



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

Office of Healthcare Inspections

Report No. 15-01599-289

Healthcare Inspection

Quality of Care Concerns in the Management of a Hepatitis C Patient, Grand Junction Veterans Health Care System Grand Junction, Colorado

May 11, 2016

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection at the request of Senator Michael Bennet, Senator Cory Gardner, and Representative Scott Tipton, to assess quality of care concerns in the management of a Hepatitis C patient at the Grand Junction Veterans Health Care System (system), Grand Junction, CO. The allegations stated that:

- Follow-up care was inadequate leading to further hospitalization.
- A non-qualified physician provided the patient's Hepatitis C treatment.
- The patient should have been admitted earlier to the hospital based on laboratory results.

We substantiated the allegation that follow-up care was inadequate and led to further hospitalization. The Hepatitis C Care Provider often did not provide the care or assess the patient thoroughly when seen. The circumstances of discontinuity of care and the lack of a thorough analysis of the patient's condition may have contributed to his progressive decline and slower recovery. Although not part of the original allegations, we also found that contingency plans were not in place to account for reduced availability of the Hepatitis C Care Provider as he started to decrease his hours.

We did not substantiate that a non-qualified physician provided Hepatitis C treatment. Neither VA policy nor general practice regarding physicians' credentialing and privileging, ongoing professional practice evaluations, and documentation of education hours require that clinicians have specific evidence of competency to manage Hepatitis C patients.

We did not substantiate that the patient should have been admitted earlier to the hospital based on laboratory results. We found that the patient had an elevated ammonia level that was acknowledged timely and treated with an appropriate medication.

We recommended that the System Director ensure adequate consultation, formalized back up, and contingency plans for specialties with limited specialty provider availability.

Comments

The System Director nonconcurred that the patient received inadequate follow-up care leading to further hospitalization. However, the Veterans Integrated Service Network and System Directors concurred with our recommendation and provided an acceptable

action plan. (See Appendixes A and B, pages 11–15 for the Directors' comments.) We will follow up on the planned actions until they are completed.

A handwritten signature in black ink, reading "John D. Daigh, Jr., M.D." in a cursive script.

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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection in response to allegations received by Senator Michael Bennet, Senator Cory Gardner, and Representative Scott Tipton, about quality of care concerns in the management of a Hepatitis C patient at the Grand Junction Health Care System (system), Grand Junction, CO. The purpose of this inspection was to determine if the allegations had merit.

Background

The system is part of Veterans Integrated Service Network (VISN) 19 and serves more than 42,000 veterans in a primary service area that includes 17 counties in rural western Colorado and eastern Utah. The system provides a broad range of inpatient and outpatient medical, surgical, mental health, geriatric, rehabilitation, and emergency services. It has 31 patient care beds, 30 community living center beds, and is one of VA's smallest facilities.

Hepatitis C Virus Overview

Hepatitis C is a blood-borne¹ virus that affects the liver. It is estimated that between 2.7 and 3.9 million people in the U.S. have chronic Hepatitis C infection.² The Veterans Health Administration (VHA) has a seroprevalence rate of 5.4 percent (three times that of the general U.S. population), and over 170,000 veterans in VHA care have confirmed chronic Hepatitis C virus.³ Infection is most prevalent among those born during 1945–1965, the majority of whom were likely infected during the 1970s and 1980s when rates were highest.⁴ Guidelines for Hepatitis C testing include adults born during 1945–1965 regardless of risk of exposure and those deemed at risk from previous or current exposure.⁵

Approximately 75–85 percent of those patients infected will have a chronic infection, 5–20 percent will go on to develop cirrhosis⁶ over a period of 20–30 years, and

¹ A blood-borne disease (sometimes referred to as a Blood Borne Virus or BBV) is one that can be spread through contamination by blood and other body fluids. The most common examples are the human immunodeficiency virus, hepatitis B, hepatitis C, and viral hemorrhagic fevers.

² *Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965*, Centers for Disease Control and Prevention (CDC), Morbidity and Mortality Weekly Report (MMWR). http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6104a1.htm?s_cid=rr6104a1_w. Published August 17, 2012. Accessed March 30, 2015.

³ VHA Directive 1300.01, *National Viral Hepatitis Program*, February 22, 2013, http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1586. Accessed March 30, 2015.

⁴ *What is the prevalence of chronic HCV infection in the United States?* CDC Viral Hepatitis - Hepatitis C Information, <http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#>. Accessed March 30, 2015.

⁵ *Guidelines to Hepatitis C testing*, CDC, MMWR, published August 17, 2012, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6104a1.htm?s_cid=rr6104a1. Accessed March 30, 2015.

⁶ Cirrhosis is a chronic degenerative disease in which normal liver cells are damaged and then replaced by scar tissue.

1–5 percent will die from the consequences of a chronic infection (cirrhosis or liver cancer).⁷ The complications of liver cirrhosis include gastrointestinal bleeding, ascites (fluid buildup in the abdomen), spontaneous bacterial peritonitis (inflammation of the membrane that lines the abdomen), hepatic encephalopathy (damage to the brain from the liver's inability to detoxify harmful substances), and coma.

The rationale for Hepatitis C treatment is to reduce mortality and liver-related complications.⁸ The mainstay of Hepatitis C treatment is drug therapy. No vaccine against Hepatitis C is available. The goal is to maintain sustained virologic response defined as the continued absence of detectable Hepatitis C Virus Ribonucleic Acid⁹ at least 12 weeks after completion of therapy.¹⁰ The introduction of highly effective Hepatitis C virus protease inhibitor therapies in 2011 has not only changed the therapies available for Hepatitis C, but has also increased the sustained virologic response¹¹ to up to 70 percent.¹²

It is VHA's policy that patients with viral hepatitis are identified and provided high quality care and appropriate treatment.¹³ Hepatitis C treatment planning can be delivered by specialists or clinical lead physicians or through Specialty Care Access Network-Extension for Community Healthcare Outcomes (SCAN-ECHO)^{14,15} and telehealth technology at the local VA. Treatment can last for months with the need for frequent laboratory testing, monitoring, and physical assessments. To that end, strong support from local VA or tertiary VA specialists with Patient Aligned Care Teams to coordinate that care is paramount to a successful outcome.

System's Hepatitis C Clinic Overview

The system's Hepatitis C clinic was developed over a period of several years. Prior to 2012, a physician having increased knowledge and interest in the disease treated patients for Hepatitis C. In March 2012, an interdisciplinary Hepatitis C clinic was started. This onsite clinic continued from March 2012 through March 2014. In

⁷ *Hepatitis C FAQs for Health Professionals*, CDC – MMWR, published August 17, 2012, <http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#->. Accessed March 30 2015.

⁸ *When and in Whom to Initiate HCV Therapy*, International Antiviral Society–USA, Revised December 19, 2014, <http://www.hcvguidelines.org/>. Accessed March 30, 2015.

⁹ Genetic Home Reference, published December 28, 2015, <http://ghr.nlm.nih.gov/glossary=rna>. Accessed March 30, 2015.

¹⁰ *Recommendations for Testing, Managing, and Treating Hepatitis C* <http://www.hcvguidelines.org/> International Antiviral Society–USA, Revised Date: December 19, 2014. Accessed March 30, 2015.

¹¹ Pearlman, Brian L., Traub, Nomi. *Sustained Virologic Response to Antiviral Therapy for Chronic Hepatitis C Infection: A Cure and So Much More*. <http://cid.oxfordjournals.org/content/52/7/889.full>. Accessed March 30, 2015.

¹² *Current and Future Therapies for Hepatitis C Virus Infection*, published N Engl J Med 2013; 368:1907–1917, <http://www.nejm.org/doi/full/10.1056/NEJMra1213651>. Accessed March 30, 2015.

¹³ VHA Directive 1300.01, *National Viral Hepatitis Program*, February 22, 2013.

¹⁴ SCAN-ECHO uses video teleconferencing technology to link several primary care providers, many of whom are in different rural communities within a service area, simultaneously to a specialist.

¹⁵ *Current and Future Therapies for Hepatitis C Virus Infection*, published N Engl J Med 2013; 368:1907–1917, <http://www.nejm.org/doi/full/10.1056/NEJMra1213651>. Accessed March 30, 2015.

April 2014, the primary care physician who led the Hepatitis C clinic began to limit his clinical hours. In October 2014, an established Rural Hepatitis C clinic at the Denver VA Medical Center agreed to provide ongoing specialty care for the Hepatitis C patients.

Allegations

In December 2014, the OIG received a request from Senator Michael Bennett, Senator Cory Gardner, and Representative Scott Tipton to review allegations about quality of care concerns in the management of a Hepatitis C patient at the system. The allegations stated that:

- Follow-up care was inadequate leading to further hospitalization.
- A non-qualified physician provided the patient's Hepatitis C treatment.
- The patient should have been admitted earlier to the hospital based on laboratory results.

Scope and Methodology

We conducted a site visit February 3–5, 2015. We interviewed the complainant, system leadership, service chiefs, physicians, nurse practitioners, clinical pharmacists, and a physician assistant. We utilized the guidelines published by The American Association for the Study of Liver Disease, Infectious Diseases Society of America, and the International Antiviral Society-USA.

We reviewed the patient's electronic health record (EHR), provider credentialing and privileging (C&P) records and ongoing professional practice evaluations (OPPE), quality reviews, and other relevant documents.

We **substantiated** allegations when the facts and findings supported that the alleged events or actions took place. We **did not substantiate** allegations when the facts showed the allegations were unfounded. We **could not substantiate** allegations when there was no conclusive evidence to either sustain or refute the allegation.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Case Summary

The patient was a male in his 60s, with a history of Hepatitis C diagnosed more than 10 years ago and liver fibrosis diagnosed by liver biopsy in 2008. He routinely received care for his Hepatitis C at the system. The patient had a urologic infection that led to sepsis in 2014. He was admitted to a non-VA hospice facility due to his severe infection, and he died shortly after admission. We describe further details of his case history below.

Hepatitis C Care

In the late 1990s, the patient was treated at a non-VA hospital for Hepatitis C with interferon¹⁶ and ribavirin¹⁷ therapy for 12 months. He had depression as a side effect from his interferon treatment. He initially responded to treatment, but 3 months after completing therapy, he had blood test results that suggested disease recurrence.

In 2008, a primary care provider (PCP) referred the patient to another VA facility liver clinic. The VA hepatologist at that facility ordered a liver biopsy to evaluate the status of his liver disease. The biopsy results noted chronic Hepatitis C and grade 2 fibrosis.¹⁸ The specialist noted stability to the patient's liver disease and recommended watchful waiting with another liver biopsy in 5 years. Over the next several years, primary care providers followed the patient.

The patient established care at the system in 2009. In 2014, upon referral from his PCP, an internist who had experience in Hepatitis C treatment (Hepatitis C Care Provider) evaluated the patient. After reviewing the medical history and completing a physical exam, the Hepatitis C Care Provider (HCCP) initiated a three-drug treatment regimen that included interferon. The patient met with the clinical pharmacist assigned to the Hepatitis C clinic to discuss medication side effects and follow-up laboratory testing. He also saw his behavioral health provider to initiate an antidepressant in anticipation of the side effects of interferon therapy.

Approximately 3 weeks later, the clinical pharmacist contacted the patient after he did not follow up for blood tests. The patient reported nausea and dizziness. He declined immediate medical attention. The clinical pharmacist notified the HCCP of the patient's condition by including the HCCP as an additional signer to a note entered into the patient's EHR.

¹⁶Hepatitis C Online. University of Washington Web site. <http://www.hepatitisc.uw.edu/go/treatment-infection/treatment-genotype-1/core-concept/all>. Accessed March 31, 2015.

¹⁷National Institute of Health Web site. <https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=ribavirin>. Accessed March 31, 2015.

¹⁸Fibrosis is the formation of an abnormal amount of fibrous tissue in an organ or part as the result of inflammation, irritation, or healing.

Three days later, the patient had a follow-up appointment with the HCCP (occasion 1).¹⁹ The patient reported mild lightheadedness, dizziness, decreased appetite, and fatigue. He denied nausea or vomiting. His most recent laboratory results showed a significant decline in his white blood count and platelets. The HCCP noted concerns for interferon toxicity. The plan was to reduce the interferon dosing, obtain weekly laboratory tests, and schedule a 1-month follow-up. At this visit, the HCCP changed the patient's prostate medication to one that had lesser side effects of dizziness.

A few weeks later, the clinical pharmacist called the patient after noting that the patient did not follow up for blood tests (occasion 2). The patient indicated that he was not feeling well and would come to the clinic the following day. Upon review of the laboratory results, the HCCP ordered a quantitative Hepatitis C level be done.

The clinical pharmacist called the patient when he did not come for the scheduled blood tests. At that time, the patient noted feeling sick with generalized fatigue and diarrhea. The clinical pharmacist contacted the HCCP who requested that the patient come into the Emergency Department (ED) for evaluation of dehydration. The patient presented to the ED later that day (occasion 3). The ED provider evaluated the patient and ordered intravenous fluids and laboratory tests. The HCCP did not evaluate the patient. Blood test results showed that the patient's liver enzymes were elevated compared to his previous laboratory results. The ED provider discharged the patient with anti-diarrheal medication and instructions to obtain follow-up blood tests in 2 days. The PCP reviewed the follow-up blood tests and noted that the liver enzymes remained elevated. The PCP contacted the HCCP who recommended adjustments of the patient's Hepatitis C medications. The patient saw the HCCP 3 days after this medication adjustment and complained of dizziness, weakness, diminished appetite, ankle swelling, and depression (occasion 4). The HCCP noted that the patient was intolerant to one of his Hepatitis C medications and was "demonstrating evidence of progressive liver insufficiency from that agent." The HCCP discussed the adjusted medication plan with the patient. The HCCP also noted that the patient's liver function would need closer monitoring for the next several weeks to demonstrate improvement. The patient followed up for retesting of his liver enzymes 4 days after his visit.

Approximately 1 week after the patient's ED visit, the clinical pharmacist ordered a Specialty Care Access Network-Extension for Community Healthcare Outcomes (SCAN-ECHO) consult with the Hepatitis C Clinical Pharmacy Specialist and a Gastroenterologist at the San Francisco Veterans Health Care System. The SCAN-ECHO consultant(s) recommended a different Hepatitis C medication once liver functions started to improve. The clinical pharmacist at the system reviewed the patient's most recent laboratory tests and noted that the liver enzymes remained elevated and slightly increased. The pharmacist contacted the HCCP who recommended repeating the laboratory tests in 6 days.

¹⁹ See discussion of four occasions of patient care in Issue 1 below.

One week after the SCAN-ECHO consult, the patient left incoherent voice mail messages with the clinical pharmacist. The clinical pharmacist contacted the Patient Aligned Care Team Registered Nurse (RN) who recommended an evaluation by his PCP the next day since follow-up blood tests were also scheduled. The PCP evaluated the patient and ordered laboratory tests to investigate the cause of his confusion. The studies showed that the patient had both a urinary tract infection and elevated ammonia level. The PCP consulted the HCCP via phone who recommended medication for treatment of the elevated ammonia level. The HCCP also advised the PCP to initiate the Hepatitis C medication recommended by the SCAN-ECHO consultants. The PCP treated the urinary tract infection with antibiotics, entered a consult for home nursing services to help with medication set-up and monitoring, and arranged a follow-up clinic appointment in 1 week.

At the time of the follow-up clinic appointment, a nurse practitioner (NP) evaluated the patient, as his PCP and the HCCP were not available. The NP documented that the patient appeared weak and confused and ordered blood tests and an abdominal ultrasound and requested another SCAN-ECHO consult with the San Francisco Veterans Health Care System. She also consulted a former system's Hepatitis C clinic physician who was practicing locally. Prior to the ultrasound study, she made a medication adjustment and requested a clinic recheck in 2 days. The patient completed his ultrasound after clinic hours that day. The finding of abdominal ascites²⁰ on ultrasound provided evidence for decompensated liver disease. As the NP had left for the day, radiology staff sent the patient to the ED for further evaluation. The ED attending noted that the patient was stable to go home.

The following day, the NP consulted with the Chief of Medicine to admit the patient for monitoring of his decompensated liver disease while stopping all Hepatitis C treatment medications. A hospitalist admitted the patient and completed a paracentesis²¹ to determine the cause of his ascites. The result was consistent with fluid accumulation from liver disease and not from an abdominal infection.

Four days after admission, a hospitalist entered a specialty consult to the VA Eastern Colorado Health Care System for further guidance on Hepatitis C treatment options. Due to limited capacity to accept new patients, the specialty clinic declined the referral and recommended referral to a university hospital for evaluation. We did not find evidence that the system's providers ordered a non-VA referral. However, the patient stabilized clinically and was transferred to the system's community living center (CLC) for both continued monitoring and for concerns about his inability to care for himself independently. The patient remained a resident of the CLC until discharged home about 9 weeks later. A Hepatitis C quantitative level that was done prior to discharge was non-detectable on blood tests.

²⁰ Ascites is the accumulation of fluid in the peritoneal cavity, causing abdominal swelling.

²¹ Paracentesis is a procedure to remove fluid from the area between the belly wall and the spine. This space is called the abdominal cavity.

Approximately 3 months later, the patient developed a urinary tract infection and sepsis and was admitted to a non-VA hospice facility. The patient expired shortly after admission. The patient's death certificate listed bilateral pneumonia as the immediate cause of death.

Inspection Results

Issue 1: Follow-Up Care

We substantiated the allegation that the patient received inadequate follow-up care leading to further hospitalization. While the patient had received regular follow-up visits and the HCCP generally documented the review of laboratory results and studies prior to initiating therapy, we found that the HCCP or other staff did not provide the care or assess the patient thoroughly on at least four separate occasions. The circumstances of discontinuity of care and the lack of a thorough analysis of the patient's condition may have contributed to his progressive decline and slower recovery.

The HCCP saw the patient who had complaints of dizziness and increased fatigue (occasion 1). The side effects of interferon could have potentially caused these symptoms, but the HCCP did not document other potential causes for the patient's symptoms. The consideration of a concurrent infection may have resulted in further workup. Hand-off for further evaluation was not completed.

A few weeks later, the clinical pharmacist contacted the patient for missing his scheduled blood test (occasion 2). The patient noted fatigue; however, the clinical pharmacist did not document any further inquiry of the symptoms. An assessment of his symptoms should have been completed to determine the urgency for care. This may have resulted in an earlier intervention by the HCCP or PCP.

A few days later, the clinical pharmacist contacted the patient for missing his scheduled blood test (occasion 3). The patient complained that he was "sick as a dog" with diarrhea for the past 4 to 5 days. The clinical pharmacist called the HCCP who requested that the patient go to the ED where an ED physician examined him. The ED treated the patient with intravenous fluids. The patient was given a prescription for diarrhea. The HCCP did not evaluate the patient, and the patient did not have any tests performed in the ED to rule out infection.

Further studies were not ordered, despite clinical decline. Six days after the ED visit, the HCCP evaluated the patient and documented that he was "symptomatically doing poorly" (occasion 4). The HCCP did not initiate further workup given his clinical deterioration on a lower dosing of interferon with the last dose given 5 days prior. A complete workup may have prevented hospitalization later in the month.

Although not part of the original allegations, while evaluating the follow-up care, we found that contingency plans were not in place to account for reduced availability of the HCCP as he started to decrease his hours. The HCCP had limited clinic hours at the system as he began transitioning to retirement. Although the HCCP may not have been

in the hospital or clinic, the provider was often available by phone but no standard schedule was known to the clinic. As the HCCP's availability decreased, critical laboratory results were relayed to the medical officer of the day or PCP and then to one of the two clinical pharmacists. The clinical pharmacist would contact the HCCP by phone and then contact the patient. The clinical pharmacist would then contact the Patient Aligned Care Team RN, PCP, or HCCP for a clinical assessment if needed. During our interviews, we noted that some primary care physicians were not comfortable addressing Hepatitis C treatment complications.

As the HCCP's availability diminished, another formalized consultative source should have been in place for the acute management of Hepatitis C treatment complications. Prior to this patient's hospitalization, urgent specialty help was obtained via SCAN-ECHO with the San Francisco VAMC. The SCAN-ECHO did result in guidance for management. Staff who covered for the HCCP addressed the patient's immediate clinical concerns. This focused approach did address the patient's acute issues but did not address the broader clinical concerns of his continued decline despite changes in drug therapy.

Issue 2: Physician Qualifications

We did not substantiate that a non-qualified physician provided Hepatitis C treatment because physicians' C&P, OPPE, and documents recording their education hours do not require physicians to have specialized education in Hepatitis C treatment in order to be able to provide that care.

We reviewed the C&P and OPPE of the HCCP from October 2000 through November 2014. Physician C&P and OPPE are processes that ensure a provider is both qualified and competent. The system completes C&P upon hire and every 2 years for any licensed independent practitioner (LIP)²² in accordance with VHA and The Joint Commission. The credentialing process involves screening and evaluating qualifications for an LIP that includes licensure, required education, relevant training and experience, current competence, and health status.²³ The privileging process specifies which type of care within the scope of an LIP's licensure is permitted. Clinical privileges must be facility-specific, practitioner-specific, and within available resources. Facilities use the OPPE as a screening tool to evaluate the clinical practice of LIPs and to identify those clinicians who might be delivering an unacceptable quality of care. The results of the OPPE may help address the specific quality of care concerns. Additionally, the OPPE may result in a Focused Professional Practice Evaluation to validate quality of care concerns.

The C&P review verified the HCCP credentials as a licensed and board certified internist. In addition, the HCCP's privileging section delineated specifically the HCCP's

²² VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012, http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2910. Accessed July 14, 2015.

²³ Ibid.

scope of primary care and emergency care at the system. The OPPEs for the HCCP collected data based on primary care and emergency care outcome measures and general clinical practices. Both C&P and OPPE data noted no concerns by the system's credentialing committee. However, neither the C&P nor the OPPEs were specific to Hepatitis C care.

We also evaluated the HCCP's training. The system, VISN, and VHA have no requirement for specific education hours, ongoing training, or formal training for PCPs who deliver specialty care services for a specialized clinic. For the HCCP we reviewed, we found documented evidence of two 1-hour training sessions specific to Hepatitis C care for the period November 1, 2012, through October 31, 2014. We did not find other documented evidence of Hepatitis C continuing medical education. However, the HCCP treating the patient described in this report had been treating patients with Hepatitis C for approximately 15 years and directed the Hepatitis C clinic at the facility.

Issue 3: Alleged Failure To Admit a Patient Earlier to the Hospital Based on Laboratory Results

We did not substantiate that the patient should have been admitted earlier to the hospital based on laboratory results. We reviewed the results of the patient's blood tests conducted during the week prior to the 2014 hospitalization. We did not find abnormal results that would have required earlier hospitalization. However, we found that the patient had an elevated ammonia level that was appropriately treated with medication. The patient was admitted to the hospital due to accumulation of fluid from liver disease.

We also reviewed the patient's laboratory results for reporting errors for a 9-month period. Laboratory staff enter laboratory results into the EHR that show as alerts for the ordering provider. In the EHR, laboratory errors will have an addendum noting the particular issue at the end of the laboratory report. For the period reviewed, we did not find any addendums that denoted reporting errors. In addition, system providers acknowledged abnormal laboratory results that were pertinent to his treatment in a timely manner.

Conclusions

We substantiated the allegation that follow-up care for the patient described in this report was inadequate leading to his hospitalization in 2014 and subsequent transfer to the CLC for continued care. The NP and clinical pharmacist provided care in the absence of the PCP or HCCP. Additionally, the HCCP often did not provide the care or assess the patient thoroughly when seen. The circumstances of discontinuity of care and the lack of a more thorough analysis of the patient's condition may have contributed to his progressive decline and slower recovery. The patient did recover and was discharged home. The patient was retested for Hepatitis C prior to his discharge and results showed no evidence of the virus. The patient died from bilateral pneumonia in hospice approximately 3 months after the CLC discharge. Although not a specific allegation, in the course of evaluating the follow-up care, we found that contingency

plans were not in place to account for decreased availability of the HCCP as he started to limit his hours.

We did not substantiate that a non-qualified physician provided Hepatitis C treatment. Neither VA policy nor accepted medical practice requires specific training for Hepatitis C to be included in physicians' C&P, OPPE, or education hours. We did determine that the HCCP had more than 15 years' experience in treating patients with Hepatitis C.

We did not substantiate that the patient should have been admitted earlier to the hospital based on laboratory results. We found that the patient had an elevated ammonia level that was appropriately treated with medication.

We reviewed laboratory results for reporting errors for a 9-month period. For the period reviewed, we did not find any addendums that denoted reporting errors. In addition, system providers acknowledged abnormal laboratory results that were pertinent to the patient's treatment in a timely manner.

Recommendations

1. We recommended that the System Director ensure adequate consultation, formalized back up, and contingency plans for specialties with limited specialty provider availability.

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: December 21, 2015

From: Director, Rocky Mountain Network (10N19)

Subj: Healthcare Inspection—Quality of Care Concerns in the Management of a Hepatitis C Patient, Grand Junction Veterans Health Care System, Grand Junction, Colorado

To: Director, Denver Office of Healthcare Inspections (54DV)
Director, Management Review Service (VHA 10E1D MRS Action)

1. I reviewed and concur on the response to this Healthcare Inspection report of the Quality of Care Concerns in the Management of a Hepatitis C Patient for the Grand Junction VAMC. If you have any questions, please contact Ms. Ruth Hammond, Quality Management Specialist at (303) 639-7016.


Ralph T. Gigliotti, FACHE

System Director Comments

Department of Veterans Affairs

Memorandum

Date: December 18, 2015

From: Director, Grand Junction Veterans Health Care System (575/00)

Subj: Healthcare Inspection—Quality of Care Concerns in the Management of Hepatitis C Patient, Grand Junction Veterans Health Care System, Grand Junction, Colorado

To: Director, Rocky Mountain Network (10N19)

The Grand Junction Veterans Health Care System (GJVHCS) Director nonconcur with the substantiation of the allegation in Issue 1: Follow-Up Care (page 7) which states that the patient received inadequate follow-up care leading to further hospitalization.

We believe the review of encounters below supports appropriate clinical care was provided to this Veteran. The Veteran was receiving triple medication therapy for Hepatitis C and presented with signs/symptoms/complaints commonly associated with this treatment regime. When an acute change in the Veteran's condition occurred in []²⁴, 2014, appropriate action and changes in the plan of care were taken, including home nursing services. The Veteran's issues were appropriately addressed at each encounter, including medication adjustments, emergency room treatment and IV fluids, and hospitalization when appropriate.

Issue 1: Follow-Up Care

The GJVHCS Director nonconcur that the patient received inadequate follow-up care leading to further hospitalization.

In the middle of []²⁵, the Veteran had complaints of dizziness and increased fatigue. These symptoms can be attributed to multiple medical and organ disease processes. During this visit, the veteran described the symptoms as mild and self-remitting within a day of

²⁴ Specific date redacted pursuant to VHA Handbook 1605.1, *Privacy and Release of Information*. May 16, 2007.

²⁵ Ibid.

medication dosing. The Veteran's pharmaceutical therapy included PEGylated Interferon, [medication 1 and 2]. The Veteran's complaints are common side effects of the listed medications. At the end of []²⁶, the Veteran was contacted due to missing his lab appointment. He reported fatigue to the clinical pharmacist, which again was associated with medication. The Veteran anticipated, and ultimately completed requested lab work within two days of the requested date.

At the beginning of []²⁷, the Veteran complained to the clinical pharmacist that he was "sick as a dog". His care was immediately managed in the emergency room (ER) with coordinated input by the Hepatitis C Care Provider (HCCP). The Veteran reported 4-5 days of diarrhea. The evaluation included laboratory and diagnostic evaluation, which confirmed dehydration and diarrhea associated with Hepatitis C treatment. The plan of care included IV hydration and additional labs scheduled two days after discharge from the ER.

Within three days after the ER visit, the Veteran reported improving symptoms during a telephone contact which included ER and lab follow-up. Nevertheless, PEGylated Interferon was discontinued as of the last dose at the beginning of []²⁸ as the probable cause of the Veteran's recent symptoms. It was recommended to continue [medication 1 and 2] for a total of 24 weeks, which also met current guidelines.

When viewed in total, care from the middle of []²⁹ through early []³⁰ appropriately treated the known side effects of the triple medication therapy.

In mid to late []³¹, the Veteran reported a change, which included confusion. Appropriate work-up was completed and care was coordinated with the HCCP as well as interfacility specialist input. Recommended treatment included the addition of [medication 2].

²⁶ Specific date redacted pursuant to VHA Handbook 1605.1, *Privacy and Release of Information*. May 16, 2007.

²⁷ Ibid.

²⁸ Ibid.

²⁹ Ibid.

³⁰ Ibid.

³¹ Ibid.

The Veteran was monitored. [Medication 1] was discontinued at the end of []³². The Veteran was appropriately subsequently admitted for inpatient care and testing within one day of discontinuation of [medication 1].

Issue 2: Physician Qualifications

The GJVHCS Director concurs with the unsubstantiated findings.

Issue 3: Alleged Failure to Admit a Patient Earlier to the Hospital Based on Laboratory Results

The GJVHCS Director concurs with the unsubstantiated findings.

Recommendation

"We recommend that the Facility Director ensure formalized backup and contingency plans for specialties with limited specialty provider availability."

The GJVHCS Director concurs with the reported recommendation and currently incorporates formal eConsult, telehealth and face-to-face consult request options for such specialty care through our VISN tertiary VA sites after local primary care is initiated. Local community treatment options are available at the same time through formal Choice First requests.



Marc A. Magill, MS
Medical Center Director

³² Specific date redacted pursuant to VHA Handbook 1605.1, *Privacy and Release of Information*. May 16, 2007.

Comments to OIG's Report

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

OIG Recommendations

Recommendation 1. We recommended that the System Director ensure adequate consultation, formalized back up, and contingency plans for specialties with limited specialty provider availability.

Concur

Target date for completion: December 31, 2015.

Facility response: The GJVHCS Director concurs with the reported recommendation and currently incorporates formal eConsult, telehealth and face-to-face consult request options for such specialty care through our VISN tertiary VA sites after local primary care is initiated. Local community treatment options are available at the same time through formal Choice First requests.

OIG Contact and Staff Acknowledgments

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