Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Quality of Care Issues
Tomah VA Medical Center and
William S. Middleton Memorial
Veterans Hospital,
Tomah and Madison,
Wisconsin

Report No. 10-02355-242 **September 8, 2010**

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Secretary and Congressman David R. Obey requested the Office of Inspector General Office of Healthcare Inspections review allegations regarding the care of a patient at several Veterans Health Administration facilities within VA's Great Lakes Health Care System. The complainant provided multiple allegations regarding deficient care including that the patient died as a direct result of mismanagement of his antiarrhythmic cardiac medications and that he was denied benefits from exposure to Agent Orange while serving in Thailand during the Vietnam War.

We did not substantiate most of the complainant's specific allegations and determined that clinical decisions made were reasonable and justifiable. The patient's death was unexpected and occurred during the course of his cardiac evaluation. We note that the death certificate lists the cause of death as acute heart failure due to or as a consequence of cardiac arrhythmia. However, an autopsy was not performed and this patient was at risk for at least two other causes of sudden death, namely pulmonary embolism (given his history of bilateral deep vein thrombosis) and myocardial infarction (given his multiple risk factors for coronary artery disease). We determined that there was disparity between the complainant's perception of the patient's care and the actual care that was documented in the patient's medical records.

We made no recommendations.

Introduction

Purpose

The VA Secretary and Congressman David R. Obey requested the Office of Inspector General Office of Healthcare Inspections review allegations regarding the care of a patient at several Veterans Health Administration facilities within VA's Great Lakes Health Care System. The widow of a veteran alleged to Congressman Obey that his (the veteran's) care was deficient in multiple aspects. Most seriously, the widow (the complainant) alleged that her husband died as a direct result of mismanagement of his antiarrhythmic cardiac medications. Additionally, she raised benefits issues concerning compensation for exposure to Agent Orange (AO) in Thailand while in the United States (U.S.) Army during the Vietnam War.

Background

A. VA Great Lakes Health Care System

VHA's Great Lakes Health Care System is also known as Veterans Integrated Service Network (VISN) 12. It comprises seven VA medical centers located in Wisconsin and parts of Indiana, Illinois, and Michigan.

Tomah VA Medical Center (VAMC) is located in Tomah, WI, and is a 271-bed facility that provides acute medicine, primary care, acute and long-term psychiatry, residential substance abuse treatment, mental health services, vocational and social rehabilitation, and long-term care. It also serves as the parent medical facility to four Community Based Outpatient Clinics (CBOCs), including Wisconsin Rapids, WI CBOC, where the patient was receiving his primary care.

William S. Middleton Memorial Veterans Hospital (WSMMVH) is located in Madison, WI, and is a tertiary care facility that is highly affiliated with the University of Wisconsin-Madison and its medical school. When complex cardiac issues were identified at the Wisconsin Rapids CBOC, the patient was referred to WSMMVH for further evaluation.

WSMMVH is also part of VISN 12 and is an 87-bed facility that provides tertiary medical, surgical, neurological, and psychiatric care for veterans which includes cardiac catheterization and surgery, magnetic resonance imaging, computerized axial tomography, primary care, mental health, and home based primary care. The WSMMVH facility operates 5 CBOCs serving 15 counties in south-central Wisconsin and 5 northwestern Illinois counties located in Janesville, Baraboo, Beaver Dam, Wisconsin and Rockport and Freeport, Illinois. The primary service area has a population of approximately 130,000 veterans.

A. Allegations

Cardiac Care

Allegation: The complainant alleged that the patient had no cardiac symptoms prior to an extensive cardiac workup being initiated by WSMMVH.

Allegation: Quinidine sulfate, which had been prescribed since the 1970s to treat ventricular tachycardia, was inappropriately discontinued. While the drug was ultimately re-prescribed, the complainant further alleged that the interruption was harmful.

Allegation: Quinidine was discontinued because VA "didn't carry the drug so they wanted to stick him on something else they did carry."

Allegation: Metoprolol was inappropriately prescribed in place of quinidine sulfate.

Allegation: There was insufficient or absent input by physicians, most particularly cardiologists in the care of her husband. The complainant wrote, "During this whole time … there was NO CARDIOLOGIST on staff at any of the clinics!"

Allegation: During one WSMMVH visit, the patient was pushed around in a wheelchair for several hours with his heart rate down to 40. He overheard a clinician state that he (the clinician) did not know what he was going to do with him (the patient).

Allegation: On September 28, 2009, the nurse practitioner (NP) at Wisconsin Rapids CBOC did not properly evaluate the patient's feet for evidence of circulatory disorder.

Lipid Management

Allegation: VA would not prescribe Lipitor® because it does not purchase expensive drugs.

Phlebotomy

Allegation: The implantable venous access device was incorrectly secured or anchored to the patient's chest wall. The complainant alleged that the device was only secured with two stitches when four were required.

Allegation: A new implantable venous access device should have been inserted and was not; instead, the same device was utilized on three occasions.

Allegation: The provider informed the veteran that he did not know how to place implantable venous access devices.

Allegation: The provider yelled at the veteran, accusing him of purposely causing the implantable device's movement.

Allegation: The provider's laboratory coat was dirty, hygiene was poor, and he left the room while wearing gloves. He returned to the room wearing the same gloves and provided services for the implantable venous access device. This lack of hygiene and sterile practice caused an infection necessitating removal of the patient's implantable venous blood drawing device.

Mental Health Care

Allegation: In receiving mental health care at Tomah VAMC the patient was seen by a different psychiatrist every visit and would have to repeat his history to each provider.

Allegation: The patient went from seeing a real person, to seeing a person on a computer screen, and then sometimes no one showed up on the computer screen.

Veterans Benefits

Allegation: Despite military service in southeast Asia during the Vietnam War era, and heavy exposure to AO herbicide, the veteran was not eligible for compensation because he was not "in Country" meaning in Vietnam.

Other Allegations

Allegation: A community physician was closing his practice and donated a point-of-care prothrombin time testing machine[1] to the Wisconsin Rapids CBOC. Clinicians at the CBOC initially refused to accept the machine; later, this machine was accepted but never used.

Scope and Methodology

On May 18, 2010, OHI inspectors met with the complainant at length and continued to speak with the complainant in order to further clarify her allegations and obtain further information. The materials and allegations provided by the complainant were extensive; therefore, we categorized allegations into major themes.

From May 18–21, OHI inspectors interviewed relevant clinical and administrative staff at the Wisconsin Rapids CBOC, Tomah VAMC, and WSMMVH.

Several key individuals were unavailable for an interview. These included WSMMVH's attending cardiologist for the first of the patient's two WSMMVH Cardiology Service visits and the WSMMVH interventional radiologist who implanted and then repositioned the patient's implantable venous blood drawing device in 2005. Both were no longer VA employees; the former had retired, while the latter has separated from VA and was said to

[1] The machine only pricks the arm for a blood sample and gives an immediate blood value, which would have alleviated the veteran of painful phlebotomy punctures.

be presently residing in a foreign country. We were unable to interview a private sector physician who, according to the complainant, had donated a point-of-care prothrombin time testing device to the Wisconsin Rapids CBOC. We were informed that he was deceased.

We obtained and reviewed pertinent documents, including VA medical records, non-VA facilities' medical records, and VHA oversight reviews. We reviewed policies, quality management data and documentation, and other administrative documents. This coupled with our interviews of the patient's caregivers enabled us to address the complainant's clinical allegations.

To address allegations pertaining to courtesy and patient interactions, we obtained patient complaint data from patient advocates. To assess allegations of poor hygiene of an interventional radiologist, we reviewed infection rates at WSMMVH. To review allegations related to an alleged denial of AO benefits, we obtained the patient's Veterans Benefits Administration (VBA) claim file and collaborated with OIG's Office of Audit's Benefits Inspection Division. To address the allegation that clinicians at the Wisconsin Rapids CBOC would not accept a donated piece of medical equipment, we reviewed policies governing such donations.

The inspection was conducted in accordance with the *Quality Standards for Inspections published by the President's Council on Integrity and Efficiency*.

Results and Conclusions

Findings

A. Case Review

Overview

The patient was a man in his sixties at the time of his death in the fall of 2009. He had multiple medical and psychiatric problems. Medical disorders included cardiovascular and peripheral vascular problems characterized by a history of ventricular tachycardia, mitral valve prolapse, bilateral deep venous thrombosis (last occurrence in 1986), and stable peripheral edema. He also had several risk factors for coronary artery disease including, in addition to his age and gender: hyperlipidemia, history of tobacco use, sleep disorder, and obesity.

Other medical problems included non-Hodgkin's lymphoma that had been in remission since 1994 after chemotherapy, but with chronic neuropathy in the hands and feet as a sequelae of treatment; seizure disorder; hypomagnesemia; vertigo, gastroesophageal reflux disease, history of colonic polyps, ventral hernia, floaters in both eyes, chronic

vasomotor rhinitis, myalgias from statins, erectile dysfunction, osteoarthritis, chronic left shoulder pain, back spasm, and hip bursitis. Since March 2008, he wore a right medial unloader brace related to a right knee injury resulting in a torn medial meniscus.

The patient had several surgical procedures including two left shoulder replacement operations, hemorrhoidectomy, subcutaneous insertions of an implantable venous blood drawing device placed to facilitate blood drawing (approximately 1994: implantable venous blood drawing device placement; 2004: repeat implantable device placement; 2005: implantable device repositioning; 2005: implantable device resuturing); and right ring finger A1 pulley release (2008) for trigger finger. The patient also had a history of psychiatric illnesses. His VHA psychiatric care was largely provided by Tomah VAMC providers.

The patient received extensive VA care beginning in 2001. Prior to 2001, his medical care was provided at non-VA facilities. He initially received his care at Tomah VAMC. However, in 2005, he switched his primary care to the Wisconsin Rapids CBOC. WSMMVH served as a referral and tertiary center for both facilities.

Phlebotomy

The patient had non-Hodgkin's lymphoma diagnosed in 1991, which was treated with chemotherapy. Residua of treatment included bilateral peripheral neuropathy in the extremities and severe scarring with diminution of superficial veins making routine blood drawing an ordeal for the patient as well as his phlebotomists and nurses. The latter was a particularly troublesome issue because the patient also had a history of bilateral deep vein thrombosis which required lifetime anticoagulation with Coumadin® (warfarin). For example, a 2004 Tomah VAMC Anti-Coagulation Clinic noted:

> Pt [the patient] stopped by clinic today. He had to have numerous punctures before a second phlebotomist was able to successfully draw his lab. Pt is rightfully concerned about getting future lab draws and is wondering what options he has. In the past, the pt had a port [i.e., an implantable venous blood drawing device], which made lab draws easy. The port was pulled about 2 years ago.

Likewise, a 2004 visit to Wisconsin Rapids CBOC noted:

> Pt with hx [history] of DVTs [deep vein thromboses] x 20 years who is on coumadin for prevention. Due to coumadin he needs INR [International Normalized Ratio – a test of the effectiveness of anticoagulation therapy] checks monthly. Pt is very difficult to do venous draw for necessary blood tests. At last visit to Tomah anti-coag clinic it took 6 tries to get blood. This is making compliance more difficult for patient. Pt with history of

> porta cath placement for large cell lymphoma in the past and is interested in this possibility in the future.

A consultation was placed with WSMMVH Interventional Radiology Service. The initial recommendation was a peripherally inserted central catheter (PICC) line. However, the patient was unwilling to perform the daily maintenance of flushing required for the long-term preservation of a PICC line. WSMMVH's Interventional Radiology Service agreed to place an implantable venous access device (e.g., see PORT-A-CATH®. The patient had previously had such implantable device(s), most recently in approximately 1994.

In the fall of 2004, WSMMVH Interventional Radiology Service placed a right-sided subcutaneous implantable venous blood drawing device. There were no intraoperative complications. However, postoperatively, the patient developed a severe allergic skin reaction at the site of the implantable venous blood drawing device placement, in his right axilla, and on his right upper extremity. Consideration was given as to whether the patient was allergic to a component of the implantable venous blood drawing device or to Betadine®, a topical cleaning and disinfection solution. Prednisone was prescribed. The problem appeared to have resolved with treatment, although the patient's medical record does not clearly elucidate the overall response and outcome.

In March 2005, while at the Tomah VAMC for an anticoagulation test, nursing staff were unable to access the patient's implantable device despite multiple attempts. X-rays of the site were obtained, and it was found that the device had flipped over. Four days later, under fluoroscopic guidance WSMMVH's Interventional Radiology Service successfully repositioned the device.

In June 2005, the patient reported that his implantable device again flipped over. At this time, WSMMVH's Interventional Radiology Service planned to place a new implantable venous blood drawing device. Under fluoroscopic guidance the port hub of the existing device was unflipped. Intraoperatively, the interventional radiologists determined that a new device was not required. The operative note indicated concern about placement of sutures that secured the port hub, writing "nonabsorbable sutures were placed to avoid again flipping of the port hub."

Four days later, the patient was seen at Tomah VAMC's Urgent Care unit complaining of brownish drainage oozing from the site of his recent implantable venous blood drawing device readjustment. In one examination the site appeared "slightly red" but was not noticeably swollen. The suture line was intact. Brownish drainage was described in one note. Another chart note described puffiness at the site and "thick green secretions". Finally, another note described, "the whole chest for a 15-20 cm diameter area was swollen, red and hot. There was and is significant pain in the site." Tomah VAMC staff recommended to the patient that he be seen at WSMMVH because parenteral antibiotic treatment was indicated, and a decision needed to be made as to the future of the device. However, the patient declined to be seen at WSMMVH. He described that he "percieved

[sic] as hostile words with the physician who did the work [at WSMMVH] and will not see him again." The patient was apparently then recommended for admission to Tomah VAMC for intravenous antibiotic therapy but this, too, was declined. The patient desired care in the private sector. Ultimately, at Tomah VAMC he was treated with an intramuscular cephalosporin injection and discharged from the Urgent Care unit.

Over the next several days, the patient went to the emergency room at Riverview Hospital,[2] and a non-VA physician removed the device and prescribed antibiotics. The device was not reimplanted.

Mental Health Care

The patient received extensive care for mental health issues from both the private sector and VHA. Medical record progress notes indicate that, overall, the patient's mental health conditions were stable. Hospitalization was not required, and in general, the patient was managed with outpatient medication therapy. He also received non-VA mental health care while receiving VA mental health care. The patient appears to have relied upon the VA system to prescribe and regulate his medications.

Lipid Management

The patient was treated for hyperlipidemia. Management was complicated by intolerance to lovastatin and simvastatin, two statin class drugs which are mainstays of modern hyperlipidemia/hypercholesterolemia management. For example, the patient attributed myalgias and sleep interference to simvastatin.

On July 2006 a provider at the Wisconsin Rapids CBOC documents a recommendation to start niacin. The patient tried non-prescription niacin, but it gave him the sensation that his "skin was crawling." The patient stated that he had tolerated atorvastatin in the past, and desired that medication instead of niacin.

The patient's primary care provider at Wisconsin Rapids CBOC made a non-formulary request for atorvastatin which was denied. However, another statin class drug, rosuvastatin (Crestor®), was approved for the patient and prescribed. During an October 2006 Wisconsin Rapids CBOC visit, the patient stated that he was "feeling much better since d/c [discontinuation of] simvastatin and [being] started on crestor."

In a March 2007 progress note, the patient's primary care provider at Wisconsin Rapids CBOC documented that after 6 months of rosuvastatin therapy the patient's LDL (low density lipoprotein) was improved at 131 mg/deciliter. She considered this value, "still a little high" and advised the patient "to continue with same dose of crestor, but to work on diet and exercise to decrease fats/chol." A that time, the rosuvastatin prescription was renewed.

[2] 410 Dewey Street, Wisconsin Rapids, WI 54494

However, 8 months later, after another visit to his primary care provider at Wisconsin Rapids CBOC, the provider wrote:

> Pt with hx of elevated cholesterol even with crestor use. Pt had not informed provider that he increased crestor to 20 mg daily as directed, but started having side effects in which [he was] having loss of vision. He switched himself back to 10 mg daily of the crestor as side effects resolved. Last LDL was 133 on the lower dose of crestor. He did not have side effects with lipitor and worked better per pt. He would like to trial lipitor if crestor does not bring LDL to goal.

A note dated November 2007 indicates that a non-formulary drug request for atorvastatin was approved and a March 2008 note indicates "LDL chol is improved with lipitor at 20 mg daily, but not at goal so will increase to 40 mg daily". A March 2009 note indicates that the patient was doing well on atorvastatin.

Cardiac Care

According to WSMMVH medical records, the patient had a cardiac arrhythmia diagnosed in approximately 1975. At that time, he had been working in a paper mill and sought medical attention due to increasing shortness of breath and excessive fatigability. He stated that he had noticed an occasional racing sensation in his chest for several years.

Soon thereafter, the patient was seen at the Marshfield Clinic.[3] VHA records indicate that a treadmill stress test was performed but reportedly stopped "within seconds because of a change in his heart rhythm." Records from the Marshfield Clinic indicated that the patient developed ventricular tachycardia (VT) during the exercise stress test. The test was aborted. In March 1976, cardiac catheterization was performed at St. Joseph's Hospital in Marshfield, WI. This test reportedly showed normal coronary arteries.

That same month a repeat treadmill stress test was performed. During Stage III of this test, the patient developed frequent premature ventricular contractions (PVCs) but no VT.

The patient was prescribed quinidine sulfate for arrhythmia and advised to find a more sedentary job. According to available medical records, in the mid-1980s, the patient was switched from quinidine sulfate to quinidine gluconate due to lack of availability of the former formulation. According to the VHA notes, the patient "preferred sulfate, *has had more symptoms overall since switch to gluconate in mid-1980s*" [OHI emphasis].

In March 2007, the patient's primary care provider at Wisconsin Rapids CBOC ordered a 24-hour Holter monitor test because the patient was experiencing a sensation of irregular heartbeat with visual changes. She wrote:

[3] Marshfield Clinic - Marshfield Center, 1000 North Oak Avenue, Marshfield, WI 54449

> Pt states he feels that he may be having sx [symptoms] of irreg rhythm again. He describes regular episodes when sitting and working at the computer when he will feel his peripheral vision is closing in on him and then feels like heart rate is irreg, this will last approx 10-20 seconds. He then will have headaches afterwards.

The patient's provider at the Wisconsin Rapids CBOC was concerned about the patient's symptoms of possible cardiac arrhythmia. The provider obtained an electrocardiogram (EKG) that showed sinus bradycardia with a right bundle branch block (RBBB) and a T wave abnormality. A Holter monitor test, carotid artery ultrasound images, and an eye consultation in view of the ocular symptoms described were also ordered.

The Holter monitor test was performed but was of suboptimal quality due to motion interference. Occasional premature atrial contractions and PVCs were identified but the patient had no sustained cardiac arrhythmia.

The carotid artery ultrasound examination showed minimal carotid atherosclerotic disease without significant stenosis of the extracranial carotid system. The echocardiogram revealed normal left ventricular systolic function, Grade 1 diastolic dysfunction, mild left atrial enlargement with an aneurysm of the interatrial septum but without evidence of an interatrial shunt, a myxomatous appearing mitral valve that had mild bileaflet prolapse with mild-to-moderate regurgitation, and mild aortic root dilation. Overall, this evaluation appeared negative for new cardiac pathology and no significant changes in the patient's cardiac treatment regimen were instituted at that time. Antibiotic prophylaxis was advised for future invasive procedures and dental work.

Two years later, when seen in March 2009 at Wisconsin Rapids CBOC for an "annual exam," the patient complained of generalized joint pain and allergy — apparently sinus — symptoms. He also told the physician's assistant (PA) who saw him that he was "becoming more symtomatic [sic] with sensation[s] of skipped [heart] beats, palpitations, sob [shortness of breath], [and] dizziness". The PA placed consultation requests to both WSMMVH's Cardiology and Allergy Services for further evaluation.

Two months later, the patient had a transthoracic echocardiogram at WSMMVH's. This test revealed mitral valvular disease characterized by a mildly thickened mitral valve, redundant leaflets, and mild anterior and posterior leaflet prolapse. There was also mild left ventricular hypertrophy, a moderately enlarged left atrium, mild global hypokinesia, and mild diastolic dysfunction. The left ventricular ejection fraction was estimated to be 50 percent.

That same day, the patient began a 24-hour Holter monitor study which revealed a baseline sinus rhythm with an average heart rate of 59 beats per minute (bpm) (range 46–103 bpm) with occasional isolated and couplet PVCs. These PVCs were not sustained and not associated with symptoms. During the study, the patient reportedly experienced

two episodes of his "Heart Pounding Hard." However, neither episode correlated with cardiac arrhythmia.

When a history was obtained at WSMMVH, the patient's possible cardiac arrhythmia symptoms were described as follows:

> Currently, he [the patient] will experience his irregular rhythm about once every few months. During the episodes, he feels and [sic] irregular and fast rhythm in his chest and eventually becomes lightheaded. They always resolve within a minute. This happened recently while he was sitting at his computer; as usual it felt fast and irregular, then things started graying out. He held his breath and symptoms resolved within ~ [approximately] 20 seconds… The symptoms happen at any time, without regard to exertion.

When seen at WSMMVH, the patient was noted to be taking quinidine gluconate, 324 mg three times daily. However, he was being prescribed quinidine gluconate 324 mg, two tablets three times a day and one tablet at bedtime. Other medications included warfarin, atorvastatin (see above), flunisolide inhaler, phenytoin, omeprazole, clonazepam, magnesium oxide, vardenafil, loratadine, sertraline, and alprazolam.

WSMMVH's Cardiology Service felt after its initial evaluation that the patient's arrhythmia history was "unclear". While noting that the patient thought it might be VT, the Cardiology Service felt that to be insufficiently specific. It noted, for example, that monomorphic VT and polymorphic VT would have different implications. Thus, at this time WSMMVH's Cardiology Service decided initially not to change the patient's therapy. A quinidine blood level was ordered "to see if he is even therapeutic." However, the Cardiology Service also noted that even if the arrhythmia was a VT, in the face of mitral valve prolapse the preferred treatment would be a beta blocker drug. The initial plan was, therefore, to check a quinidine blood level, retrieve and review the patient's records from the Marshfield Clinic, and possibly perform a treadmill stress test and Holter monitor test.

When the quinidine blood level results were returned they were noted to be subtherapeutic. At this point, WSMMVH staff concluded "it is unclear whether the quinidine is even benefitting him." Cessation of quinidine was recommended along with performing the Holter monitor test and treadmill stress test *with the patient off quinidine*. The record notes that the patient "states concerns re: going off of quinidine".

Although the patient had reservations about discontinuing quinidine he did so. In May 2009, the patient had a treadmill stress test. The test lasted for 11 minutes and 38 seconds and was halted due to leg fatigue. It showed a normal heart rate and blood pressure response to exercise, no evidence of cardiac ischemia, and "No exercise induced VT while off quinidine". The patient was prescribed metoprolol 25 milligrams (mg), to be taken twice daily as this was felt by WSMMVH's Cardiology Service to be a

preferable drug to quinidine, in view of the patient's overall cardiac history as understood at that point. Specifically, the Cardiology Service was concerned about the possible proarrhythmic effect of quinidine and its attendant risk of sudden death. An evolution of thinking and treatment regarding cardiac arrhythmias had occurred in the ensuing almost 35 years since quinidine was first prescribed for this patient. The Cardiology Service reasoned that a beta blocker drug was the drug of choice in the face of the patient's mitral valve prolapse.

In the course of the 24-hour Holter monitor test, the patient reported two prolonged episodes of his "Heart Pounding Hard". At both times, however, review of the Holter monitor tracing showed the patient to be in a normal sinus rhythm. While occasional isolated and couplet PVCs were noted, overall, the patient did not have a sustained arrhythmia.

In July the patient was seen by a WSMMVH Cardiology Service PA. During that visit, the patient complained of an irregular heart rhythm, associated with dyspnea, "greying" vision which progressed to "tunnel vision," and near-syncope. At this time, the patient's EKG showed sinus bradycardia with a rate of 47 beats per minute and a right bundle branch block.

WSMMVH providers were unclear as to the cause of these symptoms. They recommended repeating a Holter monitor test and decreasing the patient's metoprolol dose from 25 mg twice daily to 12.5 mg twice daily.

The patient did not have the Holter monitor test at this time as was recommended. In a telephone call a few days later, the patient indicated that he restarted quinidine, apparently on his own with a remaining supply at home. An August 2009 medical record note states, "He [the patient] reports resolution of his symptoms within 1 day [of restarting quinidine] in addition to improvement in fatigue and depression". However, in that same note WSMMVH's Cardiology Service also wrote, "Due to non-compliance w/Holter monitoring, and therefore an inability to monitor his heart rate/rhythm while symptomatic, Cardiology cannot manage medications to treat his symptoms."

The medical record reflects that there were continued concerns about the patient's use of quinidine. For example, another August 2009 progress note states, "Pt was told about the reasoning behind discontinuing quinidine and repeating Holter monitoring to assess arrhythmia. The potential serious side effects of quinidine therapy were discussed." A progress note written three days later by the Wisconsin Rapids CBOC PA states:

> Cardiology would like to further evaluate the arrthymia and [the patient] needs to be off the quinidine to do this. The cardiologists do not feel comfortable continuing him on the quinidine without this information as they feel there are safer antiarrthymia [sic] meds available. They understand that he has been on this med for over 30 yrs and done well.

The patient apparently then agreed to discontinue his quinidine again, at least for the performance of another Holter monitor test. A Holter monitor test with the patient off quinidine revealed an underlying normal sinus rhythm, with frequent premature ventricular beats, ventricular couplets, and occasional ventricular triplets as well as intermittent atrial premature beats.

A telephone contact note written 18 days later by WSMMVH's Cardiology Service PA, suggests that the patient self discontinued metoprolol.

At the insistence of the patient, he was again restarted on quinidine. After discussing the issue with an electrophysiologist, WSMMVH's Chief, Cardiology Service was willing to re-prescribe quinidine with the caveat that the patient be fully warned of and accepting of the risks entailed. Also, at or about this time, WSMMVH's Cardiology Service arranged for the patient to have an electrophysiology consultation.

In late September 2009, the Wisconsin Rapids CBOC PA noted that the patient was restarted on the quinidine gluconate on a temporary basis and that he had an electrophysiology consultation scheduled at WSMMVH in early October. Among the patient's several symptoms expressed in that visit were a complaint that chronic bilateral lower extremity paresthesiae attributed to past chemotherapy were now present more proximally in both feet in their entirety and ankles.

However the same note states,

> He notes that off quinidine at this time which makes him feel sob [short of breath] and tired. He is very frustrated with cardiac issues and just wishes could go back on the quinidine as worked well for over 30 yrs, but he will go through with cardiac evaluation as requested by cardiology. Pt is no longer on metoprolol as severe bradycardia with med.

On examination, there was no lower extremity peripheral edema, the feet were cool to touch but had good pedal pulses bilaterally, and diminished or absent sensation was noted over various aspects of the patient's feet.

Nine days before the patient's scheduled October electrophysiology consultation, he was found at home by his wife, unresponsive, at his computer station. He was pronounced dead by a local coroner. An autopsy was not performed. The death certificate lists the cause of death as "acute heart failure" due to or as a consequence of "cardiac arrhythmia."

B. Allegations — Findings

Cardiac Care

Allegation: The complainant alleged that the patient had no cardiac symptoms prior to an extensive cardiac workup being initiated by WSMMVH.

This allegation is not substantiated.

In late March 2009, the patient expressed to his primary provider at Wisconsin Rapids CBOC serious symptoms consistent with serious cardiac arrhythmia. These symptoms included:

> Pt states he feels that he may be having sx [symptoms] of irreg rhythm again. He describes regular episodes when sitting and working at the computer when *he will feel his peripheral vision is closing in on him and then feels like heart rate is irreg,* [OHI emphasis] this will last approx 10-20 seconds.

A subsequent WSMMVH Cardiology Service note states:

> Currently, he [the patient] will experience his irregular rhythm about once every few months. During the episodes, he feels and [sic] irregular and fast rhythm in his chest and eventually becomes lightheaded. They always resolve within a minute. This happened recently while he was sitting at his computer; as usual it felt fast and irregular, then things started graying out. He held his breath and symptoms resolved within ~ [approximately] 20 seconds … The symptoms happen at any time, without regard to exertion.

Allegation: Quinidine, which had been prescribed since the 1970s to treat VT, was inappropriately discontinued. While the drug was ultimately re-prescribed, the complainant further alleged that the interruption was harmful.

This allegation is not substantiated.

Review of the patient's medical record indicates that careful consideration was given to the patient's antiarrhythmic regimen. The decision to discontinue the patient's quinidine was not inappropriate given the current state of the medical literature on this drug. For example, Giardina, et. al. wrote, "quinidine is no longer a commonly used antiarrhythmic agent, due both to concern about side effects, particularly proarrhythmia and sudden death, and to the availability of new agents."

Additionally, this decision was not based on the availability of the drug from VA pharmacies as was also alleged.

Allegation: Quinidine sulfate was discontinued because VA "didn't carry the drug so they wanted to stick him on something else they did carry."

This allegation is not substantiated.

There is no evidence that recommendations regarding antiarrhythmic therapy, including quinidine, were based on the availability of the drug from VA pharmacies. In fact, the patient received quinidine sulfate while an ongoing patient of the Tomah VAMC and its Wisconsin Rapids CBOC. Likewise, WSMMVH's Cardiology Service ultimately prescribed quinidine sulfate for the patient at his insistence and with his acknowledgment of its risks.

Allegation: Metoprolol was inappropriately prescribed in place of quinidine sulfate.

This allegation is not substantiated.

Given the patient's underlying cardiac pathology—mitral valve prolapse—metoprolol was an appropriate drug selection as documented in the literature.

Allegation: There was insufficient or absent input by physicians, most particularly cardiologists in the care of her husband. The complainant wrote, "During this whole time … there was NO CARDIOLOGIST on staff at any of the clinics!"

This allegation is not substantiated.

When seen by WSMMVH's Cardiology Service the patient was evaluated by a medical resident and his (the patient's) case was presented to a WSMMVH's Cardiology Service attending cardiologist. When seen subsequently at WSMMVH by a Cardiology Service PA, the patient's case was presented to WSMMVH's Chief, Cardiology Service. Also, a physician at the Wisconsin CBOC was aware of the patient's case.

Allegation: During one WSMMVH visit, the patient was pushed around in a wheelchair for several hours with his heart rate down to 40. He overheard a clinician state that he (the clinician) did not know what he was going to do with him (the patient).

We could neither substantiate nor refute this allegation.

In his visit to WSMMVH in which he was symptomatic from recently prescribed metoprolol, the patient's heart rate was in the 40s. WSMMVH staff was aware of this bradycardia and had halved the patient's metoprolol dose at the time of seeing the patient. However, we could neither substantiate nor refute that the patient was pushed around in a wheelchair for several hours. Nor could we substantiate or refute that a clinician stated that he (the clinician) did not know what he was going to do with him (the patient).

We found that the patient left WSMMVH that day without completing ordered tests, namely the application of a Holter monitor. On the way home, he called a clinician at the Wisconsin Rapids CBOC and stated that he felt as if he was going to pass out. He was instructed to have the person who was accompanying him return to the WSMMVH Emergency Room for evaluation. There is no documentation in the medical record that the patient did so.

Allegation: In late September 2009, the NP at Wisconsin Rapids CBOC did not properly evaluate the patient's feet for evidence of circulatory disorder.

This allegation is not substantiated.

The medical record documents a detailed evaluation of the patient's feet at the visit in question. Her note was as follows:

> Ext: no peripheral edema bilat LE (wears compression stockings); feet with good pedal pulses bilat; monofilament with sensation change in top of right foot but can still feel pressure, plantar aspect of toes similar [sic], remainng [sic] plantar region with sensation completely lost; monofilament on left foot with sensation loss on top of foot and plantar aspect; vibratory sense noted, but decreased; normal proprioception bilat. Feet are cool to touch bilat.

Lipid Management

Allegation: VA would not prescribe Lipitor® because it does not purchase expensive drugs.

This allegation is not substantiated.

The case record shows concern regarding the patient's hyperlipidemia. When he developed myalgias secondary to two statin class drugs, niacin was recommended. This, too, caused intolerable side effects.

A non-formulary drug request was made for atorvastatin but rosuvastatin was approved instead. Rosuvastatin initially appeared both efficacious and tolerable for the patient. However, after the patient's rosuvastatin dose was increased, the patient again had side effects.

Rosuvastatin was discontinued in late November 2006 and a non-formulary medication request for Lipitor® (atorvastatin) was submitted and approved. According to the complainant, the veteran continued this medication without complaint until his death.

Phlebotomy

Due to chemotherapy treatments for lymphoma in the 1990s, blood drawing was extremely difficult with regard to this patient. He had severe scarring with diminution and hardening of his superficial veins making routine blood drawing an ordeal for the patient as well as his phlebotomists and nurses. This was a particularly troublesome because the patient also had a history of bilateral DVT which required lifetime anticoagulation with Coumadin® (warfarin) accompanied by regular and routine blood testing to monitor the patient's anticoagulation.

One way of addressing this problem was with an implantable venous access device. This device is placed in the chest wall under fluoroscopic guidance. It has a portal reservoir and a catheter that is attached and placed into a large vein within the chest. The device is accessed by inserting a needle through the reservoir under sterile technique. It may then be used to infuse medications or to draw blood. The device can remain in the chest wall for extended periods of time without daily access, but it must be flushed at regular intervals to maintain patency.

Allegation: The implantable venous access device was incorrectly secured or anchored to the patient's chest wall. The complainant alleged that the device was only secured with two stitches when four were required.

This allegation is neither substantiated nor refuted.

In that the device was implanted and subsequently removed approximately 5 years ago, we were unable to determine at this much later time whether it was initially secured or anchored to the patient's chest wall correctly. We found no diagram of the procedure in the medical record. Nevertheless, the medical record clearly reflects concern about positioning and anchoring of the device. For example, notes describing repositioning procedures in late March and early June 2005 respectively are as follows:

> Port hub was unflipped and subacute sutures were placed again *to secure the port in correct position*. [OHI emphasis]
>
> The new larger size port hub was measured with the old one and they were the same size. At that point, it was discussed with the patient again and it was decided not to change the port since it was the same size. The port hub was unflipped and it was then placed back into the pocket. This time, *nonabsorbable sutures were placed to avoid again flipping of the port hub*. [OHI emphasis]

While the device has holes to accommodate up to four sutures, placing four sutures is optimal. A patient's anatomy, (i.e., the contours and structure of the chest wall) may prevent four stitches from being placed.

Allegation: A new implantable venous access device should have been inserted and was not; instead, the same device was utilized on three occasions.

This allegation is not substantiated.

The patient did indeed have three operations concerning the placement of his implantable device. These included the November 2004 initial placement of the right-sided subcutaneous implantable device, the March 2005 device repositioning, and the June 2005 repositioning. During the last procedure, the interventional radiologists determined that a new device was not required. As noted, the proximal end of the device is placed in a large vein, and the minimum amount of disturbance possible of the entry point into a patient's venous system is preferable. Thus, if safe, repositioning would be preferable to reimplantation. As noted earlier, it is impossible to know the exact reasoning of the interventional radiologist at the time of the procedure 5 years ago due to his lack of availability. However, the medical record clearly reflects sensitivity to the issue of placement of a new device versus repositioning of an already existing device, and argues against there being a casual attitude toward the issue. Specifically, at the time of the June 8, 2005, procedure, the medical record shows that the patient would be receiving a new implantable device. However, intraoperatively the situation was carefully assessed and it was determined that a new device was not required, and the interventional radiologist proceeded with simple repositioning.

Allegation: The provider informed the veteran that he did not know how to place implantable venous access devices.

This allegation is not substantiated.

OHI was unable to determine if the interventional radiologist stated to the patient that he (the interventional radiologist) did not know how to place implantable venous access devices. We were able, however, to assess the practitioner's experience with this procedure. We found that in fiscal year 2005, the interventional radiologist in question completed 1,724 interventional radiological procedures including the insertion of 12 implantable venous blood drawing devices. More specifically, he had inserted six implantable venous blood drawing devices at WSMMVH prior to the device that the patient in this case had.

Allegation: The provider yelled at the veteran, accusing him of purposely causing the implantable device's movement.

This allegation is neither substantiated nor refuted.

As noted in the Scope and Methodology section of this report, because the interventional radiologist in question had separated from VA and was said to be now residing in a

foreign country, we were unable to interview him to address this and other issues related to the placement of the patient's implantable venous access device.

However, we did determine that when the patient was seen at Tomah VAMC's Urgent Care unit complaining of brownish drainage oozing from the site of his blood drawing device, Tomah VAMC's staff recommended to the patient that he go to WSMMVH. However, the patient declined to be seen at WSMMVH describing that he "percieved [sic] as hostile words with the physician who did the work [at WSMMVH] and will not see him again". Thus, there is real-time documentation of the patient's perception of problems between the patient and the interventional radiologist.

We asked to review complaints related to the interventional radiologist in question. We identified one additional unrelated complaint that occurred in March 2009.

Allegation: The provider's laboratory coat was dirty, hygiene was poor, and he left the room while wearing gloves. He returned to the room wearing the same gloves and provided services for the implantable venous access device. This lack of hygiene and sterile practice caused an infection necessitating removal of the patient's implantable venous blood drawing device.

This allegation is neither substantiated nor refuted.

As noted in the case history, the patient did indeed develop an infection after the June 2005 readjustment of his device. However, we could not determine the cause of this particular infection. Infection is a well-identified complication of device insertion.

There was no history according to WSMMVH staff of the interventional radiologist presenting poor hygiene or breaking infection control practices during his tenure at WSMMVH. We found no data indicating an increased infection rate for this interventional radiologist's procedures.

Mental Health Care

Allegation: In receiving mental health care at Tomah VAMC, the patient was seen by a different psychiatrist every visit and would have to repeat his history to each provider.

This allegation is substantiated for the period of July 2006–March 2008, but not for the earlier period of 2001–January 2006.

During the period of 2001–2009, the patient saw six mental health providers. From 2001 to 2006, the patient was cared for by the same psychiatrist who saw the patient 17 times at varying intervals ranging from one to four times per year. From July 2006–March 2008, the patient was evaluated by four different mental health providers for four visits. He was also evaluated by a tele-mental health provider for three visits from April 2008–March 2009.

We found that Tomah VAMC has experienced difficulty in recruiting and retaining mental health providers and this appears to be the explanation for the lack of continuity of mental care in the July 2006–March 2008 period.

Overall review of the patient's mental health care during the 9 years of his VHA care indicates the patient's mental health condition was stable.

Allegation: The patient went from seeing a real person, to seeing a person on a computer screen, and then sometimes no one showed up on the computer screen.

The veteran was evaluated by a tele-mental health provider for three visits during April 2008–March 2009.

We found three mental health appointment cancellations documented in the patient's record. The first cancellation was in January 2006, and the appointment was rescheduled 6 days later. The second cancellation was for an appointment in July 2007. This appointment was created and canceled the same in January 2007, which may be indicative of a data entry error or the veteran's preference for a date change. The third cancellation was for an appointment scheduled in August 2007, in which medical records indicate was canceled due to the provider's schedule. This appointment was re-scheduled for early September, 16 days later. We did not identify times when the tele-mental health provider was unavailable for a scheduled appointment.

Veterans Benefits

Allegation: Despite service in southeast Asia during the Vietnam War era and heavy exposure to AO herbicide, the veteran was not eligible for compensation because he was not "in Country" meaning in Vietnam.

It is not within the OIG's jurisdiction to assess the merit of or adjudicate a claim for veterans' benefits. Thus, we can neither substantiate nor refute this allegation.

Other Allegations

Allegation: A community physician was closing his practice and donated a point-of-care prothrombin time testing machine to Wisconsin Rapids CBOC. Clinicians at the Wisconsin Rapids CBOC initially refused to accept the machine; later, this machine was accepted but never used.

In 2005, according to the complainant, a community physician who was relocating his practice to another state, was liquidating some of his office and medical equipment, and volunteered to donate his point-of-care prothrombin time testing machine to the Wisconsin Rapids CBOC. A machine of this type would be useful in monitoring the patient's anticoagulation, sparing the patient (and others who might benefit from it) the

necessity of drawing blood by venipuncture. As already noted in this report, venipuncture in this patient presented great difficulties.

We identified a VA memorandum stating that an employee from Wisconsin Rapids CBOC was contacted by the complainant regarding this possible equipment donation. We found that this employee contacted Tomah VAMC for approval to accept the machine. However, the employee was told that the machine was not covered under the Wisconsin Rapids CBOC's—which at that time was a contract clinic—Clinical Laboratory Improvement Act (CLIA) certificate and therefore, could not be utilized for patient care use.

At the time of our inspection, we were informed that the physician who desired to donate the machine had died. Managers at Tomah VAMC do not recall a donation. Thus, we are unable to ascertain whether the machine was ever physically delivered to Wisconsin Rapids CBOC. However, whether or not donated and delivered, it was never used. We also note that as Wisconsin Rapids CBOC was a contract facility at that time, and was bound by the approved testing indicated by their own—as opposed to Tomah VAMC's—CLIA certificate. It would have been the contractor's decision to determine the feasibility of expanding their point-of-care testing.

Conclusions

This patient received extensive VA care with which the patient's widow was highly dissatisfied. We did not substantiate most of the complainant's specific allegations. Some areas were factual. For instance, contrary to what was alleged, the patient clearly was symptomatic with symptoms consistent with cardiac arrhythmia. Other issues were more judgmental such as the appropriateness of recommending discontinuation of the patient's quinidine sulfate. Although as noted, we felt that clinical decisions made were reasonable and justifiable.

The patient's death was unexpected and occurred during the course of his cardiac evaluation. We note that the death certificate lists the cause of death as acute heart failure due to or as a consequence of cardiac arrhythmia. However, an autopsy was not performed and this patient was at risk for at least two other causes of sudden death, namely pulmonary embolism (given his history of bilateral deep vein thrombosis) and myocardial infarction (given his multiple risk factors for coronary artery disease).

There is a mismatch between the complainant's perceptions of her husband's VA care and the actual care that was documented in the patient's records.

Recommendations

We made no recommendations.

Comments

The VISN and Medical Center Directors reviewed and concurred with the report. See pages 24–26 for the Directors' comments.

(original signed by Patricia K. Christ,
Deputy Assistant Inspector General
for Healthcare Inspections for:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: August 11, 2010

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

Subject: **Healthcare Inspection – Quality of Care Issues, Tomah VA Medical Center and William S. Middleton Memorial Veterans Hospital, Tomah and Madison, Wisconsin**

To: Director, Chicago Office of Healthcare Inspections (54CH)

I have reviewed the above mentioned Healthcare Inspection report and concur with the findings. Thank you.

Renee Oshirski

for and in the absence of
JEFFREY A. MURAWSKY, M.D.

Tomah VA Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

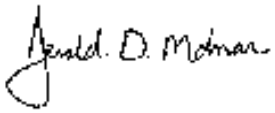
Date: August 6, 2010

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

Subject: **Healthcare Inspection – Quality of Care Issues, Tomah VA Medical Center and William S. Middleton Memorial Veterans Hospital, Tomah and Madison, Wisconsin**

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

The above report was reviewed by senior leaders at Tomah VAMC. We concur with the findings.



Jerald D. Molnar

William S. Middleton Memorial Veterans Hospital Director Comments

Department of Veterans Affairs **Memorandum**

Date: July 30, 2010

From: Director, William S. Middleton Memorial Veterans Hospital (607/00)

Subject: **Healthcare Inspection – Quality of Care Issues, Tomah VA Medical Center and William S. Middleton Memorial Veterans Hospital, Tomah and Madison, Wisconsin**

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

I have reviewed the draft report and concur with the findings. I note that there are no recommendations, therefore, I have no corrective action plans to submit.

Deborah A. Thompson

OIG Contact and Staff Acknowledgments

OIG Contact	George B. Wesley, MD Director, Medical Consultation and Review (202) 461-4705
Acknowledgments	Jennifer Reed, RN, Team Leader Verena Briley-Hudson, RN, MN Paula Chapman, CTRS Danny Clay, Office of Audits and Evaluations Judy Brown, Program Support Assistant

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