy, MD
Interim Under Secretary for Health (10)

Comments to OIG's Report

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

OIG Recommendations

Recommendation 1. We recommended that the Under Secretary for Health review current acute stroke treatment policies, and assess the use of telehealth evaluation and more aggressive local treatment in patients presenting to rural and/or low complexity VHA facilities with signs and symptoms of an acute stroke.

Concur

Target date for completion: November 30, 2015

Facility response: The Veterans Health Administration (VHA) reviewed the current acute stroke treatment polices and assessed the potential use of telehealth evaluations and more aggressive local treatment in patients presenting to rural and/or low complexity VHA facilities with signs and symptoms of acute stroke. At this time, VHA does not have national or local guidance for Emergency Department stroke management using telehealth.

VHA will complete a more in-depth review into the potential of use of telehealth to assist in the initial assessment of patients presenting with stroke-like symptoms.

To complete this action plan, VHA will provide the following documentation:

1. The outcome of the review.

Recommendation 2. We recommended that the Under Secretary for Health review processes to improve the ability to identify unauthorized access to VA medical records.

Concur

Target date for completion: April 30, 2015

Facility response: VHA has and continues to elevate this issue. VHA Office of Informatics and Analytics (OIA) recently worked with the VA Office of Information Technology (OI&T) on the feasibility of the Veterans Health Information Systems and Technology Architecture (VistA) system logging access to all patient records.

Historically, VistA system risk analyses and assessments performed for the audit of VistA Record Access have included the impact of audit data collection for patient record access to the VistA environment. Case in point, of the 153 VA Hospitals, one VA Hospital could see approximately 125,000 unique patient visits per year. Each patient is touched by approximately 8 different VistA Users (clinical and administrative) 13 times per year. Per OI&T, this would generate 3,000,000 log entries just for unique outpatient

patient visits at one facility. The number of log entries for all VHA facilities could be as high as 753,888,000, or higher, based solely on outpatient and inpatient visits. This estimate does not include access due to repeat visits, patient billing, or other reasons that might also trigger an audit event.

This volume of audit activity spread across the system can impose an adverse system resource impact, resulting in system degradation or outages due to the immense volume of data collected. Such high impact can exploit system limitations with storage, system resources (CPU, memory, and user load), journaling, contingency system relying on real-time production feeds (VistA Read Only, BCMA Backup). These factors all potentially present a patient care/safety issue due to system performance degradation and extended periods of system unavailability.

Based on this risk analysis, VA has been auditing only those records designated as sensitive. These include, but are not limited to:

1. VA Veteran employee patient health records;
2. Regularly scheduled Veteran volunteers;
3. Individuals engaged in the presentation of claims before VA, including representatives of Veterans' organizations, or cooperating public or private agencies, or Administrative Tort Claims;
4. Records involved in Administrative Tort Claim activities; and
5. Other health records per management decision.

OIA has submitted a new service request (NSR) to modify the existing warning displayed to users when accessing a record flagged sensitive, to add an additional warning for suspicious accesses which are based on set criteria, and to create a new report listing all suspicious accesses for more efficient auditing and identification of unauthorized accesses. OIA has been developing the Business Requirements Document (BRD) for the NSR and once the BRD is completed it will be submitted for OI&T prioritization.

To mitigate the risk of inappropriate access to all medical records, VA has implemented the following compensating controls:

1. All users must complete Information Security and Privacy Awareness training;
2. All users must sign the VA Rules of Behavior;
3. All users complete VHA Privacy and HIPAA Focused training;
4. Access is controlled by VistA menu options and security keys
5. All users are trained on the minimum necessary policy as well as knowing their functional category as outlined in VHA Handbook 1605.02, *Minimum Necessary Standard for Protected Health Information*;
6. Supervisors utilize the employee's functional category for the assignment of VistA menu and security.

Beyond the creation of an access log for all non-sensitive records within VistA/Computerized Patient Record System, which is not feasible, there is only one other option for identifying unauthorized access to electronic health records and it is employed within VHA today: complaint based identification of unauthorized access. When a

Veteran or employee complains about alleged unauthorized access, that complaint is reviewed and examined by the Privacy Officer and the alleged employee wrongdoer is interviewed. If it cannot be determined that the access was appropriate, then per policy, unauthorized access occurred and the employee may be disciplined.

Recommendation 3. We recommended that the Under Secretary for Health evaluate the complex rules related to reimbursement for a veteran's emergency care at non-VA facilities, and determine if changes in policy or law would make it more likely that veterans would make decisions on where to seek emergency care based upon medical circumstances, rather than fear of adverse financial impact.

Concur

Target date for completion: December 31, 2015

Facility response: The Deputy Under Secretary for Health for Operations and Management (DUSHOM) will convene a group of subject matter experts to:

1. Understand what factors patients consider when deciding where and when to seek urgent and emergency care for a medical condition.
2. Discuss the impact of current rules and laws on patients' decision making regarding VA urgent care versus non-VA care.
3. Determine whether the issue of patients receiving care at VA urgent care clinics (UCC) rather than non-VA emergency departments is a local or widespread phenomenon.

Group membership will consist of, at a minimum, subject matter experts from the VHA Office of Patient Centered Care and Cultural Transformation, the VHA Chief Business Office, VHA Emergency Services, and others, as appropriate.

To complete this action plan, the DUSHOM will provide the following documentation:
A white paper discussing the factors impacting patients' decisions about seeking care at VA UCCs versus non-VA Emergency Departments and the impact of reimbursement rules and laws on those decisions.

Appendix C

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: May 26, 2015

From: Director, VA Great Lakes Health Care System (10N12)

Subj: Healthcare Inspection—Care Concerns of an Urgent Care Clinic Patient, Tomah VA Medical Center, Tomah, Wisconsin

To: Interim Under Secretary for Health (10)

1. Attached please find Tomah VAMC's response to the above referenced Healthcare Inspection report.

Renee Oshinski
VISN 12 Acting Network Director

Appendix D

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: May 26, 2015

From: Acting Director, Tomah VA Medical Center (676/00)

Subj: Healthcare Inspection—Care Concerns of an Urgent Care Clinic Patient, Tomah VA Medical Center, Tomah, Wisconsin

To: Acting Director, VA Great Lakes Health Care System (10N12)

1. Thank you for the opportunity to review the draft report of the Tomah Veterans Affairs Medical Center inspection. I have reviewed the document and concur with the recommendations.

2. Corrective action plans have been established with planned completion dates, as detailed in the attached report. If additional information is needed please contact my office at (608) 372-1777.

John J. Rohrer
Acting Medical Center Director

Comments to OIG's Report

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

OIG Recommendations

Recommendation 4. We recommended that the Facility Director ensure that patients and their families are educated about the services the UCC is equipped to provide.

Concur

Target date for completion: May 31, 2015

Facility response: The Tomah Veterans Affairs Medical Center (VAMC) developed an educational brochure outlining the capability of the Urgent Care Clinic. This was mailed to all Veterans enrolled for care at the Tomah VAMC. This brochure will also be provided to Veterans at New Patient Orientation and given to community stakeholders such as County Veteran Service Officers to disseminate to Veterans. In addition, signage has been placed at the entrance to the Urgent Care Clinic clearly stating that emergency services are not provided at the clinic and the Madison VAMC Telephone Triage service has been provided the updated information on the capabilities of Tomah's Urgent Care Clinic. Based on the information provided, we request closure of this recommendation.

Recommendation 5. We recommended that the Facility Director ensure that employees who are involved in assessing and treating stroke patients receive the web-based acute ischemic stroke training required by the facility and that facility managers monitor compliance.

Concur

Target date for completion: August 31, 2015

Facility response: All medical providers and registered nurses working in the areas of Primary Care, Medical Officer of the Day, Acute Medicine, Urgent Care Clinic, and Community Living Centers will be assigned the web-based Talent Management System (TMS) course American Heart Association (AHA) Acute Stroke Online, ID#3893054. Compliance will be monitored by Medicine Service Line leadership to ensure 90 percent or better compliance is achieved.

Recommendation 6. We recommended the Facility Director ensure that transfer agreements are established as required.

Concur

Target date for completion: August 31, 2015

Facility response: The Tomah Veterans Affairs Medical Center will pursue a transfer agreement with Gundersen Health System in La Crosse, Wisconsin for acceptance of patients with acute ischemic stroke symptoms. This process will be monitored by facility leadership to ensure that a transfer agreement is secured.

Recommendation 7. We recommended the Facility Director review and evaluate computerized tomography scanner routine maintenance schedules to determine if routine maintenance can be conducted during periods of traditionally low utilization.

Concur

Target date for completion: June 30, 2015

Facility response: Facility response: The Tomah Veterans Affairs Medical Center (VAMC) Radiology staff will compile 3 months of computerized tomography (CT) scanner studies from the PACs system of record to determine utilization rate averages. The identified periods of lower CT scanner utilization will be used to help determine when routine maintenance of the CT scanner would best be scheduled. Based on Radiology's recommendations, Biomedical Engineering will work within the existing vendor contract to coordinate planned preventative maintenance scheduled times during these periods of lower utilization.

Recommendation 8. We recommended the Facility Director ensure Urgent Care Clinic processes are strengthened to reduce door-to-triage timeliness.

Concur

Target date for completion: June 30, 2015

Facility response: The Tomah VAMC Urgent Care Clinic (UCC) has implemented a procedure for check in to the UCC. This procedure includes possible urgent and/or emergent level complaints that will trigger immediate notification of the registered nurse (RN) for triage. Education on this check in procedure will be provided to all UCC providers, RNs, and Medical Administrative Assistant (MAA) to ensure staff understand the process and facilitate rapid identification of patients requiring medical assistance. Compliance will be monitored by the UCC Nurse Manager to ensure 90 percent or better compliance is achieved with education on this new process.

Recommendation 9. We recommended the Facility Director ensure that appropriate staff receive Emergency Department Integration Software training.

Concur

Target date for completion: June 30, 2015

Facility response: Urgent Care Clinic providers and nursing staff will receive instruction on use of the Emergency Department Integration Software (EDIS). This will include

face-to-face instruction and verification of understanding followed by dissemination of educational materials for independent staff review and verification. Compliance will be monitored by the Urgent Care Clinic Nurse Manager to ensure 90 percent or better compliance is achieved with education on this process.

Appendix E

Office of Inspector General Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	George Wesley, MD Sheila Cooley, GNP, MSN Stephanie Hensel, RN

Appendix F

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