Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 15-00187-25

Healthcare Inspection

Alleged Program Inefficiencies and Delayed Care Veterans Health Administration's National Transplant Program

November 5, 2015

Washington, DC 20420

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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 regarding how referrals for liver transplantation were processed by the Houston VA Transplant Center (VATC) as well as timeliness of care for patients referred for liver transplant evaluations at all VATCs.

In early 2013, the VA OIG Hotline Division received a complaint alleging inefficiencies in how referrals for liver transplantation were processed by the Houston VATC. In particular, the complainant alleged that the VATC determined it was unable to review a patient referral due to missing or unclear checklist information and, because the referral information was subsequently "discarded," the referring facility had to duplicate work to resubmit the referral. Staff from the OIG Hotline Division followed up with the complainant to obtain information to identify the patient, but the complainant did not provide the requested information.

In May 2014, the same complainant contacted the VA OIG Hotline Division and alleged that patients referred for transplantation at VATCs experienced delayed care. The complainant also raised policy concerns regarding the extent of referrals to community providers and the extent to which living donor transplants are provided at VATCs. In absence of specific allegations of wrongdoing or patient harm, we determined that these concerns pertained to decisions that must be made by VHA in conjunction with congressional oversight bodies and were outside the scope of this review.

We substantiated that three stable patients referred to the Houston VATC for liver transplant evaluations were referred more than once because information was missing or additional information was needed related to the initial referrals. Those three patients represent about 2 percent of patients referred to the Houston VATC for liver transplant evaluation from January 1, 2013, through December 31, 2014. Each of these patients was initially referred to the Houston VATC in 2013 and was classified as a stable patient. We did not find that the Houston VATC's practice of requiring referring facilities to resubmit referrals for a small number of patients represented a noteworthy program inefficiency.

We substantiated that some patients referred for liver transplant evaluations at all VATCs experienced delays. We estimated that 6.9 percent of emergency referrals were not responded to in VHA's electronic transplant referral system within 48 hours, as required (95 percent confidence interval (CI): 1.67–24.42). Among stable patient referrals, we estimated that 9.6 percent of referrals were not responded to in VHA's electronic transplant referral system within 5 business days, as required (95 percent CI: 6.36–14.28). About half of stable patients who were deemed eligible for further evaluation did not receive an initial patient evaluation within 30 days, as required.

While reviewing our sampled referrals, we identified several types of transplant referral data inaccuracies. These inaccuracies are problematic because the Veterans Health Administration's National Surgery Office (NSO) uses those data to inform its oversight of VATCs, including its quarterly reports that indicate whether timeliness standards are

being met. After we alerted VHA to these issues, the NSO took steps to resolve ongoing data inaccuracies.

We recommended that the Under Secretary for Health review the extent of delays in responses to referrals for transplant evaluations and delays in initial patient evaluations for transplantation, assess the risks posed by those delays, and take appropriate actions to ensure timely responses. We also recommended that the Under Secretary for Health take action to confirm that any patients who experienced delayed care that presented risks received care.

Comments

The Under Secretary for Health concurred with our recommendations and provided an acceptable action plan. (See Appendix A, pages 12–16 for the Under Secretary for Health's 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

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 regarding how referrals for liver transplantation were processed by the Houston VA Transplant Center (VATC) as well as timeliness of care for patients referred for liver transplant evaluation at all VATCs.

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In May 2014, the same complainant contacted the VA OIG Hotline Division and alleged that patients referred for transplantation at VATCs experienced delayed care. The complainant also raised policy concerns regarding the extent of referrals to community providers and the extent to which living donor transplants are provided at VATCs. In absence of specific allegations of wrongdoing or patient harm, we determined that these concerns pertained to decisions that must be made by the Veterans Health Administration (VHA) in conjunction with congressional oversight bodies and were outside the scope of this review.

Background

Liver Transplantation

The liver is a vital organ, and in instances when this organ is irreversibly damaged and no longer functional, liver transplantation may offer the only opportunity for survival. A range of diseases can lead to liver failure and the need for a liver transplant, including infectious diseases such as hepatitis C.

In 2013, 5,921 liver transplants were performed in adults across 139 liver transplant centers in the United States, according to the 2013 annual report by the Scientific Registry of Transplant Recipients.[1] As of December 31, 2013, 12,407 people were waiting for liver transplants. Because demand for liver transplantation exceeds the supply of organs, a process has been established to prioritize patients by the United Network for Organ Sharing (UNOS) under contract with the federal government. Among adult patients deemed eligible by a transplant center, a key variable in assessing adult patients during the course of severe liver disease is the Model for End

[1] The Scientific Registry for Transplant Recipients publishes annual reports with information on transplantation across the country. 2013 is the most recent available annual report. See OPTN/SRTR 2013 Annual Data Report: Liver. *American Journal of Transplantation, Vol. 15,* No. *Suppl 2,* January 2015, pp. 1–28.

Stage Liver Disease (MELD) score.[2] A patient's MELD score is derived from laboratory tests of liver and kidney function and typically ranges from 6 to 40, with higher scores reflecting more severe illness.[3] The only priority exception to MELD for adult patients are those with severe and sudden onset liver failure and a life expectancy of hours to a few days without a transplant (referred to as Status 1A).

Liver Transplantation at VA Medical Facilities

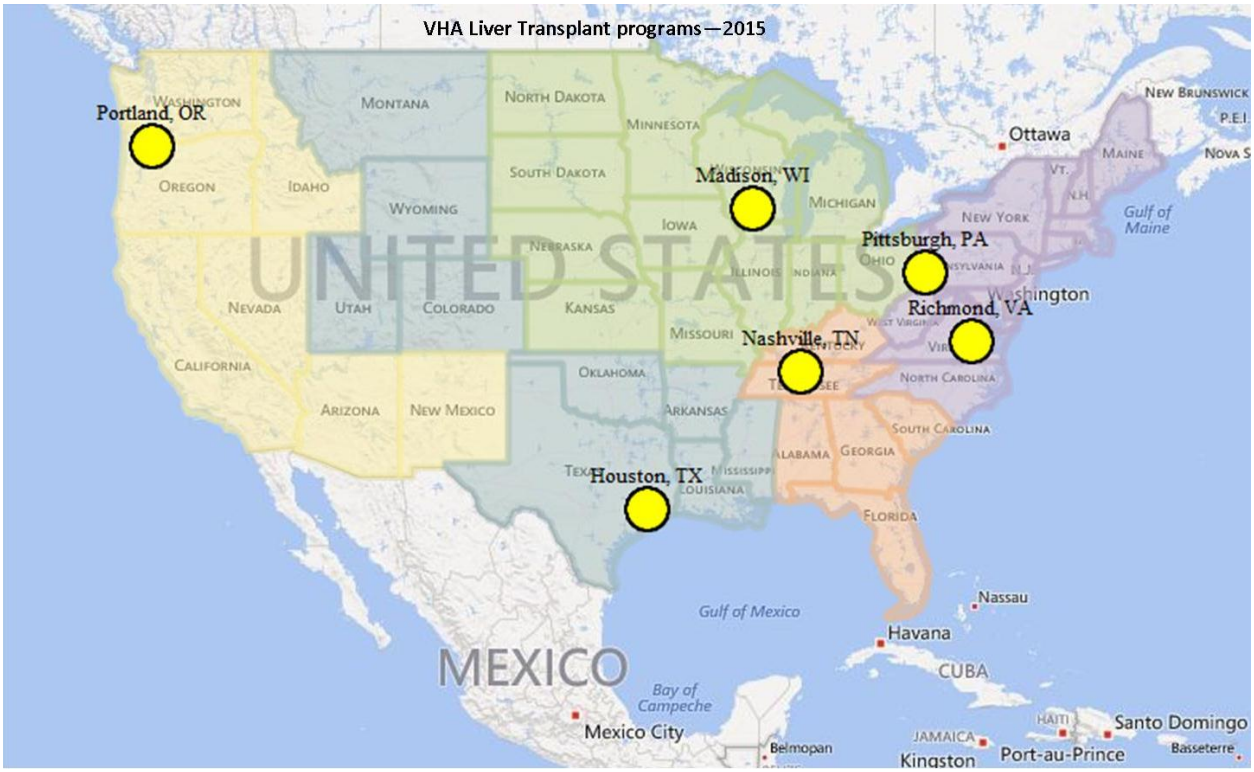
The Veterans Health Administration (VHA) provides liver transplantation at six medical facilities that operate VATCs. The locations of these VATCs are presented in figure 1.

- Michael E. DeBakey VA Medical Center, Houston, TX (Houston VATC)
- William S. Middleton Memorial Veterans Hospital, Madison, WI (Madison VATC)
- Tennessee Valley Healthcare System (HCS), Nashville, TN (Nashville VATC)
- VA Pittsburgh HCS, Pittsburgh, PA (Pittsburgh VATC)
- Portland VAMC, Portland, OR (Portland VATC)
- Hunter Holmes McGuire VAMC, Richmond, VA (Richmond VATC)

[2] Members of transplant teams, including transplant surgeons, and the institutions that perform liver transplants analyze candidates' suitability for liver transplantation. Judgments about suitability for liver transplantation reflect many factors, including, but not limited to, patients' clinical and psychosocial characteristics, and infrastructure at the transplant center.

[3] MELD scores are calculated by a formula using the following lab test results: bilirubin, prothrombin time (INR), and creatinine.

Figure 1. Locations of VA Transplant Centers



Source: VHA National Surgery Office.

In calendar year 2014, 252 patients were added to the waitlist for liver transplantation and 120 patients received liver transplants through VATCs, according to a report published by the VHA National Surgery Office.[4] Each VATC is affiliated with a medical school and university hospital, and for 3 VATCs, liver transplant surgeries and initial post-operative care are provided at the affiliated hospitals rather than the VA medical centers.[5] VHA also provides pre and post-transplant care to patients who received transplants through non-VA facilities.

[4] VHA National Surgery Office. *Q1 FY15 VA National Surgery Office Transplant Program Quarterly Report.* [Note: This report is not accessible from VA's public website.]

[5] The academic affiliations for VATCs that offer liver transplantation are as follows: Houston VATC and Baylor University, Madison VATC and University of Wisconsin-Madison, Nashville VATC and Vanderbilt University, Pittsburgh VATC and University of Pittsburgh, Portland VATC and Oregon Health Sciences University, and Richmond VATC and Virginia Commonwealth University.

Referrals to VATCs

In order to refer a patient to a VATC for transplant evaluation, a provider at the patient's primary medical center should generally take the following steps:

- Complete laboratory and other testing and a standardized assessment.[6]
- Enter a clinical note using the "VACO Transplant Referral" template into the patient's electronic health record (EHR).
- Gather supplemental documents, as applicable.
- Select a specific VATC and submit the referral and any supplemental documents using VHA's electronic transplant referral system (TRACER).

VHA policy identifies timeliness standards for reviewing and responding to referrals and completed initial patient applications, when applicable.[7] For stable patients, the selected VATC is expected to review the information and enter a decision regarding eligibility for further evaluation within 5 business days. For eligible patients, initial evaluations by the VATC should be completed within 30 calendar days of referral submission. These evaluations may be completed in-person or via telehealth if a signed telehealth agreement is in place between the VATC and the referring facility. For emergency cases, VHA established an expedited referral process that includes direct communication with the VATC and submission of some information into TRACER.

Funding for Transplant-Related Costs for Patients Referred to VATCs

VHA policy provides for reimbursement to the patient and a support person for all transplant-related round-trip travel costs for the pre-transplant evaluation, transplant episode, and post-transplant follow-up. VHA provides special purpose funding to VATCs for reimbursement for transplant procedures that are performed through the VATCs.

Scope and Methodology

The period of review was October 2014, through June 2015. The steps we took related to each allegation are described below.

Allegation 1: Alleged Program Inefficiencies at the Houston VATC

Scope. The study population consisted of all referrals to the Houston VATC for liver transplant evaluation from January 1, 2013, through December 31, 2014.

Methodology. We interviewed the complainant, providers from three judgmentally selected VA facilities that referred patients to the Houston VATC for liver transplant evaluation, and the National Director of Surgery. We conducted a site visit to the Charles E. DeBakey VA Medical Center in Houston, Texas, November 12–14, 2014,

[6] The VA National Surgery Office established checklists containing the specific tests and assessments that should be completed prior to submitting referrals for transplantation.
[7] VHA Directive 2012-018, *Solid Organ and Bone Marrow Transplantation*, July 9, 2012.

during which we interviewed providers from the Houston VATC. We reviewed TRACER records to identify patients for whom the VATC was unable to determine eligibility for further evaluation because the initial referral contained missing or unclear information and the referring VA submitted at least one additional referral to the VATC.[8] For those patients, we compiled information from TRACER and EHRs on:

- the total number of referrals (two or more),
- the amount of time between referrals,
- the disposition of the referrals, and
- whether the patients were subsequently added to the UNOS waitlist for a liver transplant.

Allegation 2: Delayed Responses to Transplant Referrals and Patient Evaluations

Scope. The study population consisted of all referrals to any VATC for liver transplant evaluation, from January 1, 2013, through December 31, 2014. As a result, this review provides a case study on the extent of delays in VHA's liver transplant program and may not be representative of the extent of delays for other organ transplants.

Methodology. We interviewed the National Director of Surgery and providers from the six VATCs that offer liver transplants. We reviewed relevant documents, including NSO oversight reports, relevant VHA policies and procedures, and reports produced by UNOS and the Scientific Registry for Transplant Recipients. We also evaluated information from patients' EHRs and TRACER records. Certain factors that may have contributed timeliness of responses to referrals and initial patient evaluations, such as the adequacy of staffing, were outside the scope of our review.

We sampled referrals from our study population for case reviews. For 5 of 6 VATCs, we selected a random sample of 60 referrals from each center. For the remaining VATC, we included all referrals in our review because that center had fewer than 60 referrals.

We reviewed the TRACER records for the sampled referrals to identify the following information for each referral.

- Date and time that the referral was submitted by the referring facility
- Whether the referral was an emergency referral
- Date and time the VATC responded to the referral
- Disposition of the referral
- Whether the VATC determined that the referred patient was eligible for further evaluation by the VATC

[8] TRACER contains records that were submitted using that system as well as those submitted using another system and migrated to TRACER.

- Date of initial patient evaluation
- Whether the initial patient evaluation was completed via telehealth

We reviewed information in referred patients' EHRs to identify the dates of initial patient evaluations and whether the initial patient evaluations were completed via telehealth.

Statistical Analysis.

We estimated the following, taking into account our sampling design:

- For emergency patient referrals, the percentage of referrals that the VATC responded to within 48 hours.
- For stable patient referrals, the percentage for which the VATC responded regarding eligibility for further evaluation within 5 business days.
- For both emergency and stable patient referrals, the percentage of referrals that had inconsistent referral submission dates listed within TRACER. In particular, we estimated the percentage of referrals for which the submission date in the main dashboard did not match the submission date listed within the more detailed TRACER record. If the dates did not match, we used the date listed in the more detailed record for our analysis.
- For referrals for stable patients who were eligible for further evaluation, the percentage that pertained to patients who were (a) evaluated before the referral was submitted, (b) evaluated within 30 days of referral submission, (c) evaluated more than 30 days after referral submission, and (d) not evaluated. For these referrals, we also estimated the percentage for which the date of the initial patient evaluation listed in TRACER matched the date listed in the EHR.

We presented 95 percent confidence intervals (95 percent CI) for the estimates of the true values (parameters) of the study population. A confidence interval gives an estimated range of values (being calculated from a given set of sample data) that is likely to include an unknown population parameter. The 95 percent CI indicates that among all possible samples we could have selected of the same size and design, 95 percent of the time the population parameter would have been included in the computed intervals. These data analyses were performed using SAS statistical software, version 9.3 (TS1M0), SAS Institute, Inc. (Cary, North Carolina).

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.

Inspection Results

Issue 1: Alleged Program Inefficiencies at the Houston VATC

We substantiated that three patients referred to the Houston VATC for liver transplant evaluation were referred more than once because information was missing or additional information was needed related to the initial referral. The three patients represent about 2 percent of patients referred to the Houston VATC for liver transplant evaluation, from January 1, 2013, through December 31, 2014. Each of these patients was initially referred to the Houston VATC in 2013 and was classified as a stable patient.

- For two of the patients, the referring facilities collected the additional information and resubmitted the referrals within 2–3 weeks.
    - In response to the second referrals, both patients were determined to be eligible for further evaluation at the VATC.
    - Subsequently, one patient was placed on the UNOS waitlist for a liver transplant, and the other was declined for liver transplantation because the patient did not meet clinical criteria.
- For the third patient, over a 2 month period, the referring facility resubmitted the referral three times.
    - In response to the first two resubmissions, the Houston VATC concluded that the patient's eligibility still could not be determined because the additional information provided was confusing or unclear and did not specifically answer the questions raised in response to the initial referral.
    - Both times, the Houston VATC clarified the information that was being requested and provided contact information in case the referring facility had questions. In response to the third resubmission, the Houston VATC determined that the patient was eligible for further evaluation at the VATC. Subsequently, the patient was declined for liver transplantation because the patient did not meet clinical criteria.

We did not find that the Houston VATC's practice of requiring referring facilities to resubmit referrals for a small number of stable patients represented a noteworthy program inefficiency. We determined that VHA's National Transplant Program provides organ-specific checklists to referring facilities and indicates that referrals for stable patients must be complete. Clear and complete referral information is important because it enables the VATC to more effectively screen and triage patients. When the Houston VATC concluded that a small number of referrals contained missing or unclear information, it was reasonable to coordinate timely with referring facilities to obtain the needed information to determine whether further evaluation was appropriate. In addition, providers from the Houston VATC and selected referring facilities described ongoing efforts of the VATC staff to meet with transplant coordinators from referring facilities to strengthen working relationships and provide additional education on the transplant evaluation process.

Issue 2: Delayed Responses to Transplant Referrals and Patient Evaluations

We substantiated that some patients referred for liver transplant evaluation at VATCs experienced delays. We estimated that 6.9 percent of emergency referrals were not responded to in TRACER within 48 hours, as required (95 percent CI: 1.67–24.42). Among stable patient referrals, we estimated that 9.6 percent of referrals were not responded to in TRACER within 5 business days, as required (95 percent CI: 6.36–14.28). See Table 1 for VATC-specific information on the extent of timeliness of responses to referrals for transplant evaluation. VATC providers we interviewed told us that reasons for these delays include staff workload, the time referring facilities needed to collect additional information requested by the VATC, and an information technology glitch that resulted in VATC providers not receiving notification emails that a patient had been referred to their center.[9] Delays in responding to referrals in TRACER could represent true delays or documentation issues only. For example, in response to one emergency patient referral, the patient's EHR indicated that VATC responded to the referral within 48 hours by directly communicating with the referring facility but that timely response was not captured in TRACER. In contrast, in response to another emergency patient referral, both TRACER and the patient's medical record reflect that the referring facility waited for a response from the VATC for more than 48 hours.

Table 1. Timeliness of Responses in TRACER to Referrals for Transplant Evaluation Submitted From January 1, 2013, through December 31, 2014

VATC	Emergency Patient Referrals		Stable Patient Referrals	
	n	Response within 48 hours (95 percent CI)	n	Response within 5 business days (95 percent CI)
Houston	3[a]	66.7 (14.45–95.95)	56	91.1 (79.85–96.33)
Madison	6[a]	100.0 (not applicable)[b]	43	100.0 (not applicable)[b]
Nashville	4[a]	100.0 (not applicable)[c]	55	100.0 (not applicable)[c]
Pittsburgh	3	100.0 (not applicable)[c]	57	86.0 (73.94–92.97)
Portland	5[a]	100.0 (not applicable)[c]	54	83.3 (70.53–91.26)
Richmond	4	75.0 (22.59–96.86)	56	96.4 (86.33–99.14)
Total	**25**	**93.1 (75.58–98.33)**	**321**	**90.4 (85.72–93.64)**

Source: OIG analysis of TRACER records.

Notes: [a]An additional patient referral was submitted during our study period but was not included in our analysis because the referral response time was not documented. [b]Confidence intervals are not presented for the Madison VATC because all referrals during the study period were sampled. [c]Confidence intervals are not presented for because responses to all sampled referrals in this category met VHA's timeliness standard.

[9] Disruptions in notification emails to VATCs occurred for a total of three days in February and April 2014, according to the NSO staff.

Among stable patients who were deemed eligible for further evaluation, about half did not receive initial patient evaluations within 30 days, as required. See Table 2 for VATC-specific information on the extent of timeliness of initial patient evaluations. VATC providers we interviewed told us that reasons evaluations may not occur within 30 days include patient preference, delays associated with establishing telehealth agreements, delays associated with obtaining additional necessary testing through the referring facility, and patients becoming too sick to travel.

Table 2. Timeliness of Initial Patient Evaluations for Stable Patients Who Were Referred From January 1, 2013, through December 31, 2014

	Timeliness based on data in TRACER		Timeliness based on data in EHRs	
VATC	**n**	**Evaluated within 30 days (95 percent CI)**	**n**	**Evaluated within 30 days (95 percent CI)**
Houston	34	58.8 (41.42–74.27)	34	52.9 (36.00–69.23)
Madison	32	81.3 (63.34–91.57)	32	84.4 (66.78–93.55)
Nashville	36	44.4 (28.91–61.15)	36	50.0 (33.79–66.21)
Pittsburgh[a]	29	51.7 (33.61–69.40)	30	53.3 (35.32–70.52)
Portland	31	22.6 (10.92–40.97)	31	19.4 (8.75–37.52)
Richmond[a]	25	92.0 (72.21–98.07)	26	92.3 (73.10–98.15)
Total	**187[a,b]**	**52.0 (44.05–59.90)**	**189[a,b]**	**52.6 (44.64–60.36)**

Source: OIG analysis of TRACER and EHR records.

Note: [a]The number of patients included in our analysis of data from TRACER does not match that for our analysis of data from EHRs because the information was missing in TRACER. [b]VATCs determined that an additional 13 stable patient referrals were eligible for an initial patient evaluation, but those evaluations never occurred for various reasons, including that the patient no longer desired transplantation, became too ill, or died.

VATC providers we interviewed indicated that the importance of timely responses to referrals and subsequent initial patient evaluations depended, in part, on how sick the patients were. In particular, these providers explained that, to be allocated an organ, patients must generally have elevated MELD scores and that allocation is a function of time on the waitlist with an elevated MELD score, not overall time on the waitlist per se. This is consistent with 2013 data published by the Scientific Registry of Transplant Recipients that indicated that only 2.8 percent of adult liver transplant recipients had MELD scores of less than 15.[10] Providers explained that for sick patients, eligibility for transplant surgery may change rapidly, and it can be helpful to make personal arrangements before patients become too sick to travel. Further, providers explained that if patients' MELD scores get too high or if patients develop other complications they may no longer be good candidates for transplantation. In contrast, providers indicated

[10] OPTN/SRTR 2013 Annual Data Report: Liver. *American Journal of Transplantation,* January 2015, 15(suppl 2): 1–28.

that it can be reasonable to delay evaluations for some patients with lower MELD scores and those without hepatocellular carcinomas.

VHA's NSO has taken steps to improve the timeliness of initial patient evaluations, including sending automated emails to VATCs when referrals have been received and when responses and evaluations are overdue. To that end, timeliness of VATCs' responses to referrals and initial patient evaluations improved from 2013 to 2014, according to an NSO analysis.

While reviewing our sampled referrals, we identified the following types of TRACER data inaccuracies:[11]

- Because of an apparent information technology glitch, the submission date in the main dashboard did not match the submission date listed within the more detailed TRACER record in some instances. In particular, 2.9 percent of referral submission dates were not internally consistent within TRACER (95 percent CI: 1.52–5.58).

- We found that TRACER may contain some data entry errors since information is entered manually. For example, 1.8 percent of referral submission dates were inaccurate because they were submitted in TRACER after patients had already been referred and evaluated for transplantation (95 percent CI: 0.69–4.79). In one such case, the referral was submitted 224 days after the patient was evaluated for transplantation and 9 days after the patient received a liver transplant.

These data inaccuracies are problematic because VHA's NSO uses TRACER data to inform its oversight of VATCs, including its quarterly reports that indicate whether timeliness standards are being met. After we alerted VHA to these issues, the NSO took steps to resolve ongoing data inaccuracies.

Conclusions

We substantiated that three stable patients referred to the Houston VATC for liver transplant evaluations were referred more than once because information was missing or additional information was needed related to the initial referrals. However, we found that those patients represented a small percentage of patients referred to the Houston VATC for liver transplant evaluation from January 1, 2013, through December 31, 2014. Further, we did not find that the Houston VATC's practice of requiring referring facilities to resubmit referrals for a small number of stable patients represented a noteworthy program inefficiency.

We substantiated that some patients referred for liver transplant evaluation at all VATCs experienced delays. We estimated that 6.9 percent of emergency referrals were not

[11] We accounted for these data inaccuracies in our analysis, as described in our section on scope and methodology.

responded to within 48 hours, as required (95 percent CI: 1.67–24.42). Among stable patient referrals, we estimated that 9.6 percent of referrals were not responded to within 5 business days, as required (95 percent CI: 6.36–14.28). About half of stable patients who were deemed eligible for further evaluation did not receive an initial patient evaluation within 30 days, as required.

While reviewing our sampled referrals, we identified several types of transplant referral data inaccuracies. These inaccuracies are problematic because VHA's NSO uses those data to inform its oversight of VATCs, including its quarterly reports that indicate whether timeliness standards are being met. The NSO took steps to resolve ongoing data inaccuracies after we alerted VHA to these issues.

Recommendations

1. We recommended that the Under Secretary for Health review the extent of delays in responses to referrals for transplant evaluations; assess the risk, if any, posed by those delays; and, take appropriate action to ensure timely responses to referrals for liver transplant evaluations.

2. We recommended that the Under Secretary for Health review the extent of delays in initial patient evaluations for transplantation; assess the risk, if any, posed by those delays; and, take appropriate action to ensure timely initial patient evaluations.

3. We recommended that, after reviewing the circumstances of delays in responses to referrals and initial patient evaluations for transplantation, the Under Secretary for Health take action to confirm that any patients who experienced delayed care that presented risks received appropriate care.

Appendix A

Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: October 2, 2015

From: Under Secretary for Health (10)

Subj: Office of Inspector General (OIG) Draft Report: Healthcare Inspection Alleged Program Inefficiencies and Delayed Care Veterans Health Administration's National Transplant Program (7639813)

To: Assistant Inspector General for Health Care Inspections (54)

1. Thank you for the opportunity to review the OIG draft report of the Healthcare Inspection Alleged Program Inefficiencies and Delayed Care Veterans Health Administration's National Transplant Program.

2. I concur with the findings and recommendations in the draft report and provide comments in response to recommendations 1-3.

3. Please direct questions or concerns regarding the content of this memorandum to Karen Rasmussen, M.D., Director, Management Review Service (10AR) at VHA10ARMRS2@va.gov.

(original signed by:)

David J. Shulkin, M.D.
Under Secretary for Health

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 Under Secretary for Health review the extent of delays in responses to referrals for transplant evaluations; assess the risk, if any, posed by those delays; and, take appropriate action to ensure timely responses to referrals for transplant evaluations.

Concur

Target date for completion: June 2016

VHA response: For calendar years 2013 and 2014, there were 92 emergency liver transplant referrals to the VA Transplant Program. In 2013, 33 emergency referrals were submitted with a mean time from referral to VA Transplant Center decision of eligibility of 1.8 calendar days (range of 1–6 days) and a completion rate within 2 calendar days of 85 percent. In 2014, 59 emergency referrals were submitted with a mean time from referral to VA Transplant Center decision of eligibility of 1.6 calendar days (range 1–4 days) and a completion rate within 2 calendar days of 86 percent.

During this same period, there were 1,087 stable liver transplant referrals to the VA Transplant Program. In 2013, 589 stable referrals were submitted with a mean time from referral to VA Transplant Center decision of eligibility of 4.9 business days (range 1–28 days) and a completion rate within 5 business days of 64 percent. In 2014, 498 stable referrals were submitted with a mean time from referral to VA Transplant Center decision of eligibility of 4.1 business days (range 1–13 days) and a completion rate within 5 business days of 72 percent.

The following was determined upon analysis of all 92 emergency and 1,087 stable liver transplant referrals:

1. Two emergency referrals waited more than two days or 48 hours for a VA Transplant Center decision of eligibility and the patient subsequently died without having been waitlisted for a transplant.
2. Eleven stable referrals were deemed eligible for evaluation yet waited greater than 5 business days for a VA Transplant Center decision of eligibility, then waited greater than 30 days for an evaluation and the patient subsequently died without having been waitlisted for a transplant.

The VHA National Surgery Office (NSO) will facilitate a peer review of the medical record for each of these 13 cases using an independent contractor in order to assess risk, if any, posed by the identified delay in accordance with VHA Directive 2010-025 and Title 38 United States Code §5705. If in any case harm is identified to have been

caused by a delay in time from liver transplant referral to VA Transplant Center decision of eligibility, the Under Secretary for Health will ensure disclosure to the patient's family per VHA Handbook 1004.08.

In addition, the NSO will disseminate a memorandum through the Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) to the VA Transplant Centers reinforcing the timeliness standards for a decision of eligibility to a liver transplant referral in accordance with VHA Directive 2012-018.

To complete this recommendation, the NSO will provide:

1. A summary report of the 13 peer reviews performed by the independent contractor.
2. A copy of the signed memo reinforcing timeliness standards.

Recommendation 2. We recommended that the Under Secretary for Health review the extent of delays in initial patient evaluations for transplantation; assess the risk, if any, posed by those delays; and, take appropriate action to ensure timely initial patient evaluations.

Concur

Target date for completion: June 2016

Facility response: For calendar years 2013 and 2014, there were 92 emergency liver transplant referrals to the VA Transplant Program. In 2013, 33 emergency referrals were submitted with a mean time from date of referral to the date of evaluation by a VA Transplant Center of 7.4 days (range of 0–62 days) representing a completion rate within 30 calendar days of 94 percent. In 2014, 59 emergency referrals were submitted with a mean time from date of referral to the date of evaluation by a VA Transplant Center of 3.6 days (range 1–21days) representing a completion rate within 30 calendar days of 100 percent.

During this same period, 1,087 stable liver transplant referrals were submitted to the VA Transplant Program. In 2013, 589 stable referrals were submitted with a mean time from date of referral to the date of evaluation by a VA Transplant Center of 45.9 days (range of 0–193 days) representing a completion rate within 30 calendar days of 33 percent. In 2014, 498 stable referrals were submitted with a mean time from date of referral to the date of evaluation by a VA Transplant Center of 27.1 days (range 1–116 days) representing a completion rate within 30 calendar days of 71 percent.

The following was determined upon analysis of all 92 emergency and 1,087 stable liver transplant referrals:

1. One emergency referral deemed eligible died without a VA Transplant Center evaluation within 30 days from the date of referral.

2. Eight stable patient referrals deemed eligible never received a Transplant Center evaluation and the patient subsequently greater than 30 days from the referral date.
3. Seventeen stable referrals deemed eligible waited greater than 30 days for a Transplant Center evaluation and the patient subsequently died without having been waitlisted for a transplant.

The NSO will facilitate a peer review of the medical record for each of these 26 cases using an independent contractor in order to assess risk, if any, posed by the identified delay in accordance with VHA Directive 2010-025 and Title 38 United States Code §5705. If in any case harm is identified to have been caused by a delay in VA Transplant Center evaluation, the Under Secretary for Health will ensure disclosure to the patient's family per VHA Handbook 1004.08.

In addition, the NSO will disseminate a memorandum through the DUSHOM to the VA Transplant Centers reinforcing the timeliness standards for a VA Transplant Center evaluation of a liver transplant referral deemed eligible on initial review in accordance with VHA Directive 2012-018.

To complete this recommendation, the NSO will provide:

1. A summary report of the 26 peer reviews performed by the independent contractor.
2. A copy of the signed memo reinforcing timeliness standards.

Recommendation 3. We recommended that, after reviewing the circumstances of delays in responses to referrals and initial patient evaluations for transplantation, the Under Secretary for Health take action to confirm that any patients who experience delayed care that presented risks received appropriate care.

Concur

Target date for completion: June 2016

Facility response: For calendar years 2013 and 2014, there were 92 emergency liver transplant referrals to the VA Transplant Program. Sixty-five of the emergency liver transplant referrals were deemed eligible for further evaluation of which 49 remain alive. Ten patients experienced a delay in referral to a VA Transplant Center decision of eligibility or evaluation of which four patients have received a liver transplant, one patient is actively receiving care and five patients are no longer deemed eligible for liver transplantation.

During the same period, 1,087 stable patient referrals were submitted to the VA Transplant Program. Six hundred eighty seven of the stable liver transplant referrals were deemed eligible for further evaluation of which 581 remain alive. One hundred nineteen patients experienced a delay in referral to a VA Transplant Center decision of eligibility or evaluation of which 82 have received a liver transplant, 21 are actively receiving care and 206 are no longer deemed eligible for liver transplantation.

The NSO will facilitate a quality management review of the 211 patients who are alive, initially deemed eligible for transplant evaluation, experienced delays in either the referral to VA Transplant Center decision of eligibility or evaluation, but are now no longer deemed eligible for liver transplantation in accordance with VHA Directive 1026. In doing so, the Under Secretary for Health will ensure that any patient that experienced a delay in the referral to VA Transplant Center decision or eligibility or evaluation received appropriate care.

To complete this recommendation, VHA's NSO will provide a summary report for the 211 quality management reviews.

Appendix B

OIG Contact and Staff Acknowledgments

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Appendix C

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