



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Quality of Mental Health Care VA Eastern Colorado Health Care System Denver, Colorado

To Report Suspected Wrongdoing in VA Programs and Operations:
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E-Mail: vaoighotline@va.gov
(Hotline Information: <http://www.va.gov/oig/hotline/default.asp>)

Executive Summary

The VA Office of Inspector General (OIG), Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by a complainant concerning the quality of mental health care a patient received at the VA Eastern Colorado Health Care System (HCS). The patient died suddenly at his home in early 2011. The complainant alleged that despite an HCS psychiatrist's conclusion that the patient was not a candidate for medication and should attend a residential treatment program for post-traumatic stress disorder (PTSD), the psychiatrist prescribed the patient the medications quetiapine (noted on the patient's death certificate as the probable cause of death), lorazepam, clonazepam, sertraline, "and others." The complainant expressed concern that other non-medication therapies were not made available to the patient. The complainant also alleged that HCS providers did not adequately manage or monitor the patient's psychiatric medications, which contributed to his sudden death.

We did not substantiate the allegation that the patient was not provided or offered other treatment options in conjunction with prescribed medications. HCS providers, as well as providers at the other Veterans Health Administration (VHA) facilities where the patient received services, offered the patient a variety of therapies in both outpatient and inpatient settings. However, we found that the patient's admission to a mental health residential rehabilitation treatment program was delayed for reasons that were not supported by VHA policy.

We did not substantiate the allegation that VHA providers improperly managed or monitored the patient's psychiatric medications, in particular the atypical antipsychotic drug quetiapine. The patient's prescribed medications were appropriate in terms of his diagnoses of bipolar disorder and PTSD. The antipsychotic medications the patient received have all been approved by the U.S. Food and Drug Administration for use in the treatment of bipolar disorder and are consistent with recommended treatments in VA/Department of Defense clinical practice guidelines for bipolar disorder and PTSD (as an adjunctive therapy). Other medications named in the allegation were utilized in a manner consistent with the patient's clinical presentation. VHA providers actively engaged the patient in his treatment, discussed medication side effects with him, and addressed reported side effects by adjusting medications when necessary.

To ensure timely access to mental health residential rehabilitation treatment programs and minimize barriers for patients in need, we recommended that the Veterans Integrated Service Network Director ensure that admission criteria comply with VHA policy.

The Veterans Integrated Service Network and HCS Directors concurred with the recommendation and provided an acceptable action plan. We will follow up on the planned actions until they are completed.



DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, VA Rocky Mountain Network (10N19)

SUBJECT: Healthcare Inspection— Alleged Quality of Mental Health Care,
VA Eastern Colorado Health Care System, Denver, Colorado

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by a complainant concerning the quality of mental health care a patient received at the VA Eastern Colorado Health Care System (HCS).

Background

VA Eastern Colorado HCS

The VA Eastern Colorado HCS is part of Veterans Integrated Service Network (VISN) 19 and comprises the Denver Medical Center, two nursing homes, and eight community based outpatient clinics (CBOCs). VISN 19 also includes medical centers in Grand Junction, CO; Salt Lake City, UT; Fort Harrison, MT; and Sheridan and Cheyenne, WY. The HCS provides inpatient services in medicine, surgery, and mental health. Outpatient services include primary care, specialty services, and mental health, and a residential treatment program is available for post-traumatic stress disorder (PTSD).

Allegations

The OIG's Hotline Division received allegations concerning the HCS. Specifically, the complainant alleged that despite an HCS psychiatrist's conclusion that a patient was not a candidate for medication and should attend a residential treatment program for PTSD, the psychiatrist prescribed the patient the medications quetiapine

(noted on the patient's death certificate as the probable cause of death), lorazepam, clonazepam, sertraline, "and others." The complainant expressed concern that other non-medication therapies were not made available to the patient. The complainant further alleged that HCS providers did not adequately manage or monitor the patient's psychiatric medications, which contributed to the patient's sudden death.

Mental Health Residential Rehabilitation Treatment Programs

Mental Health Residential Rehabilitation Treatment Program (MH RRTP) is an umbrella term used by the Veterans Health Administration (VHA) to describe a broad array of treatment programs. MH RRTPs provide residential rehabilitative and clinical treatment for a range of medical, psychiatric, vocational, educational, and social problems.¹ Specific programs include:

- Domiciliary Residential Rehabilitation Treatment Program
- Domiciliary Care for Homeless Veterans
- Psychosocial Residential Rehabilitation Treatment Program
- Substance Abuse Residential Rehabilitation Treatment Program
- PTSD Residential Rehabilitation Treatment Program
- Compensated Work Therapy–Transitional Residence Program

Scope and Methodology

We reviewed the range of mental health services the patient was offered and received at the HCS and several other treating VHA facilities during the 2-year period prior to his death in 2011, and we evaluated his medication management. We reviewed the patient's VHA medical records, selected community medical records, and the autopsy report. We reviewed VHA and HCS policies and procedures regarding mental health services and medication management. We also reviewed relevant clinical practice guidelines and medical literature. We interviewed the complainant, the Medical Examiner, staff psychiatrists, and other mental health providers at the treating facilities.

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.

¹ VHA Handbook 1160.01, *Uniform Mental Health Services In VA Medical Centers and Clinics*, September 11, 2008.

Case Summary

The patient was a male in his thirties who first sought VHA mental health treatment in early 2006 at the New Mexico VA HCS, where he presented with suicidal ideation (with a history of recent suicide attempt and another approximately 1 year prior), self-injurious behavior, depression, and alcohol abuse. He was diagnosed with major depression and alcohol dependence. He entered treatment as an outpatient in the substance use disorder (SUD) program with individual and group therapies and received citalopram as an antidepressant, trazodone as a sleep agent (later changed to doxepin and then zolpidem), and lorazepam, an antianxiety medication that is also used for alcohol detoxification. He remained in treatment through the spring of 2006 but did not complete the SUD program.

He next appeared for treatment at the Northern Arizona VA HCS in the autumn of 2006, seeking a refill of his zolpidem. He was started on the antidepressants amitriptyline and venlafaxine. He was scheduled for further treatment but had several no show appointments. In the autumn of 2007, he presented to the Flagstaff, AZ CBOC for a primary care visit, at which time he reported that he had discontinued taking the antidepressants. He was diagnosed with depression, scoliosis, chronic back pain, and mildly abnormal liver function tests, and he screened positive for PTSD. The antidepressant bupropion was added to his medication regimen. In addition, he was treated with the narcotic pain medication hydrocodone/acetaminophen (APAP) to be taken as needed. The patient was scheduled for a mental health follow-up appointment and presented to the Flagstaff CBOC a few weeks later with complaints of increased anxiety and panic attacks. He had one subsequent visit before moving to a different location.

In the early spring of 2008, the patient presented to the Phoenix VA HCS Show Low CBOC to establish care and reported that he had been taking bupropion, hydrocodone, and over-the-counter famotidine, a medicine for gastroesophageal reflux. He was given diagnoses of PTSD and scoliosis. He next presented to the Sun City, AZ, CBOC, NW Extension Clinic in the fall of 2008 to establish care at that location. He was still taking bupropion and “as needed” hydrocodone/APAP. The hydrocodone/APAP was replaced with a muscle relaxant, methocarbamol, and a non-steroidal anti-inflammatory pain medication. He was referred to the mental health clinic at Phoenix VA HCS but did not keep appointments scheduled for mid-October 2008.

In early 2009, the patient presented to the VA Salt Lake City HCS, where he was diagnosed with depression/anxiety and PTSD and was started on fluoxetine for PTSD and trazodone for insomnia. In February 2009, emergency medical services brought him to the emergency department (ED) at the VA Salt Lake City HCS due to suicidal thinking. He was intoxicated with alcohol at the time. He was transferred to a community hospital due to a lack of available beds at VA Salt Lake City. He was discharged from that facility 5 days later and was referred for mental health follow-up at the VA Salt Lake City HCS. He did not keep the follow-up appointment and could not be reached.

In the spring of 2009, the patient presented to the Phoenix VA HCS to reestablish treatment. He was diagnosed with depressive disorder not otherwise specified (NOS), anxiety disorder NOS, and PTSD by history. He had been off medications for 1 month due to running out and was restarted on fluoxetine and hydroxyzine (an antihistamine medication) at bedtime if needed for insomnia. A telephone contact note from 3 days later documents that the patient reported he had relocated to Denver and would be receiving services at the VA facility there.

That same day, the patient presented to the VA Eastern Colorado HCS seeking admission to its PTSD treatment program. His reported symptoms were anxiety, panic attacks, labile depressed mood, suicidal thinking, and difficulty sleeping. He denied alcohol or substance use. He reported his medications as bupropion, hydroxyzine, fluoxetine, clonazepam (an antianxiety medication), valproic acid (an anticonvulsant medication that is used as a mood stabilizer for patients with bipolar disorder), and trazodone but stated that he ran out of them 2 weeks earlier. He started outpatient medication management the next day and was prescribed lorazepam up to 3 times per day as needed and temazepam for sleep at bedtime. He was also referred for outpatient psychotherapy, having been informed at intake that he could only be referred to the facility's PTSD Residential Rehabilitation Program (PRRP) by his therapist once he was in outpatient treatment and assessed.

Two weeks later, the patient started outpatient psychotherapy. He was given a diagnosis of PTSD related to his military experiences. His outpatient therapist noted that he had "moved to Denver in hopes of attending PRRP [sic] program at Denver VA," and they continued to discuss referral to this program in his subsequent visits. In the initial note, the outpatient therapist recorded finding out that "the waitlist could be approx 3–4 months" and that the patient was informed of this. He continued with both outpatient psychotherapy and medication management, and clonazepam was added to his medication treatment regimen at a subsequent follow-up visit.

In July 2009, the patient presented to the HCS ED after reportedly being hit by a truck. He appeared to be intoxicated and left the ED against medical advice. Three days later, he returned to the ED for follow-up care for a related knee injury.

The patient continued outpatient mental health treatment at the HCS during July and toward the end of the month, the antidepressant sertraline was added to his regimen. One week later, the sertraline was increased. However, except for attending a PTSD group in August and obtaining a medication refill by telephone in the mid-autumn of 2009, the patient had no further mental health contacts until early December. At that time, he reported being "off most meds," having daily panic attacks, and being homeless but staying with a friend. He was restarted on clonazepam. On the same day, he had a compensation and pension examination that indicated psychiatric diagnoses of PTSD, bipolar I disorder, anxiety disorder NOS (with panic attacks, dissociative symptoms, and generalized anxiety), and alcohol abuse in remission.

The following day the patient presented to the HCS ED with complaints of panic attacks, suicidal thinking, and aggressive thoughts. He was admitted for inpatient treatment of his mood disorder, PTSD, and anxiety. In the hospital he was tapered off benzodiazepine antianxiety medications and treated with risperidone (an atypical antipsychotic medication that is also used for mood stabilization) to target his high level of impulsive agitation/aggression, prazosin (a medication aimed at reducing nightmares associated with PTSD), and trazodone. He was discharged approximately 2 weeks later with a plan to return to treatment with his previous outpatient psychiatrist and therapist as well as the homeless clinic at the system. His psychiatric diagnoses on discharge were PTSD, anxiety disorder NOS, and “rule out” mood disorder NOS. He had a psychotherapy follow-up visit 4 days later at which he was affectively stable but having 1–2 panic attacks a day. He and his therapist, along with the social worker from his recent inpatient stay, were working on a plan for him to enter an MH RRTP in Sheridan, WY.

In early 2010, however, the patient presented to the ED at VA Salt Lake City HCS with depression and suicidal ideation. Shortly after admission to an acute inpatient psychiatric unit, the patient’s risperidone was discontinued due to complaints of side effects, and quetiapine (an atypical antipsychotic medication that is also used for mood stabilization) was initiated for mood/PTSD and anxiety symptoms. At the same time, he was started on citalopram, while prazosin and trazodone were continued. His diagnoses at that time were recorded as: (1) major depressive disorder, recurrent, severe, without psychotic features; (2) PTSD, provisional; (3) alcohol dependence in remission; and (4) cannabis abuse in remission. While hospitalized, his mood gradually improved and his suicidal thinking resolved. He was discharged 17 days later and directly transferred to an inpatient unit at the Sheridan VA Medical Center (VAMC) to “allow him an extended inpatient stay to try and help with his Depression, anxiety, and PTSD.” He had no change in his psychiatric diagnoses, except that his PTSD was no longer considered provisional. His discharge psychiatric medications were citalopram, gabapentin, lorazepam, prazosin, trazodone, and quetiapine.

At the Sheridan VAMC, the patient was diagnosed with bipolar disorder and “rule out” PTSD. The medications he was taking on admission were revised—trazodone and citalopram were discontinued because of concern that they were contributing to mixed (bipolar) mood symptoms and gabapentin was decreased. The patient’s prazosin was discontinued but restarted due to ensuing sleep difficulties. The following week, quetiapine was also discontinued due to the patient’s complaint of fast heart rate, and olanzapine (an atypical antipsychotic that is also used as a mood stabilizer) was initiated in its place and titrated. Oxcarbazepine (an anticonvulsant medication) was initiated as a mood stabilizer and titrated.

Approximately 6 weeks after starting the olanzapine, the patient complained about weight gain. Considering there had been little difference in his heart rate since the change to olanzapine, together with his stated opinion that quetiapine was actually more effective in

controlling his mood swings and that he felt better on it, his medication was crossed over from olanzapine back to quetiapine. The patient's olanzapine was gradually decreased and tapered off, while quetiapine was re-initiated and gradually increased. He was discharged in early spring 2010. His diagnoses on discharge were: (1) bipolar affective disorder, last episode depressed, moderate; (2) polysubstance abuse; and (3) PTSD. His psychiatric medications on discharge were gabapentin on a tapering discontinuation schedule, lorazepam as needed for anxiety, oxcarbazepine, prazosin, and quetiapine. Follow-up was arranged at the VA Salt Lake City HCS.

In April 2010, the patient was seen at VA Salt Lake City HCS, during the week following his discharge from the treatment program at Sheridan VAMC. He had discontinued oxcarbazepine on his own, along with the muscle relaxants that he was taking for back pain. His mood was noted to be stable, and he was continued on lorazepam, prazosin, and quetiapine at the same doses as at discharge from Sheridan VAMC. He was scheduled for a return visit in 1 month. The next day, he renewed an oxycodone prescription by telephone through the HCS. The patient did not come to his next mental health appointment at the VA Salt Lake City HCS.

In late June, the patient was involved in a motor vehicle accident and was taken to a community hospital ED, where he was evaluated, given a computerized tomography (CT) scan, and released. Several days later, he presented to the ED at the VA Salt Lake City HCS complaining of "pain all over." Records of his treatment at the community hospital were reviewed by VA Salt Lake City staff, and he was subsequently assessed and discharged with tramadol for pain. After the ED visit, the patient presented to the mental health clinic requesting a refill of his quetiapine, but he left prior to being evaluated by a provider and did not obtain the refill.

Approximately 3 months later, in the late-summer/early autumn 2010, the patient presented to the HCS (rather than VA Salt Lake City HCS) for a psychiatric medication visit. He was taking quetiapine and lorazepam "as needed" and reportedly had taken himself off other medications. He was described by his psychiatrist as "remarkably different, calmer, thoughtful, and appreciative." He was scheduled to return in 2 months for a follow-up visit with the psychiatrist. He did not keep his scheduled psychotherapy appointment 2 weeks later. The following month, he had a telephone contact with his psychiatrist, who lowered the dose of quetiapine due to sedation. The patient did not keep his next medication visit with his psychiatrist that was scheduled for later that month. His psychiatrist contacted him by telephone that day, and the patient stated that he was doing well and that he would call when he wanted to come in.

In late 2010, the patient was incarcerated and had a mental health screening while in jail. He was incarcerated for approximately 28 days, during which time he was treated with quetiapine and an uncertain amount of benzodiazepine medication.

Approximately 3 weeks later, the patient was found dead in his apartment. The Assistant Medical Examiner for the City and County of Denver, Office of the Medical Examiner, performed an autopsy about 4 hours after the stated time of death. The Assistant Medical Examiner concluded that the cause of death was probable complications of quetiapine ingestion. The Assistant Medical Examiner stated that the blood quetiapine level was significantly higher than would be expected based on the prescribed dose but not so high as to clearly support an inference of deliberate overdose or to be necessarily lethal. The manner of death was therefore considered to be undetermined.

Inspection Results

Issue 1: Treatment Options

We did not substantiate the allegation that the patient was not provided or offered other treatment options in conjunction with prescribed medications. HCS providers, as well as providers at the other VHA facilities the patient went to, offered the patient a variety of therapies in both outpatient and inpatient settings. However, we found that the patient's admission to an MH RRTP was delayed for reasons that were not supported by VHA policy.

In April 2009 (more than 1–1/2 years before the patient's death) an HCS psychiatrist documented in the patient's medical record, "I doubt that meds [medications] will solve this youngmans [sic] situation. He seems like a good candidatee [sic] for the PRRP [PTSD Residential Rehabilitation Program] from my perspective." The complainant interpreted the psychiatrist's note to mean that the patient was not a candidate for medication and that other non-medication therapies should have been made available to the patient as an alternative. However, when we interviewed the psychiatrist, he indicated that his intent in writing the note was to document his impression that the patient would benefit from a more structured residential rehabilitation program *in conjunction* with medication therapy. He was not suggesting that medication would be without benefit to this patient.

Treatment Programs Offered and Provided. VHA clinical practice guidelines include various evidence-based therapies for the treatment of depression, anxiety, PTSD, bipolar disorder, and other mental health issues. Common therapies include medication, psychotherapy, and psychosocial rehabilitation.

In the 2 years prior to his death, the patient received outpatient services at three VHA facilities. At two facilities, the patient had initial mental health appointments but did not keep follow-up appointments because he relocated to other states. At the HCS, where the patient received much of his outpatient care, he kept the majority of his medication management appointments with the psychiatrist, but he was not consistent in attending individual therapy appointments with the social worker. According to the social worker's progress notes and interview, after the patient voiced his interest in receiving treatment

she referred him to several therapy groups for substance abuse, military sexual trauma, PTSD, anxiety, and anger management, as well as process-oriented groups for younger era patients. The patient only attended four PTSD group sessions; he did not participate in the other recommended groups.

The social worker documented in the progress notes that the patient reported he had difficulty attending groups due to his multiple medical appointments and that he had a difficult time relating to the older patients in the groups. Because the patient's engagement in offered outpatient therapies was limited, medication often was his primary form of treatment. Even with medication, he would sometimes discontinue one or more of his medications on his own, and on three occasions during this period he presented for treatment having been off all medication for several weeks.

The patient also received VA mental health inpatient services three times during this 2-year period. His inpatient services consisted of physical, occupational, and recreation therapy and individual and group mental health therapy sessions. The first inpatient episode was at the VA Eastern Colorado HCS after he presented to the ED with complaints of panic attacks, suicidal thinking, and aggressive thoughts. During his stay and immediately after, social workers assisted him in applying to MH RRTPs at the Sheridan VAMC and another VA facility in Ohio. However, before the application process was completed, the patient presented to the VA Salt Lake City HCS ED with depression and suicidal ideation and was admitted to an inpatient mental health unit. Following discharge, he was transferred to the Sheridan VAMC for ongoing inpatient services; he remained at the Sheridan VAMC for about 2 months.

Delay in Admission to MH RRTP. VHA policy requires that patients have timely access to residential care programs “as medically necessary to meet the patient's need for specialized, residential, intensive mental health treatment, and rehabilitation services.”² Furthermore, patients “cannot be denied admission to MH RRTPs based solely upon length of current abstinence from alcohol or non-prescribed controlled substances, the number of previous treatment episodes, the time interval since the last residential admission, the use of prescribed controlled substances, or legal history.”³ Although, the VA Eastern Colorado HCS and other VA facilities provided the patient with numerous non-medication treatment options, his admission to an MH RRTP was delayed.

In April 2009, the patient requested admission to the HCS' specialized PTSD program, which was supported by his psychiatrist and social worker. This program reportedly had a waiting list of 3–4 months. In June 2009, the social worker documented that the application process had been started. However, the application was not completed over the course of a 3-month period when the patient was persistently requesting this, nor was

² VHA Handbook 1160.01.

³ VHA Handbook 1162.02, “Mental Health Residential Rehabilitation Treatment Program (MH RRTP),” dated May 26, 2009. Note: This reference is for the VHA policy that was in effect at the time of the patient's care. A newer version of the Handbook was published on December 22, 2010; it too includes this requirement.

there any follow-up or outreach during subsequent months when he did not schedule appointments. According to the social worker, this occurred because the patient did not regularly attend recommended outpatient group therapy sessions. We found no evidence that regular attendance at outpatient group therapy sessions is a VHA requirement for admission to MH RRTPs. Furthermore, we found no documentation that such a “requirement” was clearly communicated to the patient; although, the social worker repeatedly encouraged him to attend PTSD psychoeducational classes and a PTSD process group as preparation for the MH RRTP involvement.

In December 2009, while the patient was being treated on an inpatient mental health unit at the HCS, social workers again assisted him in applying to two MH RRTPs at other VHA facilities (in Sheridan, WY and Cincinnati, OH). According to a social worker’s note in early January 2010, during the application process, Sheridan VAMC program staff notified her that the patient needed to be titrated off all opioid pain medications prior to being admitted to the program. According to an inpatient psychiatrist, this was likely necessary because the patient was not on a stable dose of opioid pain medications, which would have affected his ability to focus on the intensive program. Although the psychiatrist’s explanation presents a reasonable clinical rationale, VHA policy does not support the facility’s requirement that the patient had to be off opioid pain medications prior to admission. Before the application process could be completed for either MH RRTP, the patient was admitted for inpatient mental health services at the VA Salt Lake City HCS and later transferred to the Sheridan VAMC for longer-term inpatient treatment.

As part of discharge planning at the Sheridan VAMC, social workers again assisted the patient in applying to three MH RRTPs (two at Sheridan VAMC and one in Cincinnati, OH VAMC). He was accepted to the PTSD program at Sheridan and suspended the application for the Sheridan domiciliary, opting for the PTSD program. Ultimately, however, when the patient was discharged from the inpatient mental health unit, he decided to postpone admission to the Sheridan MH RRTP so that he could spend his summer in Utah. He did not return for the MH RRTP. In September 2010, the patient was seen by a psychiatrist at the HCS who reported that the patient was doing well and considering attending nursing school.

During the 13-month period, April 2009–April 2010, the patient repeatedly attempted to gain admission to various MH RRTPs, but he encountered numerous delays. While some of these delays were unpreventable or the result of the patient’s decision making, others were the result of facility staff applying admission requirements that were not supported by VHA policy. Whether treatment in an MH RRTP would have resulted in a different outcome for the patient is unknown.

Issue 2: Medication Management

We did not substantiate the allegation that VHA providers improperly managed or monitored the patient's psychiatric medications, in particular the atypical antipsychotic quetiapine, which was cited in the Assistant Medical Examiner's report as the probable cause of death. The Assistant Medical Examiner identified the manner of death as "undetermined." Quetiapine is an atypical antipsychotic that is commonly used in the treatment of bipolar disorder, an episodic disorder that is "characterized by periods of abnormally elevated mood or irritability, which may alternate with periods of depressed mood or a mix of symptoms."⁴ The patient was diagnosed with bipolar disorder in 2009. In general, VHA providers prescribed the patient psychiatric medications that were appropriate in terms of his diagnoses and within recommended dosages.

In 2011, the patient was found deceased at his home. According to the Assistant Medical Examiner's report, the patient died from "probable complications of quetiapine ingestion" and reported that the blood quetiapine level was "significantly higher than would be expected given the prescription instructions" but not "so high as to clearly support an inference of deliberate overdose" or to be necessarily lethal.

Over the course of the patient's treatment at VHA facilities, he was prescribed multiple medications in conjunction with recommended psychotherapy. We found that the prescribed medications, including the atypical antipsychotic medications, were appropriate in terms of the patient's diagnoses of bipolar disorder and PTSD. Furthermore, the dosages were within the typical recommended ranges. The atypical antipsychotic medications the patient received included risperidone, olanzapine, and quetiapine and have all been approved by the U.S. Food and Drug Administration (FDA) for the treatment of bipolar disorder and are consistent with recommended treatments in VA/Department of Defense (DoD) clinical practice guidelines for bipolar disorder⁵ and PTSD (as an adjunctive therapy).⁶ Clinicians at the facilities actively engaged the patient in his treatment, discussed medication side effects with the patient, and addressed reported side effects by adjusting the patient's medications as appropriate.

The patient started risperidone in late 2009 while an inpatient at the VA Eastern Colorado HCS. Prior to prescribing the risperidone, a provider conducted a history and physical, which included a physical examination and routine laboratory tests. Providers also monitored the effectiveness of the risperidone and its side effects. In early 2010, the

⁴ The Management of Bipolar Disorder Workgroup, "VA/DOD Clinical Practice Guideline for Management of Bipolar Disorder in Adults," Version 2.0 – 2010, Module E Pharmacotherapy Interventions, Antipsychotic Medications. Accessed at <http://www.healthquality.va.gov/> on 10/17/11.

⁵ The Management of Bipolar Disorder Workgroup, "VA/DOD Clinical Practice Guideline for Management of Bipolar Disorder in Adults," Version 2.0 – 2010, Module E Pharmacotherapy Interventions, Antipsychotic Medications. Accessed at <http://www.healthquality.va.gov/> on 10/17/11.

⁶ The Management of Post-Traumatic Stress Working Group, "VA/DOD Clinical Practice Guideline for Management of Post-Traumatic Stress," Version 2.0 – 2010. Accessed at <http://www.healthquality.va.gov/> on 10/17/11.

patient was admitted to the VA Salt Lake City HCS, where his provider discontinued the risperidone after the patient reported a side effect of twitching and replaced it with quetiapine. Prior to the change, a provider conducted a history and physical, including laboratory tests. Following the change, providers monitored the medication and its side effects.

When the patient transferred from the VA Salt Lake City HCS to the Sheridan VAMC, a provider completed a history and physical examination, as well as an electrocardiogram (EKG); the latter produced normal results. Shortly after admission, the patient complained of a fast heart rate, so a provider discontinued quetiapine and replaced it with olanzapine. About 6 weeks later, the provider changed the patient's treatment from olanzapine back to quetiapine after the patient complained about weight gain on the olanzapine and in consideration that there had been little difference in the patient's heart rate and the patient's stated opinion that quetiapine was actually more effective in controlling his mood swings.

At the time of his death, the patient had two active VA prescriptions—quetiapine 200 mg at bedtime and clonazepam 1 mg twice a day as needed for anxiety. The patient had stopped taking his other medications prior to his last psychiatric medication management appointment at the VA Eastern Colorado HCS in November 2010. His last VA refill of quetiapine was in mid-December 2010 for a 30-day supply.

As with any medication, there are risks associated with taking atypical antipsychotic drugs. According to the prescribing information required by the FDA, some of these risks include, but are not limited to, weight gain, diabetes and hyperglycemia, hyperlipidemia, neuroleptic malignant syndrome,⁷ and tardive dyskinesia.⁸ However, while there is a considerable amount of medical literature that addresses common risks of atypical antipsychotics, such as weight gain and diabetes, there is limited medical literature on the risk of sudden death associated with these drugs.

A 2009 retrospective study of 46,000 Medicaid patients found that “users of typical and atypical antipsychotic drugs had a similar, dose-related increased risk of sudden cardiac death”⁹ as compared to non-users of antipsychotic drugs. Based on the study, some clinicians recommend that all patients being considered for atypical antipsychotic treatment, regardless of cardiac risk or age, should have an EKG prior to and following

⁷ Neuroleptic malignant syndrome is a rare, but life-threatening, idiosyncratic reaction to a neuroleptic (type of antipsychotic medication) characterized by fever, muscular rigidity, altered mental status, and autonomic instability.

⁸ Tardive dyskinesia is a set of symptoms caused by long-term use of certain medications, and it commonly includes repetitive, involuntary movements such as lip smacking or pursing, rocking of the trunk, rotating the ankles or legs, and grimacing and chewing movements.

⁹ Ray, Wayne A., PhD, Cecilia P. Chung, MD, MPH, Katherine T. Murray, MD, Kathi Hall, BS, and C. Michael Stein, MB, ChB, “Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death,” *The New England Journal of Medicine*, 360:225–235, January 15, 2009.

initiation of treatment.¹⁰ However, clinicians disagree as to whether these precautions are necessary and/or beneficial for all patients receiving antipsychotics or if they will change outcomes.¹¹ In response to the study findings, the American Psychiatric Association recommended that providers continue to follow existing guidelines for the management of psychotic patients. These guidelines include obtaining a patient’s medical history (including cardiac and medication history), a thorough physical examination, and routine laboratory tests.¹² The VA/DoD clinical practice guidelines also remained unchanged.

Ultimately, providers must balance the risks and benefits of any medication regimen given a patient’s specific diagnoses, symptoms, and response to other treatments and medications. The patient himself identified quetiapine as a helpful treatment, and as a testament to that, it was one of the limited group of medications that he took fairly reliably. We found that the providers who treated the patient documented the patient’s histories and physical examinations, as well as discussions of medication side effects and changes in medications. They also documented challenges they encountered in assisting the patient, such as their concerns that the patient did not always comply with taking prescribed medications or participate in prescribed therapies.

Conclusions

We did not substantiate the allegation that the patient was not provided or offered other treatment options in conjunction with prescribed medications. VA Eastern Colorado HCS providers, as well as providers at the other VA facilities where the patient received services, offered the patient a variety of therapies in both outpatient and inpatient settings. However, we found that the patient’s admission to an MH RRTP was delayed for reasons that were not supported by VHA policy.

We did not substantiate the allegation that VHA providers improperly managed or monitored the patient’s psychiatric medications, in particular the atypical antipsychotic drug quetiapine. The patient’s prescribed medications were approved by the FDA, appropriate in terms of his clinical presentation, and prescribed within the typical recommended dosages.

Recommendation

Recommendation 1. We recommended that the VISN Director implement procedures to ensure that facility staff use MH RRTP admission criteria that are supported by VHA policies.

¹⁰ Schneeweiss, Sebastian, MD, ScD, and Jerry Avorn, MD, “Antipsychotic Agents and Sudden Cardiac Death—How Should We Manage the Risk?” *The New England Journal of Medicine*, 360:294–296, January 15, 2009.

¹¹ *Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death*. Transcript of Web Conference. Agency for Healthcare Research and Quality, Rockville, MD.

Comments

The VISN and Facility Directors concurred with our recommendation and provided an acceptable action plan. (See Appendixes A and B, pages 14–18 for the Directors’ comments.) We will follow up on the planned actions until they are completed.



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

¹² Moran, Mark, “Cardiac Death Risk Rises with Both Antipsychotic Types,” *Psychiatric News*, American Psychiatric Association, Vol 4, No. 5, March 6, 2009.

**Department of
Veterans Affairs**

Memorandum

Date: March 22, 2012

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

Subject: **Healthcare Inspection—Alleged Quality of Mental Health Care,
VA Eastern Colorado Health Care System, Denver, Colorado**

To: Director, Bedford Office of Healthcare Inspections (54BN)

Thru: Director, Management Review Service (10A4A4)

I have reviewed the report from Eastern Colorado Health Care System and concur with the recommendation(s). If there are any questions contact Susan Curtis 303-639-6995.

(original signed by:)

Ralph T. Gigliotti, FACHE
Director, VA Rocky Mountain Network (10N19)

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: March 22, 2012

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

Subject: **Healthcare Inspection—Alleged Quality of Mental Health Care, VA Eastern Colorado Health Care System, Denver, Colorado**

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

1. This is in response to your inquiry pertaining to the following allegations brought forth in a complaint:
 - a. The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by a complainant concerning the quality of mental health care a patient received at the VA Eastern Colorado Health Care System (ECHCS).
2. Details of the allegations/complaints:
 - a. The VA Eastern Colorado Health Care System (ECHCS) is part of Veterans Integrated Service Network (VISN) 19 and comprises the Denver Medical Center, two Community Living Centers (CLCs), and eight Community Based Outpatient Clinics (CBOCs). VISN 19 also includes medical centers in Grand Junction, CO; Salt Lake City, UT; Fort Harrison, MT; Sheridan, WY; and Cheyenne, WY.
 - b. ECHCS provides inpatient services in medicine, surgery, and mental health. Outpatient services include primary care, specialty services, mental health, and a residential treatment program is available for Post-Traumatic Stress Disorder (PTSD).
 - c. May 25, 2011, the OIG's Hotline Division received allegations concerning ECHCS. Specifically, the complainant alleged despite an ECHCS psychiatrist's conclusions a patient was not a candidate for medication and should attend a residential treatment program for PTSD, the psychiatrist prescribed the patient the medications Quetiapine (noted on patient's death certificate as the probable cause of death), Lorazepam, Clonazepam, Sertraline, "and others."
 - d. The complainant expressed concern other non-medication therapies were not made available to the patient. The complainant further alleged ECHCS providers did not adequately manage or monitor the patient's psychiatric medications, which contributed to the patient's sudden death.

3. Conclusions:

- a. The OIG did not substantiate the allegations the patient was not provided or offered other treatment options in conjunction with prescribed medications. ECHCS providers, as well as providers at other VA facilities where the patient received services, offered the patient a variety of therapies in both outpatient and inpatient settings. However, the panel found the patient's admission to a Mental Health (MH) Residential Rehabilitation Treatment Program (RRTP) was delayed for reasons not supported by VHA policy.
- b. The OIG did not substantiate the allegation VHA providers improperly managed or monitored the patient's psychiatric medications, in particular the atypical antipsychotic drug Quetiapine. The patient's prescribed medications were approved by the FDA, appropriate in terms of his clinical diagnoses, consistent with VA/DoD clinical practice guidelines, and prescribed within the typical recommended dosages.

4. Recommendations:

- a. **Recommendation 1:** VISN Director implement procedures to ensure facility staff use MH RRTP admission criteria supported by VHA policies.

5. Action items:

- a. The Program Manager, Post-Traumatic Stress Disorder (PTSD) Residential Rehabilitation Treatment Program (RRTP) completed a chart review, interviewed the Program's Admissions Coordinator, reviewed admission standards in VHA Handbooks 1162.02 (December 22, 2010) and 1160.01 (September 11, 2008), and reviewed the program's admissions procedures.
- b. Current admission criteria and practice are consistent with VHA policies. However, clinicians referring veterans to the PTSD RRTP should receive more education in the program's admission criteria and wait times. There are clinicians who are unaware of current admission criteria, which became more flexible after the release of Handbook 1162.02. In addition, referring clinicians may be unaware wait times are lower than they have been in the past.
- c. If you need additional information, please contact Ronald Wilkins RN, MHA, Risk Manager, at 303.393.5175, or via email to ronald.wilkins@va.gov.

(original signed by:)

Lynette A. Roff
Director, Eastern Colorado Health Care System (554/00)

**Director's Comments
to Office of Inspector General's Report**

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended that the VISN Director implement procedures to ensure that facility staff use MH RRTP admission criteria that are supported by VHA policies.

Concur

Target Completion Date: May 1, 2012

Facility's Response:

a. PTSD RRTP Program Manager will complete chart review of veteran, interview the program's Admissions Coordinator, and review the program's admissions procedures.

Target date: March 14, 2012

Status: Completed March 14, 2012

b. PTSD RRTP Program Manager will review with the program's Admissions Coordinator admission standards in VHA Handbooks 1162.02 and 1160.01.

Target date: March 14, 2012

Status: Completed, March 14, 2012

c. PTSD RRTP Admissions Coordinator will educate referring staff throughout ECHCS regarding admission criteria, wait times, referral process for PTSD RRTP, and access to RRTPs throughout VHA. Admissions Coordinator will also provide this education to referring clinicians at Fort Carson, CO, within the Department of Defense.

Target date: May 1, 2012

Status: March 2, 2012, PTSD RRTP Admissions Coordinator presented to Ft. Carson Warrior Transition Unit (WTU) staff and to the WTU Supervisor of Social Work. March 2, 2012, Admissions Coordinator met with VA-DoD liaison to clarify admission criteria and procedures. PTSD RRTP Admissions Coordinator will present at Mental Health Service staff meeting on April 2, 2012. Admissions Coordinator will present to ECHCS Mental Health leadership at a combined

CBOC Mental Health Administration/Mental Health Executive Board meeting on April 2, 2012. The Admissions Coordinator will present during team meetings throughout ECHCS during March/April 2012. The Admissions Coordinator will also e-mail admissions information to all ECHCS clinicians.

d. PTSD RRTP Program Manager will revise written admission procedures to emphasize that veterans will not be denied admission to the RRTP based upon the intensity of involvement in outpatient care.

Target date: February 22, 2012

Status: Completed February 22, 2012

e. PTSD RRTP Program Manager will revise the program's written admissions procedures to include a plan for referring vets to RRTPs with shorter wait times.

Target date: April 1, 2012

Status: In progress

f. PTSD RRTP Program Manager will draft a Memorandum of Understanding (MOU) with the Sheridan General RRTP regarding referral of veterans between the programs. This will facilitate rapid referrals between RRTPs in VISN 19 and will include services for veterans with Military Sexual Trauma (MST).

Target date: April 15, 2012

Status: Leadership within the Sheridan Mental Health Service and Sheridan RRTP has agreed to sign a MOU regarding referrals with ECHCS.

g. PTSD RRTP Program Manager will review with Admissions Coordinator the process for involving the National Center for PTSD in identifying programs with short wait times.

Target date: March 15, 2012

Status: Completed

h. PTSD RRTP Program Manager will review with Chief, Facilities Management Service (FMS), and the plan to construct a new PTSD RRTP at the Denver VAMC, Fitzsimmons Campus, in 2015. The plan includes the addition of one bed, which may improve wait times.

Target date: March 14, 2012

Status: Completed

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Acknowledgments	Claire McDonald, MPA, Project Leader Annette Acosta, MN, RN, Team Leader Alan Mallinger, MD Clarissa Reynolds, CNHA, MBA Michael Shepherd, MD

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