

Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Access to Post-Traumatic Stress Disorder Treatment, James J. Peters VA Medical Center, Bronx, New York **To Report Suspected Wrongdoing in VA Programs and Operations** Call the OIG Hotline - (800) 488-8244

Executive Summary

The purpose of the review was to determine the validity of allegations that the VA Medical Center, Bronx, NY, Post-Traumatic Stress Disorder (PTSD) program denied access to PTSD treatment to eligible patients if the patients were: unable or unwilling to participate in research protocols, were abusing substances, were medically or psychiatrically unstable, or were not of "the appropriate age group." We also investigated the allegation that patients who were "deemed unsuitable" for the PTSD program had to opt for treatment at the Vet Center "as a default."

We concluded that eligible patients were not denied access to treatment in the PTSD program if they would not or could not participate in research protocols. We concluded that patients who were unable to participate in treatment because of substance use/abuse, or unstable medical and psychiatric conditions were referred to more appropriate treatment programs. We further concluded that patients not accepted into the PTSD program were not referred to the Vet Center by default.

Additionally, we concluded that the medical center needed to develop a policy that clearly defined admission and exclusion criteria for the PTSD program; and that plans were in place to provide VA/Department of Defense (DoD)-recommended PTSD treatment in the PTSD program and in the mental health outpatient department (OPD).

We recommended that:

- A comprehensive policy governing the PTSD Program's admission and exclusion criteria be developed, implemented and followed consistently by all clinicians in mental health services.
- VA/DoD-recommended treatment modalities are available to clinically appropriate patients with PTSD regardless of whether they obtain treatment in the PTSD Program or the OPD.

Management concurred in the findings and submitted acceptable implementation plans.



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

TO: Director, New York/New Jersey Veterans Healthcare Network (10N3)

SUBJECT: Healthcare Inspection – Access to Post-Traumatic Stress Disorder

Treatment, James J. Peters VA Medical Center, Bronx, New York

Purpose

The Department of Veterans Affairs Office of Inspector General (OIG), Office of Healthcare Inspections (OHI), reviewed allegations that the Post-Traumatic Stress Disorder (PTSD) Program at the James J. Peters VA Medical Center, Bronx, New York, denied eligible veterans access to PTSD treatment. The purpose of this inspection was to determine the validity of the allegations.

Background

The medical center provides secondary and tertiary services to a patient population in Bronx, Westchester, and Rockland Counties in Northern New Jersey, and in the New York City metropolitan area. It is academically affiliated with the Mount Sinai School of Medicine.

The medical center's mental health services include acute inpatient treatment and outpatient treatment in the mental health outpatient department (OPD), the substance abuse services (SAS) clinic, the PTSD Program, and the Homeless Program.

A centralized mental health intake process was adopted by medical center clinical managers in 1997 for patients requesting outpatient mental health services. Patients were evaluated by OPD intake clinicians and referred to appropriate mental health clinics or programs. Patients were generally assigned to a psychiatric outpatient program within 2 weeks of their assessment by OPD intake clinicians, with the exception of those referred to the PTSD Program.

The PTSD Program required a second assessment of the intake information by PTSD clinicians in their weekly staff meetings prior to accepting a patient in the PTSD Program. The referring intake clinician and the patient were notified via electronic mail or telephone whether or not the patient was accepted into the PTSD Program. We were provided with the intake schedule for Fiscal Year 2005. This schedule indicated that the time from initial referral to the PTSD Program to the patient's first appointment averaged approximately 10 days.

PTSD treatment, in various forms, was offered in the OPD, at the Vet Center, and by the PTSD Program. Specific treatment modalities were available only in certain programs. For example, patients accepted in the PTSD Program would receive case management, medication management, PTSD-specific group therapy focusing on combat related trauma, Eye Movement Desensitization and Reprocessing (EMDR) therapy, and exposure therapy (ET). ET was utilized for patients in a specific research protocol within the PTSD Program and not offered as a treatment modality to all patients in the PTSD Program at the time of this inspection.

A patient with PTSD assigned to the OPD clinic would receive case management and medication management. Group therapy, not specific to PTSD, was also offered to the general patient population in the OPD. These groups included anger management and harm reduction group therapy (therapy to promote nonviolent responses to anger and anxiety). While the OPD therapists were not providing EMDR or ET treatment at the time of our inspection, one therapist in the OPD was collecting patient trauma histories in anticipation of beginning EMDR therapy. Since the time of our inspection, the OPD therapist has begun providing EMDR therapy in the OPD.

PTSD care was also provided by the Vet Center. Vet Center services available to patients with PTSD included case management, individual psychotherapy, and PTSD-specific group therapy, but did not include medication management. EMDR and ET therapies were also not available in the Vet Center.

On September 13, 2005, the Office of Inspector General received a letter from an anonymous "concerned citizen." The complainant alleged that:

- The PTSD Program director denied patients access to the PTSD Program if they were unable or unwilling to participate in research protocols, were abusing substances, were medically or psychiatrically unstable, or were not of "the appropriate age group."
- The patients who were "deemed unsuitable" for treatment in the PTSD Program had to opt for treatment at the Vet Center "as a default."

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¹ Vet Centers provide readjustment counseling, community outreach, and education; they are a key access link between the veteran and other VA services.

Scope and Methodology

We made two visits to the medical center on November 28–December 1, 2005, and January 3–5, 2006. We interviewed medical, nursing, and administrative employees involved in the care of PTSD patients. In addition, we interviewed the Director of the Vet Center and the Patient Representative.

We reviewed the medical records of PTSD patients who received treatment in the PTSD Program and the OPD. We reviewed medical center policies governing the PTSD Program and the OPD, and the medical center's procedures for intake, assessment, and referral of patients to outpatient mental health services. We reviewed VHA policies governing program evaluation, research protocols, protection of human subjects in research, and Research and Development Program guidelines.

Additionally, we reviewed policies governing the medical center's Institutional Review Board (IRB) and the Research and Development Program. We reviewed IRB membership and research protocols for the medical center and Mount Sinai Medical Center. We interviewed research employees and consulted with the Office of Research and Development officials and a Veterans Integrated Service Network (VISN) Chief Medical Officer to clarify differences between research protocols and program evaluations.

We also reviewed the VA/Department of Defense (DoD) PTSD clinical practice guidelines for the management of PTSD and reviewed articles in professional medical journals specific to PTSD treatment. Additionally, we toured the PTSD Program Clinic.

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

Inspection Results

According to the VA/DoD clinical practice guidelines for the management of PTSD, EMDR is a psychotherapy treatment designed to alleviate distress associated with traumatic memories by accessing and processing those memories and bringing them to adaptive resolution. According to the guidelines, ET is designed to reduce the fear associated with the PTSD experience through repetitive therapist-guided confrontation of feared places, situations, memories, thoughts, and feelings. EMDR and ET, as treatment modalities for PTSD, received an "A" level recommendation from VA/DoD, which translates into "a strong recommendation that the intervention is always indicated and acceptable."²

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² VA/DoD Practice Guidelines for the Management of Post-Traumatic Stress, December 2003, p. 15. Level of Recommendations.

Because at the time of our inspection only patients in the PTSD Clinic were receiving the EMDR and exposure therapy as recommended by VA/DoD clinical guidelines, denying patients' access to the PTSD Program effectively denied them access to EMDR and ET treatment. We therefore reviewed the criteria used by the PTSD Program to admit or deny patients access to that program.

The introduction of the PTSD Program's use of EMDR and ET as new treatment modalities was documented in a transition plan authored by a PTSD Program manager and approved by the medical center Director in October 2004. The four phase transition plan that included (1) therapist training, (2) implementation, (3) patient discharge planning, and (4) workload issues began in September 2004 and was scheduled to be fully implemented by February 2005. Admission and exclusion criteria to the PTSD Program, according to that document, required patients to be diagnosed with combatrelated PTSD. Criteria excluded patients with evidence of current substance use or abuse within the previous 6 months, patients with psychotic disorders (including psychotic depression), and patients with current organic or medical conditions that would interfere with cognitive treatment. The transition plan document indicated that patients who wished not to participate in the new PTSD Program would be discharged from the program and referred to the OPD where they would receive case management, psychopharmacology management, and group psychotherapy. A PTSD Program manager reported in an interview that no patients to date had been discharged from the PTSD Program.

We were provided with electronic mail correspondence dated February 2005. It showed additional admission and exclusion criteria for the PTSD Program. The correspondence stated, "We are interested in treating OIF [Operation Iraqi Freedom] patients. Our whole new program is geared up to do this as we think we will have better responses with our specialized approaches for those immediately returning." Electronic mail correspondence from the same PTSD Program manager in May 2005, further clarified admission criteria stating, "Our criterion for admission is based on suitability of the patient to undergo the treatment being offered, not their diagnosis." Thus the inclusion and exclusion criteria of the PTSD Program were designed to select those patients who were clinically appropriate for EMDR therapy.

Issue 1. Denied Access to the PTSD Program.

We did not substantiate the allegation that patients were denied access to the PTSD Program if they were unable or unwilling to participate in research protocols, were abusing substances, or were not of "the appropriate age group." While we did substantiate that patients who were medically or psychiatrically unstable were excluded from the program, this is consistent with appropriate standards of care.

<u>Research Participation</u>: Our review of current PTSD Program enrollment records, medical records, and a list of patients enrolled in research protocols found that of the 566 patients currently receiving services in the PTSD Program, only 21 (4 percent) were involved in research protocols in the last 2 years. A review of IRB records revealed eight protocols concerned with PTSD in the combat patient. Seven of the protocols recruited research subjects through general advertisements that were posted in public areas and on the medical center's property. One of the seven protocols recruited patients by a direct mailing to all Korean War patients utilizing primary care services at the medical center between December 2000–December 2001.

The eighth protocol did express intent to partially recruit subjects from the medical center's PTSD Program. That protocol concerned ET for OIF and Operation Enduring Freedom (OEF) patients with PTSD, and planned to enroll 185 subjects at the medical center. The protocol summary provided for recruitment to occur from the PTSD Program, as well as from the medical center's surrounding geographical area. In addition, patients would also be recruited by research employees from local military reserve units and veterans organizations. This protocol received IRB approval on September 22, 2005. No subjects had been recruited as of the date of this inspection.

<u>Substance Abuse</u>: We did not substantiate that all patients who abused substances were denied access to the PTSD Program. However, we did find evidence of inconsistent adherence to the program's admission and exclusion criteria for substance abuse as governed by the PTSD Program's policy.

Exclusion criteria for the PTSD Program was initially identified in a scope of care document, dated September 2003 and authored by a Mental Health Psychiatric Care Center manager. This document defined exclusion criteria for patients seeking admission to the PTSD Program as "Patients with active substance dependence and/or significant co-morbid psychopathology of psychotic proportions are probably best cared for in SAS or the psychiatry OPD. This is because the PCT [PTSD Clinical Team] sees a large volume of patients, mainly in groups, and does not provide an ideal milieu for dealing with substance dependence and active psychosis." An electronic mail correspondence dated July 28, 2004, identified PTSD Program exclusion criteria as "No evidence of substance abuse or dependence in the past 6 months. If there is a history of substance abuse or dependence in the past 2 years, a U-tox [urine toxicology test] should be obtained."

We reviewed a sample of 15 of the 62 patients accepted into the PTSD Program within the last year and found that 3 of the 15 patients (20 percent) met exclusion criteria for substance abuse for the PTSD Program, according to the medical center's current policy. Two patients had documented evidence of alcohol use and abuse. For example, one patient was accepted into the program even though the PTSD medical director and a social worker documented that the patient consumed six bottles of beer per night. A

second patient accepted into the PTSD Program was documented by a PTSD psychiatrist to have "mild to moderate alcohol intake."

A third patient was documented to have extensive opioid and alcohol dependence, both in remission, but the patient's documented cannabis dependence was noted to be in early remission of 5 months. The PTSD exclusion criterion indicated that patients were prohibited from the PTSD Program for use of illicit drugs within the last 6 months.

Additionally, we reviewed a sample of 10 of the 23 patients not accepted into the PTSD Program in the last year. The review showed that two patients were excluded from the PTSD Program due to "alcohol relapse" and "inconsistent sobriety" (as defined by policy as the inability to maintain sobriety for 1 year) respectively. The patient with alcohol relapse was eventually re-evaluated and accepted into the PTSD Program 3 weeks later. However, the denial of the other patient due to inconsistent sobriety appears to be inconsistent when compared with patients accepted into the PTSD Program with active substance abuse conditions.

<u>Medically or Psychiatrically Unstable</u>: We found that patients were appropriately excluded from the PTSD Program if they were medically or psychiatrically unstable. Medically or psychiatrically unstable patients would be unable to participate in many treatments offered by the PTSD Program. We reviewed several VA outpatient PTSD Program policies and found similar exclusion criteria existed and was in fact the standard of care. Patients who were too medically or psychiatrically unstable to participate in the PTSD Program were referred to more appropriate treatment programs, for example the OPD and SAS.

Age Group: We did not substantiate that patients were excluded from the PTSD Program if they were not of the appropriate age group. The complainant did not define the meaning of "appropriate age group." However, a review of the 15 patients accepted into the program in the last year found that 8 of 15 (53 percent) were Vietnam veterans. Of the 10 patients denied admission to the PTSD Program, the most frequently occurring combat era veteran was Vietnam, at 5 patients (50 percent). Patients accepted into the PTSD Program included veterans of combat in Korea, Vietnam, Beirut, OEF, OIF and the Gulf War.

Other Access to Care Issues: While not part of the original allegations, we observed that there were other factors adversely impacting PTSD Program access. In a review of medical records for nine patients not accepted into the PTSD Program in the past year, four of the patients appeared to be rejected solely because they were referred by resident physicians. We were told by a PTSD Program manager that this was to allow the patients continuity of care with their resident physicians. However, this was not identified as an exclusion criterion anywhere within medical center or PTSD Program policies. In addition, OPD staff informed us that because of the inconsistent application of the PTSD Program's inclusion and exclusion criteria, they often found it easier to care for the

patients in the OPD rather than to refer patients to the PTSD Program who might be appropriate for the additional treatment modalities offered there.

Issue 2. Vet Center Referrals.

We did not substantiate that the patients who were not accepted into the PTSD Program were referred only to the Vet Center for treatment. The complainant alleged that "as a default," PTSD patients "who are deemed unsuitable" for the PTSD Program were referred to the Vet Center. Patients who were not admitted to the PTSD Program, or who voluntarily refused admission into the PTSD Program, had the option of receiving services from the OPD, as well as the Vet Center. The Vet Center offered case management, PTSD-specific groups, and anger management groups. The Vet Center did not offer medication management because of the lack of a staff psychiatrist. Medication management was provided to Vet Center patients by either the patient's primary care physician or a psychiatrist in the OPD.

Conclusions

We concluded that patients were not denied access to the PTSD Program based on their willingness to participate in research protocols or their age. We further concluded that patients who were unable to participate in treatment provided in the PTSD Program because of substance use/abuse or unstable medical and psychiatric conditions were appropriately excluded and referred to other treatment programs. Additionally, we concluded that patients who were not accepted into the PTSD Program could access treatment in the OPD and were not "by default" referred to the Vet Center.

We concluded that there was no policy that clearly defined admission and exclusion criteria for the PTSD Program. Rather, it seemed that criteria were often changed; and multiple versions of the criteria, at varied stages of distribution, resulted in inconsistent adherence to the policy for patients referred to the PTSD Program. Additionally, patients who were referred by resident physicians may have been inappropriately excluded from the PTSD Program.

We concluded that VA/DoD recommends EMDR and ET for the treatment of PTSD. Plans were in place to provide EMDR to OPD patients, although no patients in the OPD were receiving this therapy at the time of our inspection. The OPD has since begun providing EMDR and ET services.

Recommendations

We recommend that The VISN Director ensure that the Medical Center Director requires that:

- 1. A comprehensive policy governing the PTSD Program's admission and exclusion criteria be developed, implemented, and followed consistently by all clinicians in mental health services.
- 2. VA/DoD-recommended treatment modalities are available to clinically appropriate patients with PTSD regardless of whether they obtain their treatment through the PTSD Program or OPD clinic.

OIG Comments

The VISN Director and Medical Center Director agreed with the findings and recommendations and provided acceptable improvement plans.

(original signed by:)

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

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: June 19, 2006

From: Director, New York/New Jersey Veterans Healthcare

Network (10N3)

Subject: Access to Post-Traumatic Stress Disorder Treatment, James J.

Peters VA Medical Center, Bronx, New York

To: Assistant Inspector General for Healthcare Inspections

1. We concur with the recommended improvement action plans 1 and 2.

- 2. We are confident that the mental health staff of the James
- J. Peters VA Medical Center will continue to provide specialized PTSD treatment for our veterans in both the PTSD and OPD clinics.
- 3. Should you have any questions please contact MaryAnn Musumeci, James J. Peters VA Medical Center Director at 718-584-9000 extension 6512.

(original signed by:)

JAMES J. FARSETTA, FACHE

Medical Center Director Comments

Department of Veterans Affairs

Memorandum

Date: June 16, 2006

From: Director, James J. Peters VA Medical Center

Subject: Access to Post-Traumatic Stress Disorder Treatment, James J.

Peters VA Medical Center, Bronx, New York

To: Director, New York/New Jersey Veterans Healthcare

Network (10N3)

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

The following Director's comments are submitted in response to the recommendation(s) in the Office of Inspector General's Report:

OIG Recommendation(s)

Recommended Improvement Action 1. We recommend that the VISN Director ensure that the Medical Center Director requires that a comprehensive policy governing the PTSD Program's admission and exclusion criteria be developed, implemented and followed consistently by all clinicians in mental health services.

Concur **Target Completion Date:** 4/30/06

The Mental Health Patient Care Center has carefully developed and implemented a Standing Operating Procedure (SOP-00MH #8)

Recommended Improvement Action 2. We recommend that the VISN Director ensure that the Medical Center Director continues to make available to clinically appropriate patients with PTSD VA/DoD-recommended treatment modalities regardless of whether they obtain their treatment through the PTSD Program or OPD clinic.

Concur Target Completion Date: On-going

The James J. Peters VAMC will continue to make available, to clinically appropriate patients with PTSD, VA/DOD recommended treatment modalities regardless of whether they obtain their treatment through the PTSD Program or OPD.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	George Wesley, M.D. Director, Medical Assessment and Consultation 202-565-8301
Acknowledgments	Andrea Buck, M.D.
	Hope Watt-Bucci, Ph.D.

Appendix D

Report Distribution

VA Distribution

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National Veterans Service Organizations

Government Accountability Office

Office of Management and Budget

The Honorable Charles E. Schumer, U.S. Senate

The Honorable Hillary Clinton, U.S. Senate

The Honorable Joseph Crowley, U.S. House of Representatives

The Honorable Jose E. Serrano, U.S. House of Representatives

The Honorable Eliot L. Engel, U.S. House of Representatives

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