Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection
Inappropriate Research & Development Data Entries Affecting Veterans Equitable Resource Allocation (VERA) Funding
VA Maryland Health Care System
Baltimore, MD

Report No. 10-01247-256

September 23, 2010

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The purpose of this review was to determine the merit of allegations concerning whether VA Research and Development (R&D) expenses were being over-reported by VA medical centers (VAMCs) to gain increased reimbursement funding. This review was initiated after an Administrative Investigation Board (AIB) found inappropriate reporting of R&D projects that increased the Veterans Equitable Resource Allocation (VERA) funding for R&D expenses at the VA Maryland Health Care System (VAMHCS) by $15,500,000.

We were not able to substantiate or refute the allegations because the original objective of this review was unattainable due to underlying R&D data integrity and data validation issues. Specifically, the Office of Research and Development (ORD) did not validate the FY07 R&D data used to support amounts reported in the FY09 VERA. Additionally, ORD was unable to explain variances between data reported in the Enterprise Project Management Information System (ePROMISe) and Research and Development Information System (RDIS) and other supporting data used to substantiate FY09 VERA data reported to the Allocation Resource Center (ARC).

We recommended that: (1) the Chief Research and Development Officer (CRADO) ensure that ORD establishes a process that validates ePROMISe and RDIS data with the VISN CFOs prior to submission to the ARC, including retention of historical records to document reasons for any variances between supporting data and data reported in the VERA Table 8 allocation and, (2) establish a R&D management and tracking system to help facilities meet Congressional and other reporting requirements.

The Under Secretary for Health concurred with the findings and recommendations. Additionally, the VISN 5 Director and VAMHCS included action plans to address matters reported in the AIB. The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

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

TO: Chief Research and Development Officer

SUBJECT: Healthcare Inspection – Inappropriate R&D Data Entries Affecting VERA Funding, VA Maryland HCS, Baltimore, MD.

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections, initiated a national review to determine whether VA Research and Development (R&D) expenses were being over-reported by VA medical centers (VAMCs) to gain increased reimbursement funding. Our review was initiated after an Administrative Investigation Board (AIB) found inappropriate reporting of R&D projects that increased the Veterans Equitable Resource Allocation (VERA) funding for reimbursable Research and Development (R&D) expenses at the VA Maryland Health Care System (VAMHCS) by $15,500,000.

Background

Baltimore VAMC is one of three medical centers that are part of VAMHCS, which is under Veterans Integrated System Network (VISN) 5. Human research protocols performed at VAMHCS must first be approved by the VAMHCS R&D Committee and an Institutional Review Board (IRB), which is part of University of Maryland School of Medicine (UMSM). UMSM is the VAMHCS medical research and teaching affiliate. The R&D Committee only approves VA Research, which is defined as being conducted by VA Principle Investigators (PI) utilizing VA resources.

VAMHCS spends approximately $48 million (M) on medical research to help improve the health of Veterans. VAMHCS receives an additional amount to reimburse for the administrative and support costs of approximately $17M. An event occurred at Baltimore involving the misreporting of Research and Development (R&D) funds that resulted in reviews by a VISN 5 AIB and the Office of Research Oversight (ORO). The AIB and ORO found that non-VA research expenditures performed at UMSM by part time VA PIs were misreported in the Enterprise Project Management Information System (ePROMISe) as VA research. This misreporting resulted in increased R&D indirect support cost reimbursements to the facility.

The Veterans Health Administration (VHA) Office of Research and Development (ORD) is responsible the allocation of appropriated Medical and Prosthetic Research funds. The R&D portion of a facility's budget from VERA is to be used to provide indirect support for research and not for routine clinical and or administrative support services, utilities, or normal telephone service that should be provided by the facility.

VERA uses a formula based on reported research expenditures in the following categories: VA Administered (VAA), Not VA Administered Peer Reviewed (NVAPR), and Not VA Administered Not Peer Reviewed (NVA NPR). Between October 1st and November 15th, VAMC employees enter R&D expenditures into ePROMISe according to the categories stated above. After November 15th, the ePROMISe data is migrated into the Research and Development Information System (RDIS) which generates a report that is used by ORD. This data is sent to the Allocation Resource Center (ARC) where the VERA allocations are performed. The ORD Research and Development Computing Center (RDCC) is responsible for developing, maintaining, and implementing ePROMISe and RDIS systems.

The current year's VERA allocation is based on VAMC R&D expenditure data from the prior two fiscal years (FYs) (FY09 VERA calculation uses FY07 RDIS data in the formula). The VERA allocation formula gives 100 percent credit for VAA expenditures, 75 percent for NVA PR, and 25 percent for NVA NPR.

The R&D expenditures reported by ORD can be found on the ARC website under VERA Reports Table 8 (VERA Research Support Backup Data and Allocations). R&D expenditure data from Table 8 is used for the allocations to VA facilities. ARC summarizes the discounted figures, and multiplies the summary by a "National Price for Research Support" factor to arrive at a facility allocation amount. Facility R&D allocation amounts are incorporated into the total VERA allocation to the VA facility.

Scope and Methodology

We conducted a site visit on March 3, 2010, at the Baltimore VAMC to gain an understanding of the issues and processes in place to ensure the accuracy of R&D expenditure data entered into the ePROMISe database. We interviewed staff and management from the Baltimore VAMC, RDCC, ARC, VISN 5, and ORD to understand the systems and processes that result in the VERA facility R&D funding.

We reviewed and analyzed data from ePROMISe, RDIS and ARC. We reviewed documents including the ORO For-Cause Review, VISN 5 AIB (2010-1), RDIS Part II Instructions manual, VERA Methodology, and VHA R&D 1200.series directives.

The scope of this review was limited due to data integrity issues noted between FY07 RDIS data used to support the FY09 VERA allocation.

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

Inspection Results

We found significant variances between data reported in the ePROMISe database and RDIS. There were variances between RDIS supporting data and what was reported to ARC that could not be resolved. We found that ORD did not have a process in place to validate data reported in the RDIS and was unable to explain the variances in the FY07 RDIS data that affected the FY09 R&D VERA allocation. Additionally, ORD did not maintain historical records to help resolve these discrepancies and increase transparency.

Issue 1: Variances between ePROMISe and RDIS data.

We compared FY07 R&D expenditure data from ePROMISe with data that ORD provided to ARC for the FY 09 VERA allocation. The total expenditures in ePROMISe for the Baltimore VAMC were $38M while ORD's total expenditures from RDIS totaled $30.6M. Through analysis and inquiries with RDCC, we were able to determine that the $7.4M variance resulted from data entered into ePROMISe after the November 15th cutoff date. As the ePROMISe database is not closed on a fixed date, FY07 expenditures entered after November 15th were not transferred into RDIS and were not included in the FY09 VERA allocation figures. The ORD staff that prepares the RDIS report was not aware that $7.4M of additional R&D expenditures were added after the cutoff date and not included in the R&D reporting.

Issue 2: No Validation of R&D Data.

The VA lacks a R&D system for research facilities to manage and track R&D programs that could provide additional controls for what is entered into ePROMISe. Baltimore's process for assembling the expenditure data and entering into ePROMISe was performed manually, prone to errors and lacked validation checks. There was no review of the ePROMISe system to ensure only VA research was entered and approved by the R&D committee.

For shared research at facilities that have the Institutional Review Board (IRB) located at their research affiliate we found the guidance unclear relating to the amount reported in ePROMISe for non-VA administered research by the Principle Investigator (PI). It was not clear whether the total non-VA administered grant amount be entered or only the portion expended by the VA. Determining the percentage amount expended at the VA was left to the PI with little guidance.

The Page 20 was the electronic form within the ePROMISe application that was designed to solicit PI input for non-VA administered research funds and expenditures. The Page 20 is meant to be printed and has a space for the PIs signature to certify the non-VA administered research funds entered. We found that in Baltimore the PIs were not provided the Page 20 for signature. The AIB findings in VISN 5 showed that there was a

breakdown of controls by the facility staff that allowed over $49M in non-VA research to be added to the ePROMISe database in FYs 07-08.

We found that ORD did not have a data validation process to ensure that the data extracted from RDIS and categorized by the facilities was complete and accurate prior to entry in the VERA allocation table. Inquiries with ARC personnel indicated that a new process (effective for FY10 VERA allocation) was in place that required the VISN Chief Financial Officers (CFOs) to validate RDIS data; however, it is not clear that this validation would address variances between ePROMISe and RDIS data.

Issue 3: RDIS Data Discrepancies with ARC VERA Table 8 (FY09 VERA Research Support Backup Data and Allocations).

We found discrepancies between ORD's RDIS data from FY07 and data reported in FY09 Table 8 of the VERA report (Research Support Backup Data) for all facilities. The discrepancies found affected the VERA allocation for FY 09 R&D funds to reimburse medical facilities.

VERA methodology states that NVA PR expenditures are reimbursed at 75 percent and NVA NPR at 25 percent of R&D expenditures to arrive at the discounted medical center total. We noted that ORD's summary of R&D expenditures from RDIS in categories NVA PR ($462.3M) and NVA NPR ($63.5M) were incorrectly consolidated into NVA PR for the FY09 VERA Table 8 allocation. This resulted in an additional amount of $31.8M (($63.5M * .75) – ($63.5M * .25)) credited in the NVA PR category in Table 8. ORD staff was not able to determine the basis for the NVA NPR number of $62.9M reported in the Table 8.

Table 1 shows a comparison of the supporting RDIS data provided to ORD and that reported in the FY09 VERA Table 8 allocation. The amounts should be the same; however, there were variances of $16,322,718 (VAA), $83,911,180, (NVA PR) and $548,823 (NVA NPR).

Table 1. Comparison of RDIS FY07 Data to FY09 VERA Table 8 allocation

FY07 - RDIS Data	**VA ADMIN**	**NOT VA ADMIN PR**	**NOT VA ADMIN NPR**
Total ALL VISN's	$579,656,467	$462,314,529	$63,516,114
FY09 - VERA Table 8 Data			
Total ALL VISN's	$595,979,185	$546,225,709	$62,967,291
Variance	$16,322,718	$83,911,180	$548,823

Issue 4: The Impact to Medical Services

The amount of R&D reimbursement funds for FY09 for all facilities was fixed in the budget at $442M. If a facility inflated their reported R&D the other facilities will receive marginally less, but funding for medical services provided to Veterans would not be affected since the overall budget amount for R&D indirect support costs is fixed. The VERA formula spreads that fixed amount over all the facilities. A National Price for Research Support (NPRS) (43 percent in FY09) is applied to the discounted medical center total to determine the VERA facility allocation. For Baltimore the discounted medical center total, ($26,697,321 * 43 percent) equaled an allocation to the facility of $11,553,092. As an example, if the amount of NVA NPR research is inflated by $1M, the discounted medical center total is inflated by $250,000 (25 percent), which increases the facility allocation by $107,500(43 percent).

Conclusions

The original objective, to determine whether facilities were manipulating reported R&D expenditures to gain additional funds, was undermined by the data integrity problems found in our review. At all levels we found that the system for tracking and reporting R&D expenditures lacked the internal controls necessary to ensure the accuracy of the data reported. The was no standard VA system at the facility level with adequate controls for tracking R&D Committee approvals and for reporting research funding and expenditures. We discovered large discrepancies between ePROMISe and RDIS data that were found to be timing issues related to the November 15th cutoff date. After working with ORD staff, there remained unresolved discrepancies between the RDIS data and what was ultimately reported to ARC for the VERA reimbursement calculations. Due to the unresolved discrepancies, we concluded that the original reporting by the facilities may be a factor, but that the entire reporting system needed to be revamped from the facility level up to the reported amounts used in the VERA calculation. Internal controls must be established to ensure transparency between source ePROMISe, RDIS and amounts reported to ARC.

Recommendations

Recommendation 1. We recommended that the Chief Research and Development Officer (CRADO) ensure that ORD establish a process that validates ePROMISe and RDIS data with the VISN CFOs prior to submission to the ARC. Additionally, historical records should be maintained so that ORD has the ability to support and explain any data variances between supporting data and the data reported in the VERA Table 8 allocation.

Recommendation 2. We recommended that the CRADO ensure that ORD establish an R&D management and tracking system to help facilities meet Congressional and other reporting requirements.

Comments

The Under Secretary for Health agreed with the findings and recommendations and provided acceptable improvement plans. See pages 8-14 for the full text of comments. We will follow up on the planned actions until they are complete.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Under Secretary for Health's Comments

Department of Veterans Affairs **Memorandum**

Date: September 01, 2010

From: Under Secretary for Health (10)

Subject: OIG Draft Healthcare Inspection Report: Inappropriate Research and Development Data Entries Affecting Veterans Equitable Resource Allocation Funding, VA Maryland HCS, Baltimore, MD, (VAIQ 7022812)

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and concur with the findings and recommendations.

2. Your office initiated a national review to determine whether Department of Veterans Affairs (VA) Medical Centers (VAMCs) were over-reporting Research and Development (R&D) expenses to gain increased reimbursement funding. This review was initiated after an Administrative Investigation Board (AIB) found inappropriate reporting of R&D projects that increased the Veterans Equitable Resource Allocation (VERA) funding for reimbursable R&D expenses at VA's Maryland Health Care System (VAMHCS) by $15,500,000.

3. In response to the Office of Inspector General (OIG) findings at the facility level, Veterans Integrated Service Network (VISN 5), and VAMHCS have taken specific actions and are implementing changes. Attachment A provides a summary of the current status.

4. In response to OIG's recommendations regarding national actions, VA's Office of Research and Development (ORD) is developing and implementing policy documents and guidelines to initiate a data verification system. The system will ensure data integrity related to R&D expenses, and maintain historical records.

5. Thank you for the opportunity to review the report. VHA's complete action plan to address the report recommendations is attached. If you have any questions, please contact Linda H. Lutes, Director, Management Review Service (10B5) at (202) 461-7014.

(original signed by:)

Robert A. Petzel, M.D.

Attachments

ATTACHMENT A

Actions and Progress to Address Inappropriate Research and Development Data Entries Affecting Veterans Equitable Resource Allocation Funding in the Department of Veterans Affairs (VA) Maryland Healthcare System

Veterans Integrated Service Network (VISN) 5 actions. The VISN 5 Network Director:

- Reviewed the Administrative Board of Investigation (ABI) report, contacted the Office of Research Oversight (ORO) to request that a team be brought in to review the research program at the Department of Veteran Affairs' (VA) Maryland Healthcare System (VAMHCS), and determine if procedures are being properly followed.
- Required development of an action plan to address all findings outlined during the ORO for-cause site visit.
- Will review all action plans for accuracy and follow-up prior to submission to ORO.

VAMHCS completed actions

- An Administrative Board of Investigation (ABI) was completed. All four allegations were sustained. The AIB concluded that VAMHCS received over $15 million of Veterans Equitable Resource Allocation (VERA) funding that should not have been received, although some, if not most of this funding might have qualified for Research and Development (R&D) Committee review and therefore would have been appropriately put into the Enterprise Project Management Information System (ePROMISe).
- VAMHCS Research Service identified and removed the projects that were inappropriately entered into ePROMISe.
- VAMHCS has:
  - Provided training and reviewed the requirements for this process with appropriate staff.
  - Revised the R&D Committee Standard Operating Procedure (SOP) to conform to the Department of Veterans Affairs' (VHA) Handbook 1200.01, R&D Committee requirements.
  - Implemented ePROMISe SOPs to outline criteria and procedures for entering data into database.
  - Established a working group to audit the entries in ePROMISe.
  - Modified all research consent forms of existing active protocols to include language indicating that destruction of identifiers or research records will be in accordance with VA record retention schedule, according to VA's Office of

Research and Development (ORD) guidance dated July 23, 2009, and distributed information about this throughout VAMHCS.

- Begun to maintain a current computerized list of all investigational drugs or study-related drugs used in VAMHCS facilities. Maintained VA-approved human subject research as required by VHA Directive 2008-072, Research Personnel Notification of Pharmacy Benefits Management Drug Safety Alerts and Adverse Drug Events Related to Interventional Human Subjects Research Studies.
- Secured all file cabinets in the R&D Service.

VAMHCS pending actions. VAMHCS will:

- Ensure that non-VA research projects' financial data are not included in the annual Part II Research and Development Information System (RDIS) report.
- Review annual Part II RDIS reports 5 years prior to fiscal year 2007 to identify financial data of non-VA research projects that were inappropriately included in the reports.
- Reconcile the corrected ePROMISe protocol list with the active protocol list.
- Ensure that the R&D Committee complies with all the requirements of VHA Handbook 1200.01, including:
  - Reviewing and approving complete, unredacted meeting minutes of all subcommittees.
  - Establishing of a Memorandum of Understanding (MOU) with the University of Maryland School of Medicine (UMSOM) for the use of the University of Maryland at Baltimore (UMB) Institutional Biosafety Committee (IBC) as the VAMHCS IBC of record with definitions of roles and responsibilities of each party.
  - Ensuring all required annual quality assurance reviews.
  - Reviewing the current MOU with UMSOM for the use of the UMB Institutional Review Board (IRB) to allow VAMHCS to also use VA's Central IRB as a VAMHCS IRB of record.
- Ensure that the R&D Committee corrects all identified regulatory noncompliance in a timely manner.
- Require a progress report about correcting the non-compliance issues associated with the R&DC Committee during each monthly R&D Committee meeting beginning with February 25, 2010. A final report will be presented at the September 9, 2010, meeting.

Under Secretary for Health's Comments to Office of Inspector General's Report

The following Under Secretary of Health's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

VETERANS HEALTH ADMINISTRATION
Action Plan

OIG Draft Healthcare Inspection Report: Inappropriate R&D Data Entries Affecting VERA Funding, VA Maryland HCS, Baltimore, MD.

Date of Draft Report: June 2010

Recommendation 1. We recommend the Chief Research and Development Officer (CRADO) ensure that ORD establish a process that validates ePROMISe and RDIS data with the VISN CFOs prior to submission to the ARC. Additionally, historical records should be maintained so that ORD has the ability to support and explain any data variances between supporting data and the data reported in the VERA Table 8 allocation.

VHA Comments

Concur

The Department of Veterans Affairs (VA) Office of Research and Development (ORD) will develop and implement policy documents and guidelines to initiate a data verification system to ensure the integrity of the data and maintain historical records.

Current Process:

The current process is to enter new studies in the Enterprise Project Management Information System (ePROMISe) system throughout the year when projects are scheduled to be reviewed by a facility's Research & Development Committee (R&D) and its subcommittees. At the close of the fiscal year, the following data are migrated from ePROMISEe and transmitted to the Research and Development Information System (RDIS):

- Project expenditure report

- VA-funded project detail expenditure report
- RDIS signature page
- Research office expenditure report
- Medical Research – Research Career Scientist expenditure report
- Veterinary Medical Unit expenditure report
- Percentages for animal facility use
- Cooperative Studies Program (CSP) Chairperson expenditure report

Each Department of Veterans Affairs Medical Center (VAMC) director reviews and signs the transmittal. The package is then forwarded to ORD in VA Central Office (VACO).

New Process:

A new process is under development, and current plans call for the use of both paper and electronic records. The following definition of VA research will be included in the guidelines for preparing the report:

> VA research is research that is conducted by VA investigators serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), and/or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.

This is the same definition that is included in the revision of VHA Handbook, 1200.01, Research and Development Committee, that is expected to be published in December 2010. The objective is to ensure that it is very clear what needs to be reported.

The processing, signature, retention, and transmission requirements for the paper project expenditure report and VA-funded project detail expenditures report are being updated. Also, the requirements for electronic data collection are being revised. The goal is to design and implement a data verification system to ensure the integrity of the data and maintain historical records.

In process March 31, 2011

Recommendation 2. We recommend the CRADO ensure that ORD establish an R&D management and tracking system to help facilities meet Congressional and other reporting requirements.

VHA Comments

Concur

The VA Office of Research and Development is developing a process (described in Recommendation 1) to ensure that the data repositories have correct information for VA-funded, non-VA- funded, and unfunded studies. When implemented, this new system will make data available to field offices so that they can respond to requests for their own information from the, rather than have to rely on a centralized system.

Data verification procedures to ensure the integrity of the data are being built into this system. This will provide consistency in reporting and provide valid information to meet Congressional and other reporting requirements.

In process March 31, 2011

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	Anthony Murray Leigh 410-637-4721
Acknowledgments	Victoria Coates Thomas Seluzicki

Appendix C

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