



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection Alleged Practice of Medicine by Unlicensed Research Assistants South Texas Veterans Health Care System San Antonio, Texas

**To Report Suspected Wrongdoing in VA Programs and Operations
Call the OIG Hotline – (800) 488-8244**

Executive Summary

The VA Office of Inspector General reviewed allegations that unlicensed physicians hired as research assistants at the San Antonio Veterans Health Care System (the system), San Antonio, TX, engaged in clinical activities constituting the practice of medicine. The purpose of this inspection was to determine the validity of the allegations.

We were able to determine that certain unlicensed physicians at the system functioned outside their scopes of practice, engaging in activities which may constitute the practice of medicine. The lack of adequate documentation in the medical record in many instances did, however, impair our ability to determine the extent and magnitude of the problem.

The lack of a clearly defined, published Veterans Health Administration (VHA) policy regarding educational verification of unlicensed physicians functioning as research assistants is also symptomatic of the lack of policy and guidance in this area on a national level. While representatives from the Office of Research and Development maintain that VA's web-based guidance has the full force and effect of policy, the Office of Research Oversight does not consider that this guidance can be enforced as a matter of regulatory compliance. Further, the lack of general guidance on the scope of practice that is appropriate for unlicensed physicians creates a situation in which individual facilities must make the determination of what activities constitute the practice of medicine, creating the potential for widespread variability and inconsistency within VHA. We were unable to find an instance in which this issue had been addressed as a matter of Federal policy.

The system's initiative in deciding that any procedure requiring informed consent is by definition beyond the scope of practice for a research assistant is an important first step in determining the appropriate dimensions of an unlicensed physician's scope of practice. However, it does not address the appropriateness of other activities, such as physical examinations, alteration of medications, and the assessment of acute health problems.

We recommended that management: (1) develop and implement policies to minimize the risk that research subjects might confuse unlicensed physician research assistants with licensed clinicians; (2) ensure research personnel function within their scope of practice granted by the system; and (3) require sufficient documentation in the medical record of research visits such that the Research and Development Committee at the system can determine whether research personnel are functioning within their scopes of practice as required by VA policy.



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

TO: Director, Veterans Integrated Service Network (10N17)

SUBJECT: Healthcare Inspection – Alleged Practice of Medicine by Unlicensed Research Assistants, South Texas Veterans Health Care System, San Antonio, Texas

Purpose

The Department of Veterans Affairs, Office of Inspector General (OIG), Office of Healthcare Inspections (OHI), reviewed allegations that unlicensed physicians hired as research assistants at the South Texas Veterans Health Care System (the system) in San Antonio engaged in clinical activities constituting the practice of medicine. The purpose of this inspection was to determine the validity of the allegations.

Background

Research is one of the core missions of the Veterans Health Administration (VHA). Every research project in VHA is headed by a principal investigator (PI) who is ultimately responsible for protecting the rights of human research subjects involved in the project in accordance with the Common Rule (45 C.F.R.¹ 46 Subpart A) as adopted by VA at 38 C.F.R. 16.

The Common Rule is a set of Federal regulations which contains numerous requirements for the protection of human subjects, including the requirement that all researchers (known as investigators) have the requisite skills, training, and experience to conduct the research. PIs often have several other investigators working with them on a given project. Investigator refers to “an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB.”² An Institutional Review Board (IRB) is a committee of researchers and community members that is charged with ensuring the protection of human subjects at a given facility. VA facilities

¹ C.F.R. is the Code of Federal Regulations, which codifies all rules of the executive departments and agencies of the federal government. It is divided into fifty volumes, known as titles.

² <http://answers.ohrp.hhs.gov>: FAQs for Investigators; Question: “Who are ‘investigators’?”

may utilize their own IRB to review research involving human subjects or they may use an affiliated university's IRB, providing that the university IRB complies with all applicable VA-specific regulations.

Investigators may include research assistants who are hired to perform certain tasks related to research projects. Examples of these tasks would include obtaining informed consent from individuals participating in a research project, asking research subjects questions related to the research, and compiling and managing data relevant to the projects. Research assistants may be licensed personnel, such as nurses or respiratory therapists, or they may be unlicensed, such as individuals who obtain medical degrees in other countries but are not eligible for licensure as physicians in the United States. Regardless of their licensure status, they are considered investigators within the meaning of the Common Rule if they are engaged in human subjects research. They function under a scope of practice which describes tasks they can perform and is specific to the individual and the facility involved.

A facility may not, however, grant to an unlicensed individual a scope of practice permitting them to engage in activities that would otherwise require licensure. However, we were unable to locate any specific guidance from the National Institutes of Health (NIH), the National Science Foundation, or from any other Federal agency specifically addressing the appropriate scope of practice for unlicensed physicians functioning as research assistants. Activities constituting the practice of medicine are defined by state law, and as such vary from state to state. As an example, Texas State law defines "practicing medicine" to mean "the diagnosis, treatment, or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions, by a person who: (A) publicly professes to be a physician or surgeon; or (B) directly or indirectly charges money or other compensation for those services." One reason why licensure is required of such individuals would be to ensure that they have appropriate credentials to practice medicine.

Because unlicensed physicians are not licensed independent healthcare providers or individuals claiming licensure, registration, or certification, it is unclear whether the provisions of VHA Directive 2006-067, *Credentialing of Health Care Professionals*,³ or the requirements of VHA Handbook 1100.19, *Credentialing and Privileging*,⁴ apply to the process of granting these individuals a scope of practice. VA's Office of Research and Development (ORD) however, in a January 22, 2007, ORD Field Conference Call, stated that VHA Directive 2006-067 did apply "to all research staff including research administrative personnel, who by the nature of their position have the potential to assume patient care-related duties."

³ Issued December 22, 2006.

⁴ Issued March 6, 2001.

This communication further provided an example of an unlicensed physician performing phlebotomy, stating that the unlicensed physician would be required to meet all the requirements that a phlebotomist would have to meet. ORD also stated that it would now require that unlicensed physicians among others be credentialed through VetPro. VetPro is a computer program used in the VA for the credentialing of licensed independent health care providers. It contains information on licensure, disciplinary actions, and education.

In addition, VHA published Handbook 1200.1, *The Research and Development Committee Handbook*, on March 2, 2007. This handbook requires the facility Research and Development (R&D) Committee to conduct an annual quality assurance review of research employees involved in human subjects research “to ensure the employees are working within their scopes of practice and their privileges allowed by the facility’s By-laws and granted to them by the facility.”

While the publication of this handbook and the conference call occurred after the date of the events involved in this review, ORD’s 2003 web-based guidance applied to the credentialing process for research assistants and was in effect at the time of the activities under review. This guidance was published following a 2003 Research Stand Down initiated as a result of significant human subjects protection issues. The 2003 Research Stand Down requirements applicable to credentialing and privileging required that any research personnel not considered to be independent providers would have their credentials confirmed, a scope of work established, and a record of the scope of work maintained for review.

The web-based 2003 *Guidance on Verifying the Credentials of All Individuals Involved in Human Subjects Research* created by ORD stated that all individuals engaged in human subjects research who are not licensed independent health care providers must provide the research service or facility director’s designee with a dated copy of a curriculum vitae or resume, with an education verification form, and with a completed Standard Form (SF) 85 Questionnaire for Non-Sensitive Positions. The principal investigator provides scopes of practice for research staff under his or her supervision.

The requirement for verification of education applies to all “education that leads to a degree or certification, and any education or training that is relevant to the activities performed by the employee.” In addition, the guidance requires that all documents pertaining to credentialing be maintained and retrievable in the research office unless the individual is subject to credentialing and privileging by another medical center office. As guidance posted on ORD’s website, this requirement does not have the full force and effect of policy.

During the course of a hotline inspection at another facility, we received allegations that an unlicensed physician performed muscle biopsies at the South Texas Veterans Health Care System, San Antonio, TX. The system has more than 150 investigators engaged in

over 500 research projects. The R&D program occupies 28,000 square feet in the facility and includes a NIH-funded General Clinical Research Center and a VA-affiliated research nonprofit corporation. The system, through a Memorandum of Understanding, utilizes the affiliated university's IRB to review its research.

We notified the system of the allegation and received a timely response from the system Director on December 20, 2006, acknowledging that the unlicensed physician identified performed 11 muscle biopsies as part of two diabetes studies. The system supplied us with supporting documentation of these activities. We subsequently scheduled an inspection at the system. Because this was the second facility identified as potentially having unlicensed physicians practicing medicine, we also initiated a Combined Assessment Program (CAP) Focused Review, which began June 1, 2007, to evaluate whether this problem existed at additional facilities.

On February 7, 2007, prior to the date of our inspection, the system issued Research Service Memorandum 07-33. This memorandum prohibits unlicensed personnel, including unlicensed physicians, from performing procedures which would require consent of the patient in a standard (non-research) patient care setting. This policy would not, for example, apply to phlebotomy because it is not a procedure typically requiring written informed consent of the patient. The Associate Chief of Staff (ACOS) for R&D and Chief of Staff (COS) are required to review scopes of practice and approve the requested roles and responsibilities.

The system had implemented a new scope of practice form for unlicensed research personnel prior to the date of our inspection. The new form does not permit a PI obtaining a scope of practice for a research assistant to request that the assistant be permitted to perform activities the system deemed to constitute the practice of medicine. However, because most activities reviewed in this inspection occurred during calendar years 2005 and 2006, we reviewed them under VHA and system policies existing at that time, noting when more recent events warranted review of newer initiatives.

Scope and Methodology

To investigate the allegations, we obtained documentation pertaining to 54 protocols identified by the system that involved unlicensed physicians functioning as research assistants. Twenty unlicensed physicians had scopes of practice at the system at the time of our review. We selected 3 protocols which required muscle biopsies and obtained from the system a list of 10 patients who signed informed consent forms for each protocol and a copy of their written informed consent documents. All three of these protocols involved the same department. Therefore, we subsequently selected three additional protocols not involving invasive procedures or the same department to review for comparative purposes. Because one of the three protocols identified enrolled only

two patients, we subsequently added a fourth protocol to the group of protocols not involving invasive procedures.

We reviewed medical records for patients who consented for these protocols as well as R&D Committee files for those protocols. We also reviewed scopes of practice for all unlicensed physicians involved. We conducted a site visit from May 21–25, 2007; we interviewed unlicensed physician research assistants, principal investigators, ACOS/R&D, the COS, representatives from the credentialing and privileging office, personnel, the R&D office, the affiliated university, and the system’s legal counsel.

We also piloted the CAP Focused Review at the system prior to the date of our inspection. For the pilot project, we reviewed scopes of practice, medical records, and consent forms for patients enrolled in six other protocols. The results of that pilot review are included below.

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

Inspection Results

Issue 1: Whether Unlicensed Physicians Performed Activities Constituting the Practice of Medicine.

We substantiated that unlicensed physicians functioning as research assistants performed activities that could constitute the practice of medicine. Part of the Texas definition of practicing medicine is also the requirement that individuals present themselves as physicians. We found during the course of our inspection that unlicensed physicians at the system signed consent forms with the suffix M.D. added to their name and wore name tags with the designation M.D. after their name. Progress notes authored by nurses indicated that the “study doctor,” referring to an unlicensed physician, performed a certain procedure. In addition, in at least one case, the consent form itself indicated that activities performed by an unlicensed physician would be performed by a “study doctor.” These activities could constitute representing oneself as a physician, although we note in fact that the individuals involved in this complaint are physicians, but they are not licensed in the United States.

The activities possibly constituting the practice of medicine performed by unlicensed physicians at the system include performing muscle biopsies, physical examinations, treating acute medical problems, and giving medications. In addition to the unlicensed physician named in the original complaint, four other unlicensed physicians also performed muscle biopsies on patients. We also identified numerous instances in which progress notes in the medical record were not co-signed by any licensed physician. These notes stated that unlicensed physicians conducted history and physical examinations, evaluated patients for acute problems such as chest pain, determined

whether the patient met study inclusion or exclusion criteria, and dispensed or altered medication dosages in accordance with the protocols.

Review of Protocols Involving Muscle Biopsies.

Protocols 6, 8, and 11 involved unlicensed physicians and required muscle biopsies as part of the protocol. We reviewed each of the protocols to determine the nature and extent of unlicensed physician interactions with human subjects.

Protocol 6

Two unlicensed physicians (UP 1 and 2) worked on Protocol 6, which studied factors contributing to insulin resistance in human muscle. We reviewed the medical records of 10 patients who consented for this protocol. Two patients were determined not to qualify for the study, one withdrew from the study, and three patients had no notes in the electronic medical record referencing Protocol 6. One of these three patients did have notes completed by an unlicensed physician that referenced another research protocol. In that patient's records, we noted that the unlicensed physician conducted three muscle biopsies, evaluated the patient for chest pain (the progress note was not co-signed by any licensed physician), and performed a history and physical for an inpatient stay required for the protocol. That history and physical was co-signed 43 days after the date performed.

Four of the 10 patients qualified and enrolled in Protocol 6. Of those four patients, two received muscle biopsies performed by unlicensed physicians. A third patient was evaluated for nausea and vomiting by an unlicensed physician. The note reflected that the patient was diagnosed with food poisoning, and labs were ordered. The note was not co-signed. A licensed physician acknowledged receipt of the note 2 days later. We found only two notes for the fourth patient, which included a history and physical conducted by an unlicensed physician. A licensed physician acknowledged receipt of the note the next day.

Protocol 11

The system reported that one unlicensed physician (UP 3) worked on Protocol 11. Protocol 11 involved the study of how excessive body fat impairs the way the body uses glucose. The system provided us with a list of 10 patients for this protocol. Four of the 10 patients were enrolled in Protocol 11; the remaining 6 were enrolled in another protocol (Protocol 11a) involving UP 3. UP 3 performed muscle biopsies on three of the four enrolled patients and completed the history and physical exam note for the fourth patient, whose muscle biopsy was performed by an attending physician. In one case, a fifth year endocrinology resident wrote the note but stated that UP 3 performed the biopsy. We also found that UP 1 performed muscle biopsies on one of the four patients

for this protocol as well. The information provided to us by the system did not list UP 1 as working on this protocol.

UP 3 performed muscle biopsies on five of the six patients enrolled in Protocol 11a. For one of these patients, UP 3 also evaluated a low potassium level and instructed the patient to increase the potassium in their diet. For the sixth patient, an attending orthopedic surgeon performed a fat biopsy. The patient experienced bruising subsequent to the biopsy, which was evaluated on two occasions by UP 3. The medical record reflects that an attending physician acknowledged receipt of the note but did not co-sign either note or independently evaluate the patient on those days.

Protocol 8

Protocol 8 involved the study of how individuals with normal weights respond to insulin. We reviewed records for 10 patients enrolled in this study. UP 1, UP 3, and a fourth unlicensed physician (UP 4) performed muscle biopsies on 5 of the 10 patients. One patient developed a hematoma at the site of the biopsy which was evaluated by UP 1. The note was not co-signed. UP 1 and UP 4 also performed history and physical exams. The medical record for 2 of the 10 patients contained no research notes despite the presence of signed informed consents for these patients indicating that they enrolled in the study.

Review of Protocols Not Involving Muscle Biopsies.

Because Protocols 6, 8, and 11 involved the same procedure and the same department, we evaluated an additional 4 protocols identified by the system that involved unlicensed physicians, each from a different department. These protocols did not routinely require procedures other than phlebotomy.

Protocol 52

Protocol 52 involved studying healthy volunteers to measure the brain levels of a certain chemical that may be related to the cause of bipolar disorder. Of the 10 patients identified by the system as participants in this study, the system advised us that 6 were not enrolled. We could find no electronic medical record for five of the six patients. The sixth patient had one note indicating that he signed a copy of the informed consent. However, there were no additional notes. Of the remaining four patients, no progress notes at all existed in the medical record for two of them. The remaining two had no notes written by unlicensed physicians or containing any information suggesting unlicensed physicians performed any activity that might constitute the practice of medicine.

Protocols 27 and 30

Protocol 27 involved a comparative evaluation of inhaled medications for the treatment of chronic obstructive lung disease. The system indicated that only two patients were participating in this study. Therefore, we looked at a second study from the same department which attempted to identify new ways to monitor the progression of chronic obstructive lung disease. All research notes for the two patients enrolled in Protocol 27 were completed by registered nurses. For Protocol 30, we evaluated the medical records of 10 patients. One patient had no research notes documented in the electronic medical record. There was no evidence that an unlicensed physician engaged in the practice of medicine in the medical records of a second patient. UP 2 participated in the care of the remaining eight patients. He completed notes for all eight after November 1, 2006, that contained the following language:

PROCEDURES PERFORMED IN RESEARCH UNIT: Consent, Medical History including concurrent medications and COPD exacerbation assessment, Vital Signs, Resting Oxygen Saturation, Physical Exam, Study Questionnaires, Lung Function Testing, Exhaled CO Test, Body Fat Measurement, Six Minute walk test and labs per protocol.

The progress notes in the electronic medical record did not contain the results of all of these tests nor did they provide the names of the providers conducting the tests. We therefore could not determine from the medical record whether UP 2 engaged in activities constituting the practice of medicine related to this protocol. However, we found that failure to document physical exam findings and other clinical results in the medical record as described above constituted inadequate documentation, as it may not permit the communication of clinically relevant laboratory results to other health care providers.

Protocol 38

Protocol 38 studied patients receiving chemotherapy and stem cell transplantation to identify the incidence and factors associated with developing oral mucositis. The medical records of 3 of the 10 patients we reviewed for this protocol contained no research notes. The remaining seven each contained a single research note stating that the patient had agreed to participate in the study. The consent forms for the study stated that the patient would be evaluated by a physician and nutritionist to establish oral and nutritional status before receiving high dose chemotherapy. Then, after receiving the transplant, the patient would be evaluated three times a week to note the presence of redness or ulcerations in the mouth indicating mucositis. We could not locate documentation of these visits and evaluations in the electronic medical record. We therefore can make no determination as to the nature or extent of unlicensed physician involvement, if any, in this protocol based upon the absence of documentation in the medical record.

Other Protocol Reviews Performed During the Course of the CAP Pilot.

During the course of the CAP pilot review, we examined medical records from patients enrolled in Protocols 1, 2, 3, 4, 5, and 20. We were unable to locate any electronic medical records for research visits for Protocol 20. Protocols 1–5 utilized the services of six unlicensed physicians not involved in the protocols previously discussed. In Protocols 1 and 5, we found evidence that unlicensed physicians altered medications. In Protocol 1, two unlicensed physicians interpreted blood sugar values and increased insulin dosages. These notes were not co-signed by a licensed physician. In Protocol 5, an unlicensed physician provided new medication to the patient and advised the patient to resume taking a study medication after completion of the protocol. In all five protocols, unlicensed physicians conducted physical examinations. In many instances, these notes were not co-signed by any licensed physician.

Issue 2: Whether These Activities Complied with VHA and the System Guidance and Policies.

Whether Unlicensed Physicians at the System Were Functioning Within Their Scopes of Practice.

After identifying the activities of unlicensed physicians functioning as research assistants, we then sought to determine whether these activities were consistent with their scopes of practice. We concluded that the work of the unlicensed physicians involved in this review appeared to exceed their scopes of practice. UP 1 worked under an undated document labeled scope of work/position description during the time frame in which UP 1 performed the above activities. However, this document permitted UP 1 to have only non-direct human subject involvement. UP 1's performance of muscle biopsies and physical examinations as identified above constituted direct human subject contact and were therefore beyond the scope of work granted to UP 1 by the system.

UP 2's scope of practice permitted UP 2 to consent patients, initiate consultations, special tests and studies following the PI's approval, perform venipuncture, and administer intravenous (IV) solutions and medications. It did not reference the performance of any other procedures. We therefore find UP 2's performance of muscle biopsies was beyond the scope of practice granted by the system to this individual. We further note that the scope of practice permitting unlicensed personnel to administer IV medications is not appropriate.

UP 3 and 4's effective scopes of practice permitted them to obtain informed consent, to perform insulin clamp and oral glucose tolerance tests, and to administer IV medications. It did not, however, permit muscle biopsies nor did it specify that UP 3 or UP 4 could perform physical exams. The language permitting UP 3 and 4 to determine study eligibility criteria specifically stated this would be accomplished "by reviewing patient

medical information or interviewing subjects.” There is no reference to conducting physical examinations.

Whether the Credentials of Unlicensed Physicians Were Appropriately Verified in Accordance with ORD Guidance and System Policies Regarding the Hiring of Without Compensation (WOC) Employees.

While these four unlicensed physicians each had a scope of practice in effect at the time of the activities reviewed, as well as completed SF 85s in accordance with ORD’s web-based guidance, we did not find uniform documentation of educational verification. We were told that the system verified the education of unlicensed WOC physicians by obtaining a letter from their institution or documenting three unsuccessful attempts at obtaining it. The system informed us that institutions in other countries often did not reply to their requests or requested fees for verifying education. There is also no official educational verification form adopted by VA for this purpose. As a result, attempts at educational verification may be recorded in an inconsistent manner. Further, while ORD guidance requires educational verification, we could find no VHA policy clearly requiring educational verification for unlicensed physicians functioning as research assistants.

Documentation Issues Identified During the Course of Our Inspection

In our review of the medical records relevant to this inspection, we noted inconsistent and incomplete documentation of research visits in the electronic medical record. VHA’s *Health Information Management and Health Records* policy is found in VHA Handbook 1907.1. The version in effect at the time of the activities described in this report stated: “[p]atient records must be timely, relevant, necessary, complete and authenticated.” It further stated that “[c]ompleteness implies that all required data is present and authenticated; all final diagnoses are recorded without use of abbreviations....” We noted that VHA revised Handbook 1907.1 issued on August 25, 2006, explicitly requires that a record be created when the research requires the use of any clinical resources such as laboratory or pharmacy. Further, for patients enrolled in an approved research protocol, the electronic medical record must contain a copy of the signed and dated consent, the initial enrollment progress notes and other applicable progress notes, information on possible drug interactions of investigational drugs being administered, and information on all research interventions.

Despite the fact that some of the protocols reviewed collected clinically relevant information, such as the presence or absence of mucositis in patients receiving chemotherapy or resting oxygen saturations in patients with chronic obstructive pulmonary disease, and in some cases involved the administration of medications, we could not locate documentation regarding these visits or the results of all assessments or testing in the electronic medical record. Failure to document clinically relevant information obtained during research visits violates the provisions of VHA Handbook

1907.1 and may compromise the ability of all providers involved in the patient's care to assess the current status of the patient's health problems. Further, it could prevent compliance with the requirements of VHA Handbook 1200.1,⁵ which mandates that the R&D Committee annually be provided with enough information to determine whether all employees are working within their scopes of practice. In some cases, the medical records we reviewed did not contain sufficient information to permit determination of whether the individuals involved were functioning within their scope of practice.

Conclusion

We were able to determine that certain unlicensed physicians at the system functioned outside their scopes of practice, engaging in activities which may constitute the practice of medicine. The lack of adequate documentation in the medical record in many instances did, however, impair our ability to determine the extent and magnitude of the problem.

The lack of a clearly defined, published VHA policy regarding educational verification of unlicensed physicians functioning as research assistants is also symptomatic of the lack of policy and guidance in this area on a national level. While representatives from ORD maintain that the Department's web-based guidance has the full force and effect of policy, the Office of Research Oversight does not consider that this guidance can be enforced as a matter of regulatory compliance. Further, the lack of general guidance on the scope of practice that is appropriate for unlicensed physicians creates a situation in which individual facilities must make the determination of what activities constitute the practice of medicine, creating the potential for widespread variability and inconsistency within VHA. We were unable to find an instance in which this issue had been addressed as a matter of Federal policy.

The system's initiative in deciding that any procedure requiring informed consent is by definition beyond the scope of practice for a research assistant is an important first step in determining the appropriate dimensions of an unlicensed physician's scope of practice. However, it does not address the appropriateness of other activities, such as physical examinations, alteration of medications, and the assessment of acute health problems. We therefore made the following recommendations:

Recommendations

Recommendation 1. We recommended the VISN Director ensure that the System Director develops and implements policies to minimize the risk that research subjects might confuse unlicensed physician research assistants with licensed clinicians.

⁵ VHA Handbook 1200.1, *The Research and Development Committee Handbook*, issued March 02, 2007.

Recommendation 2. We recommended the VISN Director require that the System Director ensures research personnel function within their scope of practice granted by the system.

Recommendation 3. We recommended the VISN Director ensure that the System Director requires sufficient documentation in the medical record of research visits such that the Research and Development Committee at the system can determine whether research personnel are functioning within their scopes of practice as required by VHA Handbook 1200.1.

Comments

The VISN and System Directors agreed with the findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 13–19, for the full text of comments.) We will follow up on the planned actions until they are completed.

(original signed by:)

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

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: July 10, 2007

From: VISN Director

Subject: **Healthcare Inspection - Alleged Practice of Medicine by
Unlicensed Research Assistants, South Texas Veterans
Health Care System, San Antonio, Texas**

To: Director, Ms. Peggy Seleski, Management Review Service

1. Attached is the response from the South Texas Veterans Health Care System, San Antonio, to the draft report from the Hot Line Review conducted at that facility May 21-25, 2007.
2. The medical center carefully reviewed all items identified as opportunities for improvement and has concurred in all the recommendations that were made. The Network concurs with the recommendations contained in the report.
3. If you have any questions, or need additional information, please contact Deborah Antai-Otong, 817 385 3794.

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

The following VISN Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended the VISN Director ensure that the System Director develops and implements policies to minimize the risk that research subjects might confuse unlicensed physician research assistants with licensed clinicians.

Concur **Target Completion Date:** Aug. 1, 2007

1. The HCS has already begun a process that is outlined in this report that includes working with the University Health Science Center at San Antonio IRB of record to adopt the STVHCS' scope of practice and policy to ensure that research staff at both facilities functions under the same requirements. In addition, STVHCS will establish a review and approval process of all scopes of practice for research staff that will include the IRB and R&D pre-review checklists.

2. VISN 17 will review the revised policy and scope of practice and monitor the implementation process to ensure it includes a statement prohibiting Unlicensed Physicians from using MD designation, to all VHA investigators, clinical research coordinators, Research and Development Committee members and the General Clinical Research Center, staff and administration.

Recommendation 2. We recommended the VISN Director require that the System Director ensures research personnel function within their scope of practice granted by the system.

Concur **Target Completion Date:** Sept. 15, 2007

1. The HCS is in the process of developing a Scope of Practice Policy that specifically addresses physical examination, alteration/adjustment of medication doses and assessment of acute health problems to be performed by licensed providers only. The Compliance Office will conduct focused reviews of unlicensed physician's scope of practice to ensure compliance with this policy.

2. VISN 17 will review the revised Scope of Practice policy and monitor the implementation process through monthly reports from the Compliance Office concerning results of focused reviews.

Recommendation 3. We recommended the VISN Director ensure that the System Director requires sufficient documentation in the medical record of research visits such that the Research and Development Committee at the system can determine whether research personnel are functioning within their scopes of practice as required by VHA Handbook 1200.1.

Concur **Target Completion Date:** Sept. 15, 2007

As noted in the response from the HCS, the Associate Chief of Staff for Research will develop a policy to address all aspects of appropriate documentation of research subject visits in the medical record. The ACOS for Research and OIT staff will develop templates and train researchers in their use to ensure appropriate medical documentation.

VISN 17 will obtain supporting documents, including templates and staff training, and monitor implementation of these processes through monthly reports of results from focused reviews of research subjects' medical record documentation conducted by the Compliance Office.

System Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: July 10, 2007

From: System Director

Subject: **Healthcare Inspection - Alleged Practice of Medicine by
Unlicensed Research Assistants, South Texas Veterans
Health Care System, San Antonio, Texas**

To: Network Director, VISN 17 (10N17)

Attached is South Texas Veterans Health Care System's (STVHCS) response to the recommendations in the subject healthcare inspection report.

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

The following System Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended the VISN Director ensure that the System Director develops and implements policies to minimize the risk that research subjects might confuse unlicensed physician research assistants with licensed clinicians.

Concur **Target Completion Date:** Aug. 1, 2007

1. The University Health Science Center at San Antonio. (UTHSCSA-STVHCS' IRB of record) is adopting the STVHCS' scope of practice and policy, so that research staff at both facilities will have the same requirements.
2. The Vice President for Research (VPR) and the Dean of the Medical School of UTHSCSA will send an announcement to their IRB and faculty delineating the new requirements.
3. The Associate Chief of Staff for Research (ACOS for R) will distribute and communicate the revised policy and scope of practice (which will include a statement prohibiting Non licensed Physician's from using MD designation), to all VHA investigators, clinical research coordinators, Research and Development (R&D) Committee members for review and approval, and to the General Clinical Research Center (GCRC), staff and administration.
4. Review and approval of all scopes of practice for research staff will be added to both the IRB and R&D pre-review checklists.

5. The Compliance Office will include as part of their auditing of research documentation, review of medical record documentation to ensure that MD designation is used appropriately.

Recommendation 2. We recommended the VISN Director require that the System Director ensures research personnel function within their scope of practice granted by the system.

Concur **Target Completion Date:** Sept.15, 2007

1. Enhance Scope of Practice Policy to specifically address that physical examination, alteration/adjustment of medication doses and assessment of acute health problems may not be performed by unlicensed providers.

2. Communicate to all involved in Research at UTHSCA and STVHCS as noted in Recommendation 1.

3. The Compliance Office will conduct a focused review of unlicensed physician's scope of practice.

Recommendation 3. We recommended the VISN Director ensure that the System Director requires sufficient documentation in the medical record of research visits such that the Research and Development Committee at the system can determine whether research personnel are functioning within their scopes of practice as required by VHA Handbook 1200.1.

Concur **Target Completion Date:** Sept. 15, 2007

1. The Associate Chief of Staff for Research (ACOS for R) will develop a policy to address all aspects of appropriate documentation of research subject visits in the medical record.

2. The Associate Chief of Staff for Research (ACOS for R) will distribute and communicate the new policy to all VHA investigators, clinical research coordinators, Research and Development (R&D) Committee members for review and approval, and to the General Clinical Research Center (GCRC), staff and administration.

3. The ACOS for Research and OIT staff will develop templates and train researchers in their use to enhance appropriate medical record documentation.

4. The ACOS for Research and Chief, Medical Administrative Service (MAS) will develop a process for scanning VA1090-12's into research subject's medical records.

5. The Compliance Office will conduct a focused review of research subject's medical record documentation.

OIG Contact and Staff Acknowledgments

OIG Contact	Andrea Buck, M.D., J.D. Medical Consultant Office of Healthcare Inspections
Acknowledgments	Wilma Reyes, Healthcare Inspector Marisa Casado, Healthcare Inspector Karen Moore, Healthcare Inspector

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, Veterans Integrated Service Network 17
Director, South Texas Veterans Health Care System

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and
Related Agencies
House Committee on Oversight and Government Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and
Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget
U.S. Senate: John Cornyn, Kay Bailey Hutchison
U.S. House of Representatives: Charles Gonzalez, Lamar Smith, Ciro Rodriguez, Henry
Cuellar, Solomon Ortiz, Ron Paul, Lloyd Doggett, Ruben Hinojosa

This report is available at <http://www.va.gov/oig/publications/reports-list.asp>.