Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Quality of Care in the Operating Room at the Overton Brooks VA Medical Center, Shreveport, Louisiana

Report No. 06-01458-194 **August 18, 2006**

VA Office of Inspector General
Washington, DC 20420

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

Executive Summary

During the week of May 1–4, 2006, the Office of Inspector General (OIG) conducted an inspection of the Overton Brooks VA Medical Center (OBVAMC), Shreveport, LA, to investigate the allegations made by an anonymous complainant to the Hotline Section. The complainant alleged that a Gastro-Intestinal (GI) physician was not priviliged to perform a procedure to drain a pancreatic cyst, along with other allegations.

We found that three of the four allegations were not substantiated. However, we substantiated the allegation that the GI physician was not privileged in Endoscopic Ultrasounds (EUS) at the time the allegation was made. We also found that a peer review related to the case was not completed within 45 days as required by VHA directives.

We identified opportunities to improve processes and made recommendations that:

- Physicians performing EUS are privileged according to VHA Directive 1100.19.
- Peer reviews are performed within 45 days as required by VHA Directive 2004-054.
- The peer review process in the case identified in the complaint is completed.
- Complications derived in procedures performed in GI lab are referred to Risk Management for review.

The VISN and Medical Center Director agreed with the findings and recommendations and provided acceptable improvement plans. We will follow up on planned actions until they are completed.

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

TO: Director, Veteran Integrated Service Network (10N16)

SUBJECT: Quality of Care in the Operating Room at the Overton Brooks VA Medical Center, Shreveport, LA

1. Purpose

The Office of Inspector General (OIG) conducted this inspection in response to multiple allegations by an anonymous complainant to the Hotline Section alleging poor quality of care, inadequate credentialing and privileging (C&P), violations of patient confidentiality, and violations of physician time and attendance (T&A) requirements in the Gastroenterology Section at the Overton Brooks VA Medical Center (OBVAMC), Shreveport, LA.

2. Background

Over 131,000 veterans reside within OBVAMC's primary service area, which encompasses 15 northeast Texas counties, 5 southwestern Arkansas counties, and 12 northwest Louisiana parishes. OBVAMC is affiliated with the Louisiana State University (LSU) School of Medicine in Shreveport and has sharing agreements with the 2nd Medical Group at Barksdale Air Force Base and the LSU Health Sciences Center. The OBVAMC provides tertiary care in medicine, surgery, neurology, and psychiatry, as well as a broad spectrum of outpatient services. The Ambulatory Care Program provides primary care services at the OBVAMC and at community based outpatient clinics in Monroe, Louisiana; and Texarkana and Longview, Texas.

An anonymous complainant to the Hotline Section alleged that an OBVAMC Gastrointestinal (GI) physician:

- Performed surgery to drain a pancreatic cyst without the necessary competence and without the patient's consent.
- Performed certain GI procedures without the appropriate privileges.
- Improperly accessed a VA patient database and used patient information without proper authorization.

- Abused VA T&A requirements by using time allocated for consults for research, referring patients to non-VA physicians in order to use clinical time for research, and using VA time for unauthorized educational purposes.

3. Scope and Methodology

We conducted a site visit at the OBVAMC in May 2006. We reviewed VHA and policies and procedures pertaining to quality management/patient safety, C&P, and time and attendance. On site, we interviewed clinicians and management officials as needed to investigate the allegations. We examined internal documents and patient records, including quality of care/patient safety management reports, C&P records, research administration documents, and time and attendance reports.

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

4. Inspection Results

Case Review:

The complainant alleged that the physician did not have the necessary professional competence to perform endoscopic ultrasound-related procedures[1] (EUS). The complainant provided a case with specific patient identifiers in which the physician performed an EUS-related procedure which resulted in a complication. In this case, the complainant alleged that, on February 8, 2006, during EUS-guided placement of a gastrostomy tube for pancreatic pseudocyst drainage, the physician perforated the patient's stomach.

We found the patient named by the complainant did not have an endoscopic procedure on February 8, 2006. However, another patient did have an EUS-guided gastrostomy tube drainage of a pancreatic cyst on that date. In this case, the patient had a large cyst adjacent to the posterior wall of the stomach. The attending physician for the procedure was the physician named in the allegation. There was a question in the medical record as to whether the cyst represented a pancreatic pseudocyst[2] or a mesenteric cyst.[3] A pseudocyst would be appropriate for endoscopic drainage, while a mesenteric cyst would generally require surgical excision.

[1] EUS is a procedure that combines endoscopy and ultrasound to obtain images and information about the digestive tract and the surrounding tissue and organs. In EUS, a small ultrasound transducer is installed on the tip of the endoscope, allowing the transducer to get close to the organs inside the body so the resultant ultrasound images are often more accurate and detailed than ones obtained by traditional ultrasound.
[2] A pancreatic pseudocyst is a collection of tissue, fluid, debris, pancreatic enzymes, and blood that can develop after acute pancreatitis.
[3] A mesenteric cyst is a congenital thin-walled cyst of the abdomen between the leaves of the mesentery, which may be of wolffian or lymphatic duct origin; as it enlarges, it may cause colicky pain and intestinal obstruction.

The physician obtained the patient's consent to an endoscopic drainage procedure. Although the consent form did not specify that an open surgical procedure would be necessary to excise a mesenteric cyst, the consent form did state that the patient consented to "such additional operations or procedures as are found to be necessary or desirable." The attending physician stated that he also verbally informed the patient of the possible need for surgery.

The procedure was done in an operating room designated for special gastroenterological procedures in case surgery was needed, rather than in the endoscopy lab. The gastroenterologist discussed the case with surgery prior to the procedure. The surgical attending physician for the case indicated that he believed that endoscopic drainage was a reasonable initial approach in this case, considering that surgical team members attended the case as well. During the course of the procedure, the physician deployed a stent to maintain an opening for drainage; the stent recoiled into the cyst cavity and was lost. The physician terminated the endoscopic procedure and the surgical team converted to an open gastrostomy tube placement and repaired a small stomach perforation. The patient did well postoperatively and was discharged home without further complication.

Issue 1: Quality of Care/Patient Safety

We did not substantiate the complainant's allegations that an OBVAMC GI physician performed surgery on a patient without proper consent or that the physician performed the procedure incompetently. However, during our review of the quality of care and patient safety issues involved in this case, we found that OBVAMC did not perform a peer review related to this case within the required time frame.

The patient named by the complainant as the basis of his complaint did not have surgery on February 8, 2006, the day stated in the complaint. We concluded that the complainant had intended the allegations to relate to another patient who did have the procedures indicated in the complaint on that date. Accordingly, we reviewed the quality of care and patient safety issues related to that case.

We found that the GI physician obtained adequate patient consent in recognition of the risks associated with the endoscopic procedure as well as the possible need for surgery. The procedure was done in an operating room designated for special gastroenterological procedures rather than in the endoscopy lab. Surgical team members attended the case. During the course of the procedure, the physician deployed a stent to maintain an opening for drainage; the stent recoiled into the cyst cavity and was lost. The physician appropriately terminated the endoscopic procedure and the surgical team converted to an open gastrostomy tube placement with repair of a small stomach perforation. There were no post-surgical complications and the patient was properly discharged home.

We found that OBVAMC did not comply with VHA policy in performing a peer review related to this case. VHA Directive 2004-054 requires that peer reviews be performed

within 45 days after the related event. The GI procedure in this case was performed on February 8, 2006; the risk manager received notification on March 16 that the case involved complications requiring surgery; and the case was referred for external peer review on April 12, 2006. At the time of our inspection on May 1–3, external peer reviews had not been completed. We found that OBVAMC service chiefs or section chiefs do not routinely provide risk management personnel with complication rates or cases involving complications by service or by provider. Because the case was not identified by risk management for peer review purposes until March 16, 2006, a panel of individuals outside the medical center with expertise in pancreatic surgery and endoscopic ultrasound could not be assembled until April 12, 2006—63 days after the date of the occurrence.

Issue 2: Credentialing and Privileging

We substantiated that the GI physician was not properly privileged to perform EUS procedures at OBVAMC at the time he performed the EUS procedure on February 8, 2006. We did not substantiate the complainant's allegations that the GI physician performed endoscopic ultrasound procedures without the necessary professional competence.

VHA Handbook 1100.19 outlines the process for credentialing and privileging a provider to render medical or surgical services in a VHA facility. Credentialing refers to the process by which a physician is determined to have the appropriate licensure and board certification, if applicable, to provide patient care otherwise within the scope of the provider's licensure. Privileging refers to the procedures by which a facility determines that a provider has the relevant training, experience, and current competence to perform certain procedures at the facility.

VHA Handbook 1100.19 places responsibility on the provider to initiate a request for privileging. The service chief then reviews the request and can recommend approval, disapproval, or modification of the requested clinical privileges. After the service chief's review and recommendation, the request for privileges along with the appointment recommendation of the Professional Standards Board is submitted to the medical staff's Executive Committee for approval. Reprivileging occurs every 2 years through a similar process. A provider may request modification of clinical privileges at any time, providing that appropriate documentation of competence is included with the request. A query to the National Practitioner Database (NPDB) is required at the time of the request for additional privileges.

Our review of OBVAMC C&P records showed that the GI physician involved in the February 8, 2006, EUS procedure had not completed the appropriate privileging process as of that date. We also found that OBVAMC did not run the required NPDB query when the GI physician was re-privileged. During an interview with the C&P coordinator, we were told that the C&P forms utilized when that GI physician was privileged were

general privileging forms and did not include EUS procedures. Upon determining that there were two C&P forms, the C&P Coordinator presented these forms to Service Chiefs throughout the medical center for their decision on which form should be used for privileging. The form selected for GI included EUS as a privilege. The GI physician was properly privileged on April 12, 2006; before that date, he performed 130 EUS procedures at OBVAMC without being properly privileged. While we were onsite, we requested that the facility perform an NPDB query, which revealed no malpractice claims or adverse actions against the physician.

VA physicians are responsible for ensuring that they have the proper privileges to perform specific procedures at VA facilities. Therefore, despite the administrative oversight that resulted in the use of an incorrect form, the GI physician should have taken action to ensure that he was properly privileged before performing EUS procedures at OBVAMC.

Although he was not properly privileged, we found sufficient evidence in the C&P file for the facility to determine that the GI physician met competency requirements to perform EUS procedures. Our review of his education record showed that he had received the necessary training to perform EUS procedures. We also determined that he was privileged by the affiliate to perform EUS procedures as of February 2004.

Issue 3: Violation of Patient Confidentiality

We did not substantiate that the GI physician named in the complaint violated VHA policies or Federal regulations regarding use or disclosure of confidential patient information from the VISN patient data warehouse. The complainant alleged that the GI physician improperly accessed the VISN data warehouse and used confidential patient information for unauthorized research purposes. We found that the VISN and OBVAMC had adequate management controls to prevent improper access to the data warehouse, and the GI physician did not obtain any patient information improperly.

The VISN patient data warehouse maintains confidential patient information in a centralized location on VA patients treated by the VISN's clinical facilities. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, related Federal regulations, and VHA policy restrict disclosure of such information.[4] At the time of our review, VHA was still in the process of developing a national policy to govern access to confidential patient information contained in VISN patient data warehouses. We found that the VISN Clinical Director of Data Warehouse and OBVAMC Information Security

[4] The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provides comprehensive Federal protection for the privacy of personal health information. Research organizations and researchers may be covered by the HIPAA Privacy Rule for certain purposes; Standards for Privacy of Individually Identifiable Health Information (45 Code of Federal Regulations Parts 160 and 164) are the Federal regulations implementing the privacy requirements of HIPAA; VHA Handbook 1200.5 requires VA researchers to comply with HIPAA.

Officer (ISO) established a process to ensure compliance with the HIPAA and VHA policy until the national policy is issued. Individual researchers are not permitted to directly access the data warehouse; both the researcher's Institutional Research Board and OBVAMC Research and Development Committee must approve requests for patient information from the data warehouse. The OBVAMC ISO as well as the VISN Clinical Director of Data Warehouse must authorize each request to query the data warehouse; and only designated data warehouse personnel are permitted to run the queries. Our review of documentation of the GI physician's requests to access the data warehouse showed that he followed proper procedures and channels. We also interviewed the Director of the Data Warehouse and the OBVAMC ISO, who confirmed that the GI physician followed proper procedures and was never improperly allowed access to restricted data.

Issue 4: Physician Time and Attendance Requirements

We did not substantiate that OBVAMC GI physicians misused time allocated for research or clinical practice or that they improperly referred fee basis consults to non-VA physicians.

Protected Research Time

We determined that both OBVAMC GI physicians had part of their work time properly allocated to research until January 2006. At that time, a new VHA pay bill for physicians was implemented and OBVAMC physicians, including the GI physicians, were changed to full-time clinical status with no protected research time.

Clinical Consults

We did not substantiate that the GI physician cancelled procedures in order to refer fee basis consults to private sector physicians so that he could spend more time on research. We reviewed GI consults and interviewed the Chief of Gastroenterology, the GI Administrative Assistant, the named GI physician, and the Chief of Medicine. We found that the process used for referring consults to non-VA physicians includes proper clinical and administrative controls and that the process was consistently followed. We also determined that, of 102 GI procedures cancelled since the start of fiscal year 2006, the GI physician named in the complaint was listed in only 2 cases.

Education

We did not substantiate that a GI physician abused T&A procedures for unauthorized education. We reviewed GI T&A logs, GI department schedules, and progress reports for the period from November 2005–April 2006. We determined that he was not given time off on Fridays or other scheduled days for educational or other personal purposes. The Chief of Medicine told us that a GI physician requested time off for continuing education, but the request was denied due to lack of coverage in the GI.

5. Conclusion

The GI physician named in the complainant was not properly privileged to perform EUS procedures at the time when he began to perform these procedures at the facility. However, his C&P file contained evidence of both his competence to perform these procedures and of privileges including these procedures at the affiliated university. A peer review related to the case described in the complaint was not performed in the time frame required by OBVAMC's internal policy for peer reviews. OBVAMC needs to review its C&P process to ensure that all OBVAMC physicians are properly credentialed and privileged. The peer review for the case described in the complaint needs to be completed timely, and the peer review process needs to be strengthened to include procedures to ensure the Risk Manager is timely informed of complications or events that may trigger peer reviews. We did not substantiate any other allegation.

6. Recommendations

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

1. Physicians performing EUS are privileged according to the Medical Center's policy and VHA Directive 1100.19.

2. The peer review process in the case identified in the complaint is completed.

3. Peer reviews are performed within 45 days as required by VHA Directive 2004- 054.

4. Complications arising from procedures performed in GI are timely referred to Risk Management for review.

7. Comments

The VISN and Medical Center Director agreed with the findings and recommendations and provided acceptable improvement plans. We will follow up until they are completed.

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

Appendix A

Director Comments

Department of Veterans Affairs **Memorandum**

Date: June 27, 2006

From: Director, Veteran Integrated Service Network (10N16)

Subject: **Quality of Care/Patient Safety, Credentialing and Privileging, Patient Confidentiality, and Physician Time and Attendance Issues in the Gastroenterology Division at the Overton Brooks VA Medical Center**

To: Director, Bay Pines Regional Office of Healthcare Inspection

I have reviewd the above mentioned report and concur with findings, recommendations and corrective actions.

(original signed by:)

Robert Lynch, M.D.

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(s) 1. The VISN 16 Director needs to ensure that the OBVAMC Director takes action to ensure Physicians performing Endoscopic Ultrasounds are privileged according to the Medical Center's policy and VHA Directive 1100.19.

Concur Target Completion Date:

1. Two Gastrology privileging forms were in use therefore the old form was deleted and only one Gastrology form is used which contains the Endoscopic Ultrasound as a Special Procedure. This privilege form is used during the initital credentialing and/or recredentialing process. A review was conducted by the Credentialing & Privileging Coordinator on all Gastrology physicians and all were found to contain the correct requested privilieges. Target Completion Date: April 12, 2006.

Recommended Improvement Action(s) 2. The VISN 16 Director needs to ensure that the OBVAMC Director takes action to ensure the peer review process in the case identified in the complaint is completed.

Concur Target Completion Date:

1. The initial peer reviews in this case have been received with review and concurrence of both the Chief of Staff and the Medical Center Director.

Target Completion Date: May 18, 2006

2. The final review of this case will be completed by the

Peer Review Committee within the required time limit of 120 days from

time of determination that a peer review was necessary.

Target Completion Date: July 18, 2006

Recommended Improvement Action(s) 3. The VISN 16 Director needs to ensure that the OBVAMC Director takes action to ensure peer reviews are performed within 45 days as required by VHA Directive 2004-054.

Concur Target Completion Date:

1. Risk Manager developed a formal process whereby peer reviews are reviewed weekly to track completion of deadlines for both the 45 day requirement (completion of the initial review) and the 120 day requirement (final Peer Review Committee review), and to ensure compliance with requirements per VHA Directive 2004-054 and Medical Center policy 11-03. (See attached.)

Target Completion Date: June 10, 2006

2. Risk Manager tracks and trends compliance with requirement deadlines, and reports information quarterly to the Peer Review Committee and the Medical Executive Committee. (See attached.)

Target Completion Date: July 20, 2006

Recommended Improvement Action(s) 4. The VISN 16 Director needs to ensure that the OBVAMC Director takes action to ensure complications arising from procedures performed in GI are timely referred to Risk Management for review.

Concur Target Completion Date:

1. A formal process has been developed whereby all surgical and invasive procedure providers are required to report complications to their respective Service Chiefs immedicately upon recognition of the adverse event or complication.

Target Completion Date: June 10, 2006

2. Service Chiefs, as part of the process, are required to report any adverse events/complications directly to the Risk Manager within 24 hours of discovery for further action. Since initiation of this process, three complications/adverse events have been reported to the Risk Manager.

Target Completion Date: June 15, 2006

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	Marisa Casado, Director Bay Pines Regional Office of Healthcare Inspections (727) 395-2416
Acknowledgments	Raymond M. Tuenge, Associate Regional Director Annette Robinson Andrea Buck, M.D. Triscia Weakley

Appendix C

Report Distribution

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