Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 07-02271-20

Combined Assessment Program Review of the VA Medical Center Louisville, Kentucky

November 6, 2007

Washington, DC 20420

Why We Did This Review

Combined Assessment Program (CAP) reviews are part of the Office of Inspector General's (OIG's) efforts to ensure that high quality health care is provided to our Nation's veterans. CAP reviews combine the knowledge and skills of the OIG's Offices of Healthcare Inspections and Investigations to provide collaborative assessments of VA medical facilities on a cyclical basis. The purposes of CAP reviews are to:

- Evaluate how well VA facilities are accomplishing their missions of providing veterans convenient access to high quality medical services.
- Provide fraud and integrity awareness training to increase employee understanding of the potential for program fraud and the requirement to refer suspected criminal activity to the OIG.

In addition to this typical coverage, CAP reviews may examine issues or allegations referred by VA employees, patients, Members of Congress, or others.

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Executive Summary

Introduction

During the week of August 13–17, 2007, the OIG conducted a Combined Assessment Program (CAP) review of the VA Medical Center (the medical center), Louisville, KY. The purpose of the review was to evaluate selected operations, focusing on patient care administration and quality management (QM). During the review, we also provided fraud and integrity awareness training to 33 medical center employees. The medical center is part of Veterans Integrated Service Network (VISN) 9.

Results of the Review

The CAP review covered seven operational activities. We made recommendations in two of the activities reviewed. For these activities, the medical center needed to:

- Improve peer review, root cause analysis (RCA), and operative and other invasive procedure review processes.
- Improve the process to permanently mark beds that pose an entrapment risk.

The medical center complied with selected standards in the following five activities:

- Computerized Patient Record System (CPRS) Business Rules.
- Dupont Community Based Outpatient Clinic (CBOC).
- Patient Satisfaction.
- Scope of Practice for Unlicensed Physicians.
- Surgical Care Improvement Project (SCIP).

This report was prepared under the direction of Victoria Coates, Director, Atlanta Office of Healthcare Inspections.

Comments

The VISN and Medical Center Directors agreed with the CAP review findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 12–15, for the full text of the Directors' 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

Introduction

Profile

Organization. The medical center is a tertiary care facility located in Louisville, KY, that provides a broad range of inpatient and outpatient health care services. Outpatient care is also provided at five CBOCs. Three CBOCs are located in the Louisville metropolitan area; the other two are located in Fort Knox, KY, and in New Albany, IN. The medical center is part of VISN 9 and serves a veteran population of about 155,000 throughout 35 counties in Kentucky and southern Indiana.

Programs. The medical center provides medical, surgical, mental health, geriatric, rehabilitation, and home health care services. It has 112 hospital beds and operates several regional referral and treatment programs. The medical center has sharing agreements with Ft. Knox and Ireland Army Medical Center military bases.

Affiliations and Research. The medical center is affiliated with the University of Louisville and supports 92 medical resident positions in 21 training programs. Allied health affiliations include nursing, pharmacy, respiratory care, and psychology. In fiscal year (FY) 2007, the medical center research program had 81 projects and a budget of $1.8 million. Important areas of research include surgical sepsis, heart disease, liver disease, and cancer prevention.

Resources. In FY 2006, medical care expenditures totaled $195 million. The FY 2007 medical care budget was $211 million. FY 2006 staffing was 1,204 full-time employee equivalents (FTE), including 95 physician and 245 nursing FTE.

Workload. In FY 2006, the medical center treated 39,834 unique patients and provided 29,467 inpatient days of care in the hospital. The inpatient care workload totaled 5,519 discharges, and the average daily census was 78. Outpatient workload totaled 402,752 visits.

Objectives and Scope

Objectives. CAP reviews are one element of the OIG's efforts to ensure that our Nation's veterans receive high quality VA health care services. The objectives of the CAP review are to:

- Conduct recurring evaluations of selected health care facility operations, focusing on patient care administration and quality management (QM).
- Provide fraud and integrity awareness training to increase employee understanding of the potential for program fraud and the requirement to refer suspected criminal activity to the OIG.

Scope. We reviewed selected clinical and administrative activities to evaluate the effectiveness of patient care administration and QM. Patient care administration is the process of planning and delivering patient care. QM is the process of monitoring the quality of care to identify and correct harmful and potentially harmful practices and conditions.

In performing the review, we inspected work areas; interviewed managers, patients, and employees; and reviewed clinical and administrative records. The review covered the following seven activities:

- CPRS Business Rules.
- Dupont CBOC.
- Environment of Care (EOC).
- Patient Satisfaction.
- QM.
- Scope of Practice for Unlicensed Physicians.
- SCIP.

The review covered medical center operations for FY 2006 and FY 2007 through August 17, 2007, and was done in accordance with OIG standard operating procedures for CAP reviews. We also followed up on selected recommendations from our prior CAP review of the medical center (*Combined Assessment Program Review of the VA Medical Center, Louisville, Kentucky,* Report No. 04-03270-172, July 8, 2005). The medical center had corrected all health care related conditions identified during that CAP review.

During this review, we also presented fraud and integrity awareness briefings to 33 medical center employees. These briefings covered procedures for reporting suspected criminal activity to the OIG and included case-specific

examples illustrating procurement fraud, conflicts of interest, and bribery.

In this report, we make recommendations for improvement. Recommendations pertain to issues that are significant enough to be monitored by the OIG until corrective actions are implemented. Activities in the "Review Activities Without Recommendations" section have no reportable findings.

Results

Review Activities With Recommendations

Quality Management

The purposes of this review were to determine if: (a) the medical center had a comprehensive, effective QM program designed to monitor patient care activities and coordinate improvement efforts; (b) senior managers actively supported QM efforts and appropriately responded to QM results; and (c) the medical center was in compliance with Veterans Health Administration (VHA) directives, appropriate accreditation standards, and Federal and local regulations. To evaluate QM processes, we interviewed senior managers and reviewed the self-assessment form completed by QM staff regarding compliance with QM requirements. We also evaluated relevant QM documents and committee minutes.

The QM program was generally effective in providing oversight of the quality of patient care in the medical center, and managers were supportive of QM efforts. Performance improvement (PI) efforts, patient complaints, medication management, blood products usage, resuscitation outcomes, medical records, patient flow, and advanced clinic access were monitored effectively. However, we identified several program areas that needed strengthening.

Peer Review. As of August 7, 2007, 61 percent of the peer reviews for FY 2007 exceeded timeframes for initial peer review, and 37 percent exceeded timeframes for review and discussion by the Peer Review Committee (PRC). VHA Directive 2004-054, *Peer Review for Quality Management,* issued September 29, 2004, requires initial reviews to be completed within 45 days and PRC discussions to occur within 120 days.

Peer review is a confidential, non-punitive, and systematic process to evaluate quality of care at the individual provider level. Peer review can result in both immediate and

long-term improvements in patient care by revealing areas for improvement in individual providers' practices. When peer review is not conducted timely, managers cannot be assured that prompt corrective actions are taken when indicated.

Root Cause Analysis. We found that elements of the RCA process did not comply with VHA guidelines. RCAs are designed to identify and resolve the root cause of system and/or process deficiencies involved in an actual or potential adverse event. VHA Handbook 1050.1, *VHA National Patient Safety Improvement Handbook*, issued January 30, 2002, requires that RCAs be conducted within 45 days of the medical center's identification of need. We found that none of the five RCAs completed between May 31, 2006, and June 13, 2007, were completed within the 45-day requirement. Without prompt identification of problems, managers could not be assured that corrective actions had been implemented.

In addition, at the time of our review, outcome evaluations had not been completed on two of the five RCAs. Without outcome evaluations, managers could not be assured that corrective actions were effective.

Operative and Other Invasive Procedure Review. The medical center's PI process did not include all elements of the operative and other invasive procedure review, as required by Joint Commission[1] (JC) standards and medical center policy. There were no documented reviews by the Invasive Procedure and Tissue Committee of major discrepancies between pre- and post-operative diagnoses after October 2006. In addition, the Committee did not review aggregate data, including National Surgical Quality Improvement Program (NSQIP) data, on surgical procedures to identify opportunities for improvement. The JC requires data aggregation and analysis and identification of trends. Without appropriate evaluation, managers could not be assured that PI activities were initiated when indicated.

Recommendation 1 We recommended that the VISN Director ensure that the Medical Center Director requires that peer reviews are completed in accordance with VHA policy.

[1] The Joint Commission was formerly the "Joint Commission on Accreditation of Healthcare Organizations," also known as JCAHO.

The VISN and Medical Center Directors concurred with the findings and the recommendation and provided acceptable improvement plans. The medical center will revise the peer review policy to include timeframes for peer review completion and will monitor timeliness. The results will be reported to the Clinical Executive Board (CEB) quarterly beginning in FY 2008. We will follow up on planned actions until they are completed.

Recommendation 2 We recommended that the VISN Director ensure that the Medical Center Director requires that RCAs are completed in accordance with VHA policy.

The VISN and Medical Center Directors concurred with the findings and the recommendation and provided acceptable improvement plans. The medical center will monitor RCA completion timeframes and the implementation of corrective actions using a new checklist. Results will be reported to the Quality Executive Board quarterly beginning in FY 2008. We will follow up on planned actions until they are completed.

Recommendation 3 We recommended that the VISN Director ensure that the Medical Center Director requires that all requisite elements of operative and other invasive procedures are analyzed.

The VISN and Medical Center Directors concurred with the findings and the recommendation and provided acceptable improvement plans. The NSQIP data will be added to the agenda of the Invasive Procedure and Tissue Committee. The Laboratory and Pathology Service will present discrepancies between pre- and post-operative diagnoses to the committee monthly. The committee will submit reports on this data to the CEB quarterly beginning in FY 2008. We will follow up on planned actions until they are completed.

Environment of Care

The purpose of this review was to determine whether the medical center had a comprehensive EOC program that complied with VHA policy, Occupational Safety and Health Administration regulations, and JC standards. We inspected 11 clinical areas for cleanliness, safety, privacy, infection control, and general maintenance. We followed up on EOC concerns cited in our 2005 CAP report and the 2007 JC report and found that those issues were resolved.

Our inspection revealed that the medical center generally maintained a safe and clean environment. However, we

identified a patient safety deficiency that required management attention.

We found that managers did not ensure permanent marking of beds with entrapment risks, as required in VHA's National Patient Safety Alert, *Bed Rail Entrapment*, issued July 2001. Some beds pose a hazard because high-risk patients could be caught, trapped, or entangled in the space in or about the bed rail, mattress, or hospital bed frame.

We were told that the VISN 9 Director required assessment of all beds to ensure that they were in compliance with the requirements. Medical center staff completed the assessment in January 2007 and identified 21 beds that posed an entrapment risk; however, staff were initially unable to tell us the location of the beds and could not confirm that they had been marked. We were later told that although 18 of the beds were not in use, 3 were occupied by hospitalized patients. Staff reported that these three beds were not permanently marked; therefore, nurses could have unknowingly placed high-risk patients in these beds. Staff removed the three beds from use while we were onsite.

Recommendation 4

We recommended that the VISN Director ensure that the Medical Center Director implements a process to permanently mark beds that may pose an entrapment danger to high-risk patients.

The VISN and Medical Center Directors concurred with the findings and the recommendation and provided acceptable improvement plans. All beds that pose an entrapment risk have been removed from service. Biomedical engineers have added the bed rail entrapment test to their safety checklist for patient care equipment. They will be responsible for marking all beds and notifying Nursing Service. We will follow up on planned actions until they are completed.

Review Activities Without Recommendations

Computerized Patient Record System Business Rules

Business rules define which groups or individuals are allowed to edit, amend, or delete documentation in electronic medical records. The health record, as defined in VHA Handbook 1907.01, *Health Information Management and Health Records*, issued August 25, 2006, includes the electronic and paper medical record. It includes items, such as physician orders, progress notes, and examination and

test results. In general, once notes are signed, they should not be altered.

On October 20, 2004, the VHA Office of Information (OI) sent software informational patch USR*1*26 to all medical centers with instructions to assure that business rules complied with VHA regulations. The guidance cautioned that, "The practice of editing a document that was signed by the author might have a patient safety implication and should not be allowed." In January 2006, the OIG identified a facility where progress notes could be improperly altered and recommended that VHA address the issue on a national basis. On June 7, 2006, VHA issued a memorandum to VISN Directors instructing all VA medical centers to comply with the informational patch sent in October 2004.

We found all business rules to be in compliance with VHA policy. We made no recommendations.

Dupont Community Based Outpatient Clinic

The purpose of this review was to assess CBOC operations and delivery of health care services. CBOCs were designed to improve veterans' access to care by offering primary care in local communities while delivering the same standard of care as the parent facility (the medical center). The Dupont CBOC opened in 1996 with a primary focus of providing mental health services. Several years later, the CBOC expanded its services to include primary care. The CBOC, located about 9 miles from the medical center, is staffed by VA employees and served 6,938 veterans in FY 2006.

We reviewed CBOC policies, performance documents, and provider credentialing and privileging (C&P) files. We conducted an EOC inspection to assess compliance with environmental standards. In addition, we evaluated how CBOC patients requiring warfarin[2] were managed. During our site visit, we interviewed four patients about their perceptions of care.

We found that the CBOC's emergency management plan was current, and staff members were knowledgeable about rendering emergency care. CBOC providers' C&P files contained appropriate background screening and professional practice documentation. The facility was clean,

[2] Medication used to prevent blood clots.

well maintained, and met JC, Health Insurance Portability and Accountability Act, and Life Safety requirements.

The CBOC did not provide warfarin therapy to enrolled patients. CBOC patients requiring warfarin were referred to the medical center's anticoagulation clinic for treatment and monitoring. Pharmacists managed the warfarin clinic at the medical center and worked cooperatively with CBOC providers. Pharmacists conducted patient education on warfarin use and side effects and gave patients a toll-free telephone number to call if they had problems or concerns. The patients we interviewed reported being satisfied with their care.

We found that the CBOC complied with selected standards. We made no recommendations.

Patient Satisfaction

The Survey of Healthcare Experiences of Patients (SHEP) is aimed at capturing patient perceptions of care in 12 service areas, including access to care, coordination of care, and courtesy. VHA relies on the survey data to improve the quality of care delivered to patients. VHA's Executive Career Field Performance Plan stated that in FY 2007, at least 77 percent of ambulatory care patients treated and 76 percent of inpatients discharged during a specified date range would report their experiences as "very good" or "excellent." Medical centers are expected to address areas in which they are underperforming. The graphs on the next page show the medical center's performance in relation to national and VISN performance.

VA Medical Center, Louisville, KY										
INPATIENT SHEP RESULTS										
FY 2007 Quarters 1 and 2	**Access**	**Coordination of Care**	**Courtesy**	**Education & Information**	**Emotional Support**	**Family Involvement**	**Physical Comfort**	**Preferences**	**Transition**	**Overall Quality**
National	80.2	77.8	89.5	67.1	64.9	75.4	82.8	74.1	69.2	**
VISN 9	80.3	77.7	90.6	69.4	67	76.6	82.5	74.6	72	**
Medical Center	81.9	80.2	91.6	69.9	67.7	78.3	84.6	73.4	70.4	**
OUTPATIENT SHEP RESULTS										
FY 2007 Quarter 2	**Access**	**Continuity of Care**	**Courtesy**	**Education & Information**	**Emotional Support**	**Overall Coordination**	**Pharmacy Mailed**	**Pharmacy Pick-up**	**Preferences**	**Specialist Care**	**Visit Coordination**
National	80.2	77.8	94.3	72.1	82.3	75	81.2	65.1	81.1	80.9	84.1
VISN 9	80.7	78.7	94.8	73.3	82.3	76	86.4	71	82.1	83.3	83.7
Medical Center Clinics	80.9	76.6	94.4	71	83.8	75.8	92.9	79.8	84.9	86.6	84.8
"**" indicates less than 30 respondents											

The medical center's Customer Service Board (CSB) has oversight and coordination responsibility for customer service activities. The CSB had instituted multiple initiatives, including service recovery ambassadors, patient and provider education, and improved telephone triage systems. In most areas, the medical center's SHEP scores exceeded national scores for the 1st and 2nd quarters of FY 2007. Some areas for improvement were identified in both inpatient and outpatient areas, and services have developed action plans to address deficiencies.

In 2006, the medical center received one of the Under Secretary for Health's customer service awards for an initiative that educated employees on the SHEP program and collected ideas and best practices to improve customer satisfaction. We made no recommendations.

Scope of Practice for Unlicensed Physicians

The purpose of this review was to determine whether research activities performed by unlicensed physicians constitute the practice of medicine.

In order to practice medicine in the United States, a graduate of medical school generally must complete a United States medical residency. This requirement exists regardless of the skills, training, or experience of the graduates. With few

exceptions, medical school graduates who cannot or do not complete an internship or residency in the United States are not eligible for licensure. If engaged in research activities, these individuals may function in roles such as study coordinators or research assistants, but they cannot practice medicine. Activities traditionally considered to constitute the practice of medicine include performing invasive procedures, conducting physical examinations, and altering medications.

VHA Handbook 1200.5, *Requirements for the Protection of Human Subjects in Research,* issued July 15, 2003, requires the medical center Director to ensure that Institutional Review Board members and investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and all applicable regulations. As a result, unlicensed physicians operate under a scope of practice. "Scope of practice" is a term used to describe activities that may be performed by health care workers, regardless of whether they are licensed independent health care providers. The 2003 Guidance on Verifying Credentialing of All Individuals Involved in Human Subjects Research, located on VA's Research and Development website, requires that scopes of practice be granted and signed by the Principle Investigator(s) and reviewed and approved by the Associate Chief of Staff for Research and Development (ACOS/R&D).

The medical center identified two unlicensed physicians assigned to one human subjects research study. The study is retrospective and does not require the practice of medicine. However, upon review of the unlicensed physicians' scopes of practice, we found that they had not been reviewed and approved by the ACOS/R&D. This is a violation of the 2003 guidance on verifying credentialing.

While we were onsite, the ACOS/R&D reviewed and approved the scopes of practice for the two unlicensed physicians. We made no recommendations.

Surgical Care Improvement Project

The purpose of the review was to determine if clinical managers implemented strategies to prevent or reduce the incidence of surgical infections for patients having major surgical procedures. Surgical infections present significant patient safety risks and contribute to increased post-operative complications, mortality rates, and health care costs.

We evaluated the following VHA performance measure (PM) indicators:

- Timely administration of prophylactic (preventive) antibiotics to achieve therapeutic serum and tissue antimicrobial drug levels throughout the operation. Clinicians should administer antibiotics within 1–2 hours prior to the first surgical incision.
- Timely discontinuation of prophylactic antibiotics to reduce risk of the development of antimicrobial resistant organisms. Clinicians should discontinue antibiotics within 24–48 hours after surgery.
- Controlled core body temperature for colorectal surgery, which should be maintained at greater than or equal to 36 degrees Centigrade or 96.8 degrees Fahrenheit immediately after surgery. Decreased core body temperature is associated with impaired wound healing.

VHA set target PM scores for each of the above indicators. To receive fully satisfactory ratings, a facility must achieve the following scores:

Performance Measure	FY 2007 Target Score
Timely antibiotic administration	90 percent
Timely antibiotic discontinuation	87 percent
Controlled body temperature – colorectal surgery	70 percent

At the time of our site visit, the medical center's most recent PM scores for timely antibiotic administration and core body temperature met targets. The medical center did not meet the target for antibiotic discontinuation; however, managers had developed automatic "stop order" sets, and PM scores in this area have shown continuous improvement over the last 4 quarters.

We reviewed the medical records of 30 patients who had colorectal, vascular, or orthopedic (knee and hip replacement) surgery during the 2nd quarter of FY 2007. We found timely discontinuation of antibiotics in 30 of 30 surgical cases. We made no recommendations.

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: September 21, 2007

From: VISN Director, VA Mid South Healthcare Network (10N9)

Subject: **Combined Assessment Program Review of the VA Medical Center, Louisville, Kentucky**

To: Director, Atlanta Office of Healthcare Inspections (54AT)

Director, Management Review Office (10B5)

I concur with the responses to the recommendations outlined in this report.

(original signed by:)

JOHN DANDRIDGE, JR.

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: September 14, 2007

From: Director, Louisville VA Medical Center (603/00)

Subject: **Combined Assessment Program Review of the VA Medical Center, Louisville, Kentucky**

To: Director, VA Mid South Healthcare Network (10N9)

I concur with the responses to the recommendations outlined in this report.

(original signed by:)

WAYNE L. PFEFFER, MHSA, FACHE

Comments to Office of Inspector General's Report

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

OIG Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the Medical Center Director requires that peer reviews are completed in accordance with VHA policy.

Concur

Target date: October 1, 2007

Facility response:

The VA Medical Center, Louisville, Kentucky, revised their current policy for peer review to include the timeframes for completion of the initial review at 45 days and the committee discussions within 120 days. On receipt, cases will be distributed for initial peer review. The peer review database has been updated to include dates of initial and final peer review for tracking of timeliness.

Monitoring of the timeliness will be included in the quarterly Peer Review Report to the Clinical Executive Board.

Recommendation 2. We recommended that the VISN Director ensure that the Medical Center Director requires that RCAs are completed in accordance with VHA policy.

Concur

Target date: October 1, 2007

Facility response:

Administrative support from the Strategic Management Service has been provided to the Patient Safety Manager for data entry specifically related to the RCA process. A checklist procedure for timeframes has been implemented and will be tracked from notification of occurrence through approval.

Ongoing monitoring will take place to review the status of the RCA timely completion and the implementation of corrective actions with outcome

evaluations. The 1st quarter report for FY 2008 will be presented to the Quality Executive Board.

Recommendation 3. We recommended that the VISN Director ensure that the Medical Center Director requires that all requisite elements of operative and other invasive procedures are analyzed.

Concur

Target date: October 1, 2007

Facility response:

The VA Medical Center, Louisville, Kentucky, added the surgery procedure and NSQIP data to the Invasive Procedure and Tissue Committee's meeting agenda. Pathology and Laboratory Medicine Service will provide discrepancies between the pre-operative and post-operative diagnosis on a monthly basis.

The Invasive Procedure and Tissue Committee will report this data to the Clinical Executive Board on a quarterly basis. The initial report will be on the 1st quarter of FY 2008.

Recommendation 4. We recommended that the VISN Director ensure that the Medical Center Director implements a process to permanently mark beds that may pose an entrapment danger to high-risk patients.

Concur

Target date: October 1, 2007

Facility response:

All the beds in question have been removed from service. The VA Medical Center, Louisville, Kentucky, has a plan in place to insure the organization does not purchase any of the beds identified in the National Patient Safety Alert of July 2001 on entrapment risks. Nursing Service, who orders all beds, is aware of the bed rail entrapment alert, and the Biomedical Engineers, who check in all patient care equipment, have added to their safety checklist the bed rail entrapment test detailed in the July 2001 Safety Alert. Biomedical Engineers are responsible for marking the bed and notifying Nursing Service.

OIG Contact and Staff Acknowledgments

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