Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged Vision Care Issues and Research Improprieties James A. Haley VA Hospital Tampa, Florida

Report No. 09-02554-28

November 18, 2009

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations

Telephone: 1-800-488-8244 between 8:30AM and 4PM Eastern Time, Monday through Friday, excluding Federal holidays

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Executive Summary

The purpose of the review was to evaluate allegations of inadequate vision care, unapproved research activities, and improper influence in directing a research study at the James A. Haley VA Hospital (JAHVAH) in Tampa, FL.

While we confirmed that some polytrauma and traumatic brain injury outpatients did not receive complete eye examinations prior to a Veterans Health Administration Directive requiring them, we did not substantiate that this condition deviated from expected standards at the time. In an effort to comply with the October 2008 Directive, staff have since mailed letters to patients asking them to follow up with JAHVAH and schedule an eye examination.

We did not substantiate the allegation that an occupational therapist (OT) provides all of the diagnostic and therapeutic eye care. The OT holds appropriate credentials, and record review reflected that the OT functioned within her Scope of Practice.

We did not substantiate the allegation that patients' rights were being violated. The Institutional Review Board had not yet reviewed the protocol, and we found no evidence that active research related to vision restoration therapy (VRT) was being conducted or that data was being collected for any reason other than treatment. As VRT was initiated for treatment (rather than research) purposes, informed consents were not indicated.

We did not substantiate the allegation that some patients may have received VRT instead of traditional blind rehabilitation services that have proven benefits. Only five patients received VRT during the previous year, a negligible number compared to more than 1,000 patients who received traditional eye care and rehabilitation services.

We could not confirm or refute the allegation that there was political pressure to conduct a research study related to VRT. We had no way to evaluate the complainant's assertions that former and/or unknown high-level government officials influenced VA to test VRT. Both the researchers and the JAHVAH Director deny that they were pressured to conduct a research study on VRT. However, we believe that the subject protocol's goals appropriately align with VA's strategic plan. We made no recommendations.

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

TO: Director, VA Sunshine Healthcare Network (10N8)

SUBJECT: Healthcare Inspection – Alleged Vision Care Issues and Research Improprieties, James A. Haley VA Hospital, Tampa, Florida

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) received an anonymous complaint alleging inadequate vision care, unapproved research activities, and improper influence in directing a research study at the James A. Haley VA Hospital (JAHVAH) in Tampa, FL. The purpose of the review was to determine whether the allegations had merit.

Background

The JAHVAH is a tertiary care facility that provides medical, surgical, mental health, geriatric, rehabilitation, and spinal cord injury services. Further, the JAHVAH is one of four VA Polytrauma Rehabilitation Centers (PRCs) that provide comprehensive inpatient rehabilitation services to individuals with traumatic brain injuries (TBI) and other severe cognitive, physical, and mental health conditions. In fiscal year (FY) 2008, the JAHVAH research program had 207 active projects and a budget of $6.7 million. Non-VA research funding totaled about $10.2 million. The facility is part of Veterans Integrated Service Network (VISN) 8.

As of November 24, 2008, 33,424 service members have sustained non-mortal injuries during Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) that were severe enough to require immediate medical attention.[1] The majority of combat injuries are blast-related, and it has been estimated that over 60 percent of blast injuries result in TBI.[2] Neurological vision impairment, or damage to the optic nerves or parts of the brain associated with eyesight, is a common condition resulting from brain injury.

[1] www.defenselink.mil
[2] Veterans Health Administration Handbook 1172.1, *Polytrauma Rehabilitation Procedures*, September 22, 2005.

Neuroplasticity describes the brain's ability to compensate for injury and disease by reorganizing and forming new connections between intact neurons. In order to reconnect, neurons need to be stimulated through activity. Research has shown that repeated exposure to stimuli targeting a vision deficit could help activate the brain to restore vision.

Vision Restoration Therapy (VRT) is a treatment designed to treat stroke and TBI patients with neurological vision loss. A company (referred to here as Company A) has developed equipment and technology to allow patients to receive VRT in their homes. Patients are evaluated by an eye care professional, and diagnostic testing results are sent to Company A for development of a customized treatment plan unique to the patient's unique visual deficits. VRT is typically prescribed for one session twice daily for 3–6 months. Based on data of patient performance, Company A adjusts the treatment plan as needed.

On March 10, 2009, a complainant contacted the Office of General Counsel (OGC) to express concerns about the possible violation of patient rights in the PRC. On April 24, OGC referred the case to an OIG field office in Florida, which in turn notified the OIG's Hotline Division of the issues. The complainant made multiple allegations related to vision care for and research involving polytrauma patients. Specifically, the complainant alleged that:

(1) Polytrauma and TBI patients did not receive eye examinations prior to the issuance of a Veterans Health Administration (VHA) Directive requiring them.

(2) An occupational therapist (OT) provides all of the diagnostic and therapeutic care, and also hires and supervises vision therapy staff. These functions are beyond the OT's training.

(3) Patient rights in the PRC were possibly being violated. To support this allegation, the complainant asserted that:
   (a) It appeared research involving Company A's VRT equipment and technology was being conducted, yet it was unclear whether the IRB had approved the protocol.
   (b) If research was being conducted, patients may not have completed informed consents to participate in the study.
   (c) There is no controlled study showing VRT is effective, yet some patients may have received this therapy instead of "traditional" blind rehabilitation services that have proven benefits.

(4) There was political pressure to conduct a research study of Company A's VRT, a proprietary instrument that would benefit a private company with connections to the previous administration.

Scope and Methodology

We reviewed the subject research protocol, the Polytrauma/Blast-Related Injuries (PT/BRI) Quality Enhancement Research Initiative (QUERI) Center 2008 Strategic Plan; VHA Handbook 1172.1, *Polytrauma Rehabilitation Procedures*, September 22, 2005; VHA Directive 2007-013, *Screening and Evaluation of Possible Traumatic Brain Injury in Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) Veterans*, April 13, 2007; and VHA Directive 2008-065, *Performance of Traumatic Brain Injury Specific Ocular Health and Visual Functioning Examinations for Polytrauma Rehabilitation Center Patients*, October 20, 2008. We also reviewed the National Institute for Health's (NIH's) National Eye Institute strategic plan, and the JAHVAH's PRC organizational and functional charts, action plans, and the research compliance officer's investigation results. We interviewed the complainant, the principal investigator (PI) and the co-investigator, the visual therapy OT, the PRC coordinator, and other clinical and administrative staff knowledgeable about the issues.

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

Inspection Results

Issue 1: Vision Care

While we confirmed that some PRC and TBI outpatients did not receive complete eye examinations prior to a VHA Directive requiring them, we did not substantiate that this condition deviated from expected standards at the time.

On October 20, 2008, VHA issued Directive 2008-065, which requires that optometrists or ophthalmologists complete very specific eye examinations on current and former PRC patients. Prior to this Directive, guidance was outlined in Handbook 1172.1, which states that core disciplines are to conduct discipline-specific assessments of each patient. The Handbook does not reflect specific assessment requirements relative to eye evaluations.

The complainant did not provide us with the names of patients who did not receive complete eye examinations; therefore, we randomly selected 10 TBI patients enrolled for care between 2007 and 2008. We found that 2 of the 10 records did not contain documentation of complete eye examinations; however, the primary care providers did comment on eye/vision function and changes in their respective History and Physical notes. One of those patients enrolled in 2007 and the second enrolled in 2008. We noted that the remaining eight patients' records did reflect eye evaluations by an OT, an optometrist, or an ophthalmologist.

In an effort to comply with VHA Directive 2008-065 requiring visual functioning examinations for current and former PRC patients with a diagnosis of TBI, the JAHVAH

staff mailed notification letters to 104 patients who had been seen at the JAHVAH sometime between February 2005 and December 1, 2008. Of the 104 letters mailed, 22 were returned with no forwarding address available. Three patients called back and were scheduled for eye examinations; however, the remaining 79 patients never responded. According to the PRC Coordinator, many of the 104 patients were seen at the JAHVAH PRC for a 2-week evaluation for mild TBI and returned to active duty. Also, the JAHVAH sends a monthly report through the VISN to the National Rehabilitation Program Office showing the status of compliance with the Directive. We did not substantiate the allegation that an OT provides all of the diagnostic and therapeutic eye care, which is beyond the OT's training. The OT in question possesses a Master of Science in Visual Disabilities degree and is appropriately registered and licensed to practice in the State of Florida. During our record review, we found that this OT's progress notes reflected diagnostic testing and therapeutic interventions that fell within her Scope of Practice.[3] We found no evidence that the OT improperly diagnosed patients' eye conditions.

We did not substantiate the allegation that the OT hires and supervises vision therapy staff. The OT functions as part of an interdisciplinary PRC team and as such, works with other PRC and vision therapy staff in a collaborative manner. Because of the OT's background and experience, the OT is consulted about job applicants and vision therapy activities; however, we found no evidence that the OT hires or supervises other vision therapy staff. According to the organizational chart, this OT does not have supervisory authority.

Issue 2: Violation of Patient Rights

We did not substantiate the allegation that patients' rights were being violated. VHA Handbook 1200.5, *Requirements for the Protection of Human Subjects in Research,* adopted July 15, 2003, and updated on July 31, 2008, outlines policy regarding the ethical conduct of research involving human subjects. In VHA, all research projects must have both Institutional Review Board (IRB) and Research and Development (R&D) Committee approvals.

The PI submitted the subject research protocol for VA Merit Review and received a notification memorandum on November 20, 2008, stating that "due to high programmatic relevance" the proposal had been recommended for funding. The JAHVAH R&D Committee reviewed the subject protocol and returned it to the PI for modifications. At the time of our review, those modifications were still in process. As such, the IRB had not yet received or reviewed the protocol.

[3] "Scope of practice" is a term used to describe activities that may be performed by health care workers regardless of whether they are licensed independent health care providers. The scope of practice is specific to the individual and the facility involved.

We found no evidence that active research related to VRT was being conducted or that data was being collected for any reason other than treatment. For the period October 1, 2008, to July 30, 2009, five patients[4] received VRT therapy in accordance with their clinical treatment plans. In several of those cases, the medical records reflected the patients' wishes to pursue VRT therapy in their homes. As VRT was initiated for treatment (rather than research) purposes, informed consents were not indicated. Progress notes reflect that patients and staff discussed VRT as a treatment option, and patients were educated about risks and benefits of the therapy.

We did not substantiate the allegation that some patients may have received VRT instead of traditional blind rehabilitation services that have proven benefits. VRT is a therapy already in use at the JAHVAH and approximately 50 other neurological, eye, and rehabilitation centers nationwide. Over the course of 10 months, only 5 patients received VRT treatment, several at their own request. According to staff, VRT is a desirable treatment for some patients because it can be completed in their homes at their convenience; they are not required to travel to JAHVAH or another location for the service.

For the period October 1, 2008, to August 12, 2009, workload reports show the following:

Clinic/Service	Number of patients
Blind Rehabilitation	163
Low Vision Clinics (4 total)	485
Eye TBI Clinics	172
VIST Clinic	265

Due to the small number of patients receiving VRT, compared with the relatively substantial number of patients receiving services in other eye clinic or rehabilitation settings, we concluded that patients were, in general, receiving traditional blind rehabilitation services.

Issue 3: Improper Influence in Directing a Research Protocol

We could not confirm or refute the allegation that there was political pressure to conduct a research study related to VRT. We had no way to evaluate the complainant's assertions that former and/or unknown high-level government officials influenced VA to test VRT.

We also could not confirm the complainant's statement that Company A had "liberal access to congressional committees." Public records reflect that on April 2, 2008, the House Veterans Affairs Committee (HVAC) held a hearing on the topic of TBI-related vision issues. The panels consisted of blinded veterans, and included officials from

[4] A sixth patient was referred but never received the therapy.

VHA, the Blinded Veterans Association, Company A, and Company B (another private-sector company whose equipment is also part of the proposed protocol). We found the panel composition to be fairly typical, representing both public and private stakeholders. We have no other information about Company A's access to congressional committees.

Both the researchers and the JAHVAH Director deny that they were pressured to conduct a research study on VRT. The PI told us that because TBI is a high profile condition, he was asked to consider research projects related to TBI and vision loss. The PI reported that while there are studies showing that some current procedures and interventions improve vision, there are no studies showing that these procedures and interventions help patients in their everyday functioning. His proposal compares three similar therapies that are all currently in use and evaluates their respective impacts on life functioning.

We found that the objective of the subject protocol—*to test specific functional vision outcomes that reflect the functional deficits in everyday vision tasks…after a course of vision rehabilitation in veterans with TBI*—aligns with the NIH and VA research and strategic plans. The PT/BRI QUERI website shows five clinical priority areas, one of which is "screening and evaluation for high frequency impairments in individuals with PT/BRI." It further states that "Projects within the area of screening focus on TBI, PTSD [post-traumatic stress disorder], pain, headaches, and vision loss."

Given the number of OEF/OIF veterans with wounds and trauma resulting in visual impairment, we believe that the focus of this protocol is an appropriate research endeavor.

Conclusion

We did not substantiate the allegations. It appeared that vision examinations for PRC and TBI patients were conducted in accordance with guidelines in place at the time. Further, JAHVAH staff have taken appropriate measures to comply with new guidance issued in October 2008. Also, the PRC OT provided services within her Scope of Practice. As we found no evidence that research was being conducted, we did not confirm that patients' rights were being violated. Only five patients received VRT during the previous year, a negligible number compared to the number receiving traditional eye care and rehabilitation services. We could not confirm or refute that there was improper political pressure to conduct research on VRT. However, we believe that the subject protocol's goals appropriately align with VA's strategic plan. The VISN and JAHVAH Directors agreed with our findings. We made no recommendations.

(original signed by:)

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

Appendix A

OIG Contact and Staff Acknowledgments

OIG Contact	Victoria H. Coates, Director Atlanta Office of Healthcare Inspections (404) 929-5961
Acknowledgments	Melanie Cool Susan Zarter

Appendix B

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