Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Liver Transplant Denial
Veterans Health Administration

Report No. 11-03671-207 **June 27, 2012**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:
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Executive Summary

VA's Office of Inspector General was requested by Congressman John Kline to review why a veteran patient was "unable to receive a [liver] transplant through the VA system."

We found that the patient in question had chronic hepatitis C as well as serious comorbidities, including coronary artery disease that was treated in 2003 with placement of a coronary artery stent (a device inserted into a coronary artery to help keep it patent [open]).

Despite medical therapies, the patient's hepatitis C progressed inexorably. By 2011, it was clear that absent a remission or a liver transplant the patient's hepatitis C was progressive and would almost certainly soon be fatal. Minneapolis VAHCS embarked upon the process of having the patient evaluated for a liver transplant.

We found that, as alleged, the patient was indeed "unsuccessful in obtaining approval for a VA transplant." Two VA Transplant Centers (VATCs), Houston and Pittsburgh, reviewed the patient's case and did not accept the patient as a candidate for further evaluation. On appeal, Portland VATC also reviewed the patient's case, and also did not accept the patient as a candidate for further evaluation. Ultimately, in August 2011, the patient had a deceased donor orthotopic liver transplant at the University of Minnesota Medical Center.

We found that each of the three reviewing VATCs independently provided a decision based upon the clinical data presented and in a manner consistent with VHA policy. Nevertheless, we found and were concerned that Portland VATC—the reviewing VATC on appeal—lists the presence of a cardiac stent as one of five "absolute contraindications to liver transplantation." Two other VATCs, Nashville and Richmond, consider patients with cardiac stents for liver transplantation.

We concluded that when a patient has a condition regarded as an absolute contraindication at some but not all VATCs, the patient's case should be evaluated by VATCs that do not view the condition as an absolute contraindication.

We recommended that the Veterans Health Administration (VHA) consider whether or not changes to their review process should be made to address facility specific absolute contraindications to transplants.

Pursuant to OIG's recommendation, VHA considered if changes to the transplant review process should be made to address facility specific absolute contraindications to transplant. VHA's Under Secretary for Health wrote:

> VHA has decided to continue the referral process as currently designed. VHA developed the transplant referral process to emphasize clinical reviews by SMEs

[subject matter experts]. VHA's experience is that reviews are timely and provide each Veteran with individualized medical care. To begin to deny referral of packages prior to SME review would not provide this Veteran-centric medical care. VHA has decided that it is not the best practice for the VHACO [Veterans Health Administration Central Office] NTP [National Transplant Program] to review transplant referral packets and determine appropriateness for further transplant evaluation. Subject matter experts should make the clinical decisions on each individual case because each case is so unique that although a particular transplant center may have general contraindications, an individual case may merit consideration because of specific clinical information.

Contents

Introduction

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) was asked to review why a veteran patient was allegedly unable to receive a liver transplant through the Veterans Health Administration (VHA). The purpose of this inspection was to review that patient's care, the decision-making processes concerning the patient's suitability for a VHA-performed liver transplant, and to provide an overview of selected aspects of VHA's liver transplantation policies and guidelines.

Background

1. Allegations

VA's OIG was contacted by Congressman John Kline, who wrote,

> I draw your attention to the experiences of my constituent [patient named], a veteran working to obtain a liver transplant in the VA system. While [the patient] continues to be unsuccessful in obtaining approval for a VA transplant, he was deemed eligible through his private insurance for an immediate transplant, once available at a local medical center. I request that you investigate [the patient's] case as to why he was unable to receive a transplant through the VA system.

The patient was a patient of the Minneapolis VA Health Care System, which is anchored by Minneapolis VA Medical Center (the medical center). In his communication with the Congressman, the patient wrote "[I was] denied three times for liver transplant by three different [VA] transplant centers. I was given three different reasons. I am requesting a review of my transplant request by [a] higher authority."

2. Minneapolis VA Health Care System

The medical center is a 288-bed facility that provides primary and specialty healthcare in medicine, surgery, mental and behavioral health, physical medicine and rehabilitation, neurology, oncology, dentistry, geriatrics and extended care to veteran patients in the upper Midwest. In addition to its 288 inpatient beds, on an outpatient basis, the medical center most recently recorded 729,485 yearly outpatient visits.[1] It serves as the referral center for community-based outpatient clinics in Cook, Hibbing, Mankato, Maplewood, Ramsey, Rochester, and St. James, Minnesota; and Chippewa Falls, Hayward, Rice Lake, and Superior, Wisconsin. The medical center is part of Veterans Integrated Service Network 23. It has an active affiliation with the University of Minnesota Medical School and the University of Minnesota Dental School.

[1] Quality Management Data received electronically on 03/09/2012 from Minneapolis VAMC's Compliance Office.

3. Liver Transplantation

The liver is a vital organ, and in instances in which this organ is irreversibly damaged and no longer functional, liver transplantation may offer the only opportunity for survival. Patients may arrive at a state of liver failure and end-stage liver disease (ESLD) for which a liver transplant offers the only hope of survival through a wide variety of underlying diseases, including infectious diseases such as chronic hepatitis C, the underlying clinical condition in this case.

Over 6000 liver transplantations are performed yearly in the United States in 124 liver transplant centers,[2] five of which are operated by VHA within the following VA medical centers: Michael E. DeBakey VA Medical Center (Houston VAMC), Houston, Texas; Tennessee Valley Healthcare System (HCS), Nashville, Tennessee; VA Pittsburgh HCS, Pittsburgh, Pennsylvania; Portland VAMC, Portland, Oregon; and Hunter Holmes McGuire VAMC, Richmond, Virginia.

However, the demand for the procedure exceeds available resources. Keeffe reports that there is currently "a waiting list that has grown to approximately 16,000 patients."[3] In contrast to some other organ failures, such as kidney failure, in which temporizing measures such as dialysis are available, the technology does not presently exist in which an end-stage diseased liver may be removed and its functions performed mechanically (artificially) until a suitable donor becomes available.

A key issue in liver transplantation is patient selection for the operation. Transplant surgeons, institutions that perform liver transplants, and liver transplant programs, analyze candidates' suitability for liver transplantation. "Absolute" and "relative" contraindications to liver transplantation have been established. Absolute contraindications are those clinical or social situations that preclude a patient from being considered for the procedure, and may include cardiac (advanced and/or irreversible severe cardiopulmonary disease); pulmonary (advanced chronic obstructive pulmonary disease and pulmonary fibrosis); infectious (acute sepsis, serious chronic infection refractory to treatment, and acute pneumonia); metabolic (morbid obesity); anatomic (an abnormality of the patient's blood supply that would prevent a successful transplant); and psychosocial and/or psychiatric (active alcohol or substance abuse and documented poor compliance with medical care).[4,5]

Virtually any serious concurrent medical condition may be viewed as a potential or relative contraindication to liver transplantation depending upon the transplant surgeon and the institution performing the operation. However, many serious concurrent

[2] http://www.cincinnatitransplant.org/patient_choosing_center.htm [accessed 23/2/2012].
[3] Emmet B. Keeffe. *Goldman: Goldman's Cecil Medicine, 24th Ed.*
[4] Emmet B. Keeffe. *Goldman: Goldman's Cecil Medicine, 24th Ed.*
[5] Liver transplantation -- *Bope and Kellerman: Conn's Current Therapy. 2012, 1st Ed.*

conditions such as hepatorenal syndrome (progressive kidney failure accompanying liver cirrhosis[6]), chronic renal (kidney) failure, reversible acute renal failure, gastrointestinal bleeding, coronary artery disease, advanced age, human immune deficiency virus positivity, some extrahepatic (non-liver) cancers, and irreversible brain damage, require serious deliberation and meticulous evaluation, but are not absolute contraindications, but instead are relative contraindications to the procedure.[7,8] Furthermore, as technology advances, clinical conditions that may have once been absolute contraindications may become relative contraindications or not contraindications at all.

Liver transplant surgery involves significant institutional commitment. As well as transplant surgeons technically capable of performing the operation, an institution performing the procedure must have necessary laboratory, radiology, nursing, nutrition, and subspecialty services and infrastructure to successfully support a liver transplant program. Even under the best of circumstances, 1-year and 3-year survival rates after liver transplantation are approximately 90 percent and 80 percent, respectively.[9]

A key variable in assessing patients during the course of severe liver disease is the Model for End Stage Liver Disease (MELD) score. This value is derived from the patient's laboratory tests of liver and kidney function including the bilirubin, international normalized ratio (INR) (a test of blood clotting), and creatinine (a test of kidney function).[10] The MELD score is a good 3-month prognosticator of mortality from liver disease, with higher scores predictive of higher 3-month mortality. They are used to clinically follow patients with severe liver disease and by the United Network for Organ Sharing (UNOS)[11] for prioritizing allocation of liver transplants. MELD scores typically range from 6 to 40. MELD scores should be recalculated on an ongoing basis, as the underlying tests used to calculate them (bilirubin, INR, and creatinine) change with improving or deteriorating liver and kidney condition.[12,13,14] The MELD scores at which liver transplants are performed vary between centers performing liver transplantation. The United States national average MELD score for liver transplantation is 22.[15]

[6] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001519/ [accessed 3/4/2012].
[7] Emmet B. Keeffe. *Goldman: Goldman's Cecil Medicine, 24th Ed.*
[8] Liver transplantation -- *Bope and Kellerman: Conn's Current Therapy. 2012, 1st Ed.*
[9] Emmet B. Keeffe. *Goldman: Goldman's Cecil Medicine, 24th Ed.*
[10] Formula as follows: MELD Score = (0.957 * ln(Serum Cr) + 0.378 * ln(Serum Bilirubin) + 1.120 * ln(INR) + 0.643) * 10 (if hemodialysis, value for Creatinine is automatically set to 4.0). See http://www.gastrotraining.com/calculators/meld [accessed 3/4/2012].
[11] United Network of Organ Sharing is a private, non-profit organization that manages the nation's organ transplant system under contract with the federal government.
[12] http://www.mylivercanceroptions.com/mylivercanceroptions/pages.aspx?page=About/LiverCancer [accessed 3/4/2012].
[13] http://www.eurotransplant.org/cms/index.php?page=public_meld [accessed 3/4/2012].
[14] http://www.gastrotraining.com/calculators/meld [accessed 3/4/2012].
[15] http://www.hcvadvocate.org/hcsp/articles/Multiple_listing.html [accessed 3/2/2012]

A more detailed discussion of liver transplantation is beyond the scope of this report. However, many of the issues discussed above, including the concept of absolute versus relative contraindication to the procedure, tracking MELD scores, and institutional ease with performing the procedure enter into this case.

4. Liver Transplantation in the Veterans Health Administration

VHA operates a National Transplant Program (NTP). In 1961, it performed its first kidney transplant and its first liver transplant was performed in 1989. In Fiscal Year 2011, VHA performed 100 liver transplants at the five VA Transplant Centers (VATCs). Each VHA VATC program is highly affiliated with a medical school, including the Baylor College of Medicine (Houston VAMC); Vanderbilt University School of Medicine (Nashville VAMC); University of Pittsburgh School of Medicine (Pittsburgh VAMC); Oregon Health and Sciences University (Portland VAMC); and Virginia Commonwealth University (Richmond VAMC).

VHA's National Surgery Office (NSO) has an established transplant referral process that attempts to facilitate the referral of a patient from a referring VAMC to a VATC. The request for an organ transplant originates from the primary VAMC where a patient is receiving his or her care (Minneapolis VAMC in the case for this inspection). The VATC is responsible for making a timely decision regarding whether or not the patient referred for transplant services is eligible for further evaluation based upon a VATC expert's review.

The referring VAMC prepares an exhaustive "Liver Transplant Evaluation Packet." If the patient is determined to be a candidate for liver transplantation, the reviewing VATC notifies the patient and the referring VAMC of the decision and plan of care. All approved candidates are evaluated in person at the accepting VATC.

An accepted candidate is listed in the UNOS system and placed on a waiting list for a liver transplant. UNOS manages the national transplant waiting list, maintaining the database that contains organ transplant data, matches donors to recipients, and monitoring organ allocation policies. In 2002, UNOS developed the system for prioritizing candidates waiting for liver transplants based on the MELD score discussed above.[16,17,18]

If a candidate is not accepted, the NTP office notifies the referring VAMC of the denial. The name, decision, and comments of the VATC reviewers are submitted electronically to the referring VAMC provider.

[16]http://www.mylivercanceroptions.com/mylivercanceroptions/pages.aspx?page=About/LiverCancer [accessed 3/4/2012].
[17] http://www.eurotransplant.org/cms/index.php?page=public_meld [accessed 3/4/2012].
[18] http://www.gastrotraining.com/calculators/meld [accessed 3/4/2012].

In July 2011, the NSO established a process by which the name, decision, and comments of the VATC reviewer are sent electronically to the VA referring provider. In addition, a VATC point of contact is continuously available for telephone consultation. [19]

Scope and Methodology

We reviewed the care of the patient at the medical center, the course of his liver and other diseases that ultimately placed him in ESLD, and the process by which he was evaluated for liver transplantation by VHA's liver transplant program.

We reviewed VHA's Organ Transplants policy, its National Liver Transplant Guide, relevant VHA directives, and the criteria of the three VHA VATCs that reviewed the patient's case (Houston VAMC, Pittsburgh HCS, and Portland VAMC). We reviewed both policies used to review this patient's case as well as updated VHA policies. We interviewed senior transplant staff from each of these VHA referral institutions.

In August 2011, the patient had a deceased donor orthotopic liver transplant[20] at the University of Minnesota Medical Center (UMMC). We interviewed the transplant surgeon and liver transplant coordinator at that institution. We reviewed VHA and UMMC medical records.

We also interviewed VHA's NTP and senior surgical leaders, including VHA's National Director of Surgery.

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.

Results and Conclusions

Case Summary

The patient is a 59-year-old man who is Service-Connected for cirrhosis of liver and who received extensive care at the medical center for multiple medical conditions.

Specific to his liver disease, the patient had chronic hepatitis C, genotype 2a.[21] He underwent multiple liver biopsies at the medical center which showed G3, S3 disease.[22]

He was followed closely by the medical center's Internal Medicine, Gastroenterology, and Hepatology Clinics, and additionally, went to other medical center clinics as the need

[19] Ibid.
[20] Orthotopic refers to placement of the donor liver in the same anatomic location as the patient's removed liver.
[21] Hepatitis C virus is found with several different genetic structures. Identification of the type, e.g., in this case 2a, may provide prognostic information related to drug treatment of the virus.
[22] G3, S3 refers to the grade and stage of the patient's hepatitis C disease

arose. In the course of the monitoring and treating the patient's chronic hepatitis C, he underwent several courses of antiviral chemotherapy. In 1994, he was treated with interferon monotherapy for 6 months but was a nonresponder. In the 1999-2000 time period, he was treated with Rebetron™, a combination drug regimen containing both an antiviral component (ribavirin) and an immune system modulator (recombinant interferon alpha-2b) but relapsed.

In addition to liver disease, the patient also suffered from coronary artery disease (CAD), diastolic dysfunction, and hypertension and in August 2003, he underwent percutaneous intervention with percutaneous transluminal coronary angioplasty and placement of a single coronary artery stent. In addition to his CAD, the patient subsequently developed congestive heart failure due to diastolic dysfunction.

The patient's other medical issues included musculoskeletal and neurologic problems including cervical spondylosis, cervical radiculopathy, ulnar nerve lesion, and carpal tunnel syndrome; sleep apnea; hypoglycemia; hyperplasic colon polyps; and right inguinal hernia.

Until 2010, the patient was generally stable from the point of view of his liver disease. In late 2010, the patient's medical records describe worsening ascites and "worsening HCV cirrhosis." Mental status concerns were identified such as falling asleep at work, generalized fatigue and "fogginess."

The patient's MELD score was recorded as 11 in October 2010, and was referred to in that note as his "baseline" MELD score. The MELD score was also recorded at 12 and 13 in November and December 2010, respectively. The nurse practitioner following the patient raised the issue of liver transplantation, noting, for example, in late December 2010, "MELD 13, up from 11 in October; briefly discussed liver transplant criteria; MELD not high enough at this time."

The patient was admitted to the medical center in early March 2011, after presenting with mental status changes. It was felt that the patient had acute mental status changes most likely due to hepatic encephalopathy precipitated by dehydration. Also, the medical record noted indications of renal insufficiency, in that the patient's creatinine level had risen to 2.7 milligrams/deciliter (mg/dL) (normal = 0.7 to 1.3 mg/dL for men). This value improved with intravenous fluids and came down to 1.8 mg/dL. Overall, it was felt that the patient had ESLD.

In late February, 2011, the patient began an evaluation for a liver transplant, which included diagnostic tests, and medical, mental health, and psychosocial evaluations.

Four days later, the patient was again hospitalized at the medical center. While the patient had demonstrated improvements at the time of discharge from the medical center four days earlier, he "never came back to his baseline mental status." He later was taken

to the medical center's Emergency Room (ER) after being found in an obtunded state. In the ER, the patient was combative, and laboratory tests revealed an elevated blood ammonia level at 233 (normal = 35 to 65 mcg/dL).[23] The patient's creatinine was also elevated at 2.0 mg/dL. Dehydration again appeared to play a large role in the exacerbation of the patient's liver and kidney failure. After several days of treatment, the patient was discharged from the medical center in mid-March.

The patient was again hospitalized at the medical center in April 2011, for continued complications of his ESLD. He had altered mental status, ascites (fluid in the abdomen) refractory to diuretics, and renal insufficiency. His MELD Score was 20.

Despite discharge in April 2011, the patient was re-admitted to the medical center that same day due to altered mental status. At this time, he had a clinical picture consistent with an *Escherichia coli* urinary tract infection (UTI). The patient was treated and discharged. However, in early May , the patient was again hospitalized at the medical center for continued complications of ESLD. His principal diagnoses included decompensated cirrhosis, acute and chronic renal failure requiring dialysis, coagulopathy (failure of the blood to clot properly) due to acute liver failure, UTI, pulmonary edema causing respiratory failure, anemia (low red blood cell counts), and thrombocytopenia (low platelet counts). The Nephrology Service evaluated the patient and concluded that the patient's renal dysfunction was an indication of hepatorenal syndrome. After treatment, the patient was discharged from the medical center twelve days later.

In early May, the patient's MELD Score had increased to 26. As a result, the medical center submitted an electronic referral to VHA's NTP Office requesting the patient be placed on the liver transplant list. The patient's preference was the Houston VATC because he had family support in Houston. The NTP Office asked the Pittsburgh VAMC to review the request for transplant. VHA's Pittsburgh VAMC's VATC denied the request citing that the request was a clinically late referral, the veteran was in kidney failure on dialysis, and that he had significant cardiovascular disease. Meanwhile, Houston VAMC VATC's reviewer indicated that the patient was a candidate for further evaluation at a VATC. However, the reviewer's concerns were that due to the patient's current renal insufficiency requiring hemodialysis that he should be assigned to a transplant center where an option for simultaneous liver-kidney transplantation is available in case it is needed.

Later in May, Portland VAMC's VATC was asked to evaluate the patient because his clinical status had further deteriorated and his MELD Score had increased to 35. Two days later, Portland VAMC's VATC denied the patient's transplant request citing the patient's

[23] Elevated blood ammonia may be present in severe liver disease. It is associated with mental status changes.

cardiovascular disease, specifically the presence of a cardiac stent, as making him ineligible for liver transplantation at that institution.

Ten days later, the patient was evaluated for a liver transplant at UMMC. The evaluating surgeon took note of the patient's ischemic cardiac disease and renal failure. Nevertheless, he wrote in his evaluation note, "I think he is a good candidate from the surgical point of view if cleared by Cardiology."

The patient was hospitalized at UMMC in July. During the patient's July UMMC hospitalization his medical records revealed similar diagnoses and conditions that characterized his multiple medical center admissions, including hepatic encephalopathy, ESLD due to hepatitis C, ascites refractory to diuretic (fluid reducing) treatment, coagulopathy due to ESLD, acute and chronic renal failure, anemia of chronic disease, and esophageal varices (swollen veins). The patient was treated with therapeutic paracenteses (procedures to remove excess fluid from the abdomen), blood transfusions, lactulose, hydration, vitamin K, and cryoprecipitate (a protein that promotes blood clotting). He had a nasogastric tube placed for nutrition. After stabilization, the patient was transferred back to the medical center in late July, to await availability of a donor liver.

The patient thereafter was admitted to the medical center's Community Living Center (CLC) , to await availability of a donor liver. While at the CLC, the patient had a stormy course with increasing confusion, increasing abdominal girth that required paracentesis, and worsening renal failure. In early August , the patient was transferred to the intensive care unit (ICU). Four days later, a donor liver became available at UMMC, and the patient was transferred to UMMC for transplantation.

The patient was readmitted to UMMC the following day, at which time he underwent a deceased donor orthotopic liver transplant.

Postoperatively and over the ensuing months of 2011, the patient had a stormy course complicated by intraabdominal bleeding which required an exploratory laparotomy (surgical opening of the abdomen); recurrent fevers and rising liver function tests indicative of possible cell damage to his newly transplanted liver; a stricture (narrowing) of the common hepatic duct at the anastomotic site (where the transplanted liver was attached to the patient's body); anemia requiring blood transfusions, right leg thrombus (blood clot); electrolyte imbalance; cholangitis (inflammation of the bile ducts) with a biliary stricture was found in the post-transplant donor duct; acute renal failure; and SPB. These problems were all treated with varying degrees of resolution.

The patient continues to be followed by both the medical center and UMMC.

Issue 1: Quality of Care

We found that the patient's medical record reflected exhaustive and comprehensive care of the patient rendered over a period of many years. The patient was followed for numerous acute and chronic medical conditions by numerous and appropriate specialty and subspecialty clinics.

The patient's baseline MELD score was recorded at 11 in October 2010. It was recorded at 12 and 13 in November and December 2010. The nurse practitioner following the patient raised the issue of liver transplantation, noting, for example, in late December 2010, "MELD 13, up from 11 in October; briefly discussed liver transplant criteria; MELD not high enough at this time." Caregivers we interviewed at the medical center described the patient as deteriorating very rapidly in the first half of 2011.

We identified no problems with treatment as prescribed and administered.

Issue 2: Denial of Liver Transplantation by Two VHA Referral Centers

We substantiated that the patient was "unsuccessful in obtaining approval for a VA transplant."

Two VATCs, Houston and Pittsburgh, reviewed the patient's case.

The Houston VATC identified the Veteran as high risk due to a number of comorbidities including coronary artery disease and renal insufficiency. The Houston VATC did not accept the Veteran as a candidate for further evaluation on the basis of the patient's renal insufficiency requiring dialysis, commenting that, "we would not be able to offer simultaneous liver/kidney transplantation and recommend assignment to Portland or Pittsburgh VATC."[24]

Pittsburgh VATC reviewed the case and responded that the patient was not eligible for further liver transplant evaluation due to the comorbid conditions including renal failure on dialysis, coronary disease, and pulmonary edema.[25]

Portland VAMC reviewed the patient's packet. The Portland VATC did not accept the patient as a candidate for further evaluation on the basis of the presence of his cardiac stent. This was confirmed in our interview with Portland VATC staff. An Oregon Health & Science University (OHSU) document entitled "Clinical Transplant Services"

[24] VHA Preliminary Comments in Response to Draft Report: Healthcare Inspection, VHA Denial of Liver Transplant. Transmitted to OIG on April 10, 2012.
[25] Ibid.

was provided to OHI from Portland VATC, attributed to the OHSU Liver Transplant Program Protocol Handbook:

Absolute Contraindications to Liver Transplantation

A. Active sepsis outside the biliary tract.
B. *Cardiac stents of any kind* [OHI emphasis]
C. Presence of significant organ system failure other than liver, kidney except in the setting of fulminant hepatic failure.
D. HIV-positive state.
E. Active alcoholism or active substance abuse, including nicotine.
F. Inability to accept the procedure, understand its nature and cooperate in the medical care required following transplantation. [26]

Conclusions and Discussion

We did not assess the clinical judgment of the patient's status and suitability for transplant. Three VATCs independently provided a decision regarding the patient's eligibility for further liver transplant evaluation based upon the clinical data.

However, we were concerned that the patient's package was sent to the Portland VATC for evaluation for liver transplantation even though that VATC lists as an "Absolute Contraindications to Liver Transplantation" "cardiac stents of any kind." Of note is that two other VATCs, Nashville and Richmond, will consider for liver transplantation, patients with cardiac stents.

In August 2011,the patient described in this report had a deceased donor orthotopic liver transplant at UMMC. However, future VHA patients may find themselves in this patient's situation, namely with a condition considered an absolute contraindication to a transplant at one or more VATCs that other VATCs do not regard as an absolute contraindication. We believe the patient's case should be evaluated by VATCs that do not view the condition as an absolute contraindication. We concluded that this issue is worthy of further consideration.

Recommendation

VHA should consider if changes to their transplant review process should be made to address facility specific absolute contraindications to transplant.

[26] Pages 25-26. Stated: "created on 1/9/2008 Revised 8/6/2009 Revised 2/9/2010 Revised 9/22/2011

Comments

VHA's Under Secretary for Health's comments, which are attached in Appendix A, meet the intention of OIG's recommendation.

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

Appendix A

Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: June 6, 2012

From: Under Secretary for Health (10)

Subject: **Healthcare Inspection – VHA's Liver Transplant Program and Denial of a Liver Transplant Referral for a Veteran, Minneapolis VA Health Care System, Minneapolis, MN**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and want to comment on the report findings and recommendation.

2. The Executive Summary of the report indicates:

   When a patient has a condition regarded as an absolute contraindication at some but not all VATCs, we believe the patient's case should be evaluated by VATCs that do not view the condition as an absolute contraindication.

   And, the Office of the Inspector General (OIG) recommends:

   VHA should consider if changes to their transplant review process should be made to address facility specific absolute contraindications to transplant.

   The current Veterans Health Administration (VHA) process requires the VHA Central Office (CO) National Transplant Program (NTP) to refer transplant referral packets to Department of Veterans Affairs Transplant Center (VATC) specialty specific subject matter experts (SME) who work in VA Medical Centers (VAMC). These VATC SMEs review the transplant referral packet in a timely manner and determine whether further VATC evaluation is appropriate and warranted based upon the available clinical and psychosocial information for each individual Veteran. The VATC does not determine if a patient is

Appendix A

Under Secretary for Health Comments

determined to be a candidate for liver transplantation based upon initial transplant referral packet review.

For the case involved in this review, the referring VAMC submitted a liver transplant referral packet and requested a review by the Houston VATC. Upon Houston VATC's denial for further patient evaluation and the Houston VATC recommendation, the NTP directed the patient's liver transplant referral to Pittsburgh VATC and Portland VATC. All three VATCs denied the patient further liver transplant evaluation based upon an assessment of the clinical and psychosocial information related to an individual Veteran.

VHA has considered the OIG recommendation to consider if changes to the transplant review process should be made to address facility specific absolute contraindications to transplant. After this consideration, VHA has decided to continue the referral process as currently designed. VHA developed the transplant referral process to emphasize clinical reviews by SMEs. VHA's experience is that reviews are timely and provide each Veteran with individualized medical care. To begin to deny referral of packages prior to SME review would not provide this Veteran-centric medical care. VHA has decided that it is not the best practice for the VHACO NTP to review transplant referral packets and determine appropriateness for further transplant evaluation. Subject matter experts should make the clinical decisions on each individual case because each case is so unique that although a particular transplant center may have general contraindications, an individual case may merit consideration because of specific clinical information.

3. Thank you for the opportunity to review the draft report. Attached are additional technical comments. If you have any questions, please contact Linda H. Lutes, Director, Management Review Service (10A4A4) at (202) 461-7014.

//signed//
Robert A. Petzel, M.D.

Attachment

Appendix B

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	Wachita Haywood, RN, Project Leader Verena Briley-Hudson, ARNP, MN Roberta Thompson, LCSW Laura Spottiswood, RN, MPH George Wesley, MD Judy Brown, Program Support Assistant

Appendix C

Report Distribution

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