STATEMENT OF

DR. JOHN D. DAIGH JR., M.D.

ASSISTANT INSPECTOR GENERAL FOR HEALTHCARE INSPECTIONS

OFFICE OF THE INSPECTOR GENERAL, DEPARTMENT OF VETERANS AFFAIRS

BEFORE

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COMMITTEE ON VETERANS AFFAIRS

THE UNITED STATES HOUSE OF REPRESENTATIVES

ON

PATIENT SAFETY ISSUES AT THE DEPARTMENT OF VETERANS AFFAIRS

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INTRODUCTION

Mr. Chairman and Members of the Committee, thank you for the opportunity to testify today on patient safety issues that directly impact the quality of life of millions of veterans who receive their medical care from Department of Veterans Affairs (VA) medical facilities. Today I will present you with the results of the Office of Inspector General's (OIG) Combined Assessment Program (CAP) evaluations of Veterans Health Administration (VHA) medical centers, selected hotline evaluations, and national reviews that are relevant to the discussion of VHA patient safety issues.

I believe, from my personal experience and OIG work, that VHA leadership and employees are committed to provide veterans with the highest quality medical care. In addition, I am convinced that VHA leadership strongly supports patient safety to the betterment of all veterans. There is no better example of VA employees' commitment to veterans than the recognition received by the Portland VA Medical Center when they were recently named a nursing Magnet facility by the American Nurses Credentialing Center.

The OIG evaluates the quality of medical care provided to veterans through a variety of methods. The CAP review process is one in which VHA medical facilities are evaluated on a 3-year cycle. These reviews are designed to ensure that the processes are in place at each medical center to ensure that VHA leadership can effectively provide veterans with quality health care. A strong patient safety culture is one of the attributes of a well-managed medical facility. Rarely have we determined, in the course of our CAP inspections, that VHA facilities did not have the processes in place to ensure that quality medical care was likely to be provided and that a strong patient safety culture was not present. When we have found and reported these conditions, VHA has taken appropriate and timely actions to remedy the situation.

CAP reports describe areas where VHA needs to improve and highlight areas where standards are properly maintained. A summary of CAP quality assurance findings representing evaluations of 93 VHA medical centers for FY 2004 and FY 2005 provides the basis for the conclusion that VHA leaders and employees support the processes and procedures that are required to ensure that veterans receive quality healthcare.

During this period, two facilities had significant deficits in their overall quality improvement processes[1]. Dallas and Altoona had significant deficits in the management and operation of their quality assurance programs. Altoona has significantly improved the overall quality of its programs as reported in their follow up CAP report[2]. The Dallas VA medical center (VAMC) has recently had a change in senior leadership and we will monitor their progress and reevaluate their quality assurance programs.

VHA facilities maintain a strong patient complaint program and have improved these programs between fiscal year (FY) 2003 and FY 2005 with improved data analysis and resulting actions. VHA's patient safety handbook requires that adverse events be

[1] *Combined Assessment Program Review of the James E. VanZandt VA Medical Center Altoona, PA*, Report No. 03-03208-76, February 2, 2004; *Combined Assessment Program Review of the VA North Texas Health Care System, Dallas, Texas,* Report No. 04-01878-34, November 26, 2004.
[2] *Combined Assessment Program Review of the James E. Van Zandt VA Medical Center Altoona, Pennsylvania,* Report No. 06-00008-130, April 17, 2006.

disclosed to affected patients. VHA made improvements in this effort with 25 percent of the facilities in FY 2003 having appropriate processes in place as evaluated during the CAP inspections and 86 percent of programs in FY 2005 having appropriate programs in place. OIG inspectors report that this process would be improved with a more consistent definition of situations that should be disclosed, given the variety of methods used to review clinical care (peer review, morbidity and mortality review, patient safety reviews).

The OIG recommended VHA issue a new program directive on utilization management when CAP data suggested that facilities were not meeting goals for admission appropriateness and utilization review programs were having less impact. A new program directive was issued by VHA and became effective on July 1, 2005. We will monitor the implementation of this policy through CAP inspections.

The OIG finds that documentation of the use of restraints is well performed in 88 percent of facilities. The OIG believes that this is an area that can be improved. The use of templates in the electronic medical record has improved documentation that is required with the use of restraints at facilities that utilize medical record templates. VHA's quality management processes, which in most facilities are excellent, have shown continued improvements over the last 4 fiscal years. Analysis of mortality data is routinely appropriately performed at VHA facilities in an attempt to trend outcomes.

The OIG believes that there is room for improvement in the re-privileging process. In FY 2005, 84 percent of the facilities analyzed the minimum required data for re-privileging providers, which is a decrease from 90 percent of facilities in FY 2004 and 94 percent in FY 2003. In addition to CAP data, the OIG issued three recent reports[3], which suggest that further attention is required to the re-privileging of credentialed

[3] *Review of a Surgical Technician's Duties John D. Dingell VA Medical Center, Detroit, MI*, Report No. 05-02986-125, April 21, 2006; *Healthcare Inspection Operating Room Nurses Scope of Practice Issues Edward Hines, Jr. VA Hospital, Hines, IL*, Report No. 05-01552-102,March 10, 2006; *Healthcare Inspection Credentialing and Privileging Irregularities at the South Texas Veterans Health Care System San Antonio, Texas,* Report No. 06-00703-147, May 22, 2006.

providers and the determination of the scope of practice for non-credentialed providers. These efforts to improve re-privileging should strengthen the importance and value of the peer review process.

Patient Safety and the Operating Room

At Tampa VAMC and Bay Pines VAMC, procedures designed to ensure that instruments and prosthetics were properly sterilized and cleaned broke down. This resulted in either cancelled surgeries with significant disruption to the function of the hospital or patient exposure to improperly sterilized prosthetic devices.

The modern operating room requires the use of complex equipment, reusable medical supplies, and novel prosthetic devices. Additionally there is a requirement to document and then retrieve data regarding procedures should a patient safety issue arise after the procedure has been completed. The OIG issued a report on a review of the use of improperly sterilized skull implants in the repair of skull defects at the Tampa VAMC[4]. The review revealed that there was a break in sterile procedure during the repair of a skull defect in two veterans. To date, the OIG has not identified any adverse patient outcomes as a result of these errors. The medical needs of those veterans who were placed at risk from these breaks in sterile procedure were promptly addressed by the VHA. VHA alerted its own National Center for Patient Safety (NCPS) and the Food and Drug Administration (FDA) of the facts surrounding these cases. The review reached several conclusions:

- Two patients were affected: one patient received a non-sterile implant and another patient was exposed to a non-sterile implant. Neither patient experienced any complications.
- The redundancy built into the system for verification that products taken into the operating room are sterile failed in these two cases.

[4] *Health Care Inspection Quality of Care in Cranial Implant Surgeries at James A. Haley VA Medical Center Tampa, Florida,* Report No. 06-01642-126, April 10, 2006.

- Accurate reporting up the chain of command was impeded by difficulty in retrieving information regarding what custom implants were utilized in which patients.

The review made two recommendations:

- Review and modify policy and procedures on sterilization, and make appropriate changes to ensure products from all sources are sterilized before delivery to the operating room.
- Review and modify policy and procedures that identify non-autologous products that remain with the patient after a surgical procedure.

The Under Secretary for Health agreed with the findings and has implemented a plan to address the issues. In addition, he committed that VHA would (a) monitor facility progress involving surgical equipment inventory management and oversight of vendor negotiations and (b) NCPS would work in coordination with FDA and other agencies to determine whether more universal safety checks should be applied.

In FY 2004, the OIG inspected the Bay Pines VAMC[5] at the request of Congress and the Secretary because the operating room was closed in November of 2003 and February of 2004 because of serious deficiencies in the process that provides sterilized surgical instruments and equipment to the operating room. VAMC managers cancelled 81 surgeries because critical surgical supplies and instruments were not consistently sterilized by the Supply Processing and Distribution section of the hospital. This inspection also found deficiencies in sterilization techniques, inventory practices and staff training. VHA agreed to correct these practices. A follow up evaluation[6] of the Bay Pines VAMC was published on June 12, 2006.

[5] *Interim Report – Patient Care and Administrative Issues at VA Medical Center Bay Pines, Florida)*, Report No. 04-01371-108, March 19, 2004; *Issues at VA Medical Center Bay Pines, Florida and Procurement and Deployment of the Core Financial and Logistics System (CoreFLS)*, Report No. 04-01371-177, August 11, 2004.

[6] *Healthcare Inspection Follow-Up Evaluation of Clinical and Administrative Issues Bay Pines Health Care System Bay Pines, Florida,* Report No. 06-01217-154, June 12, 2006.

The VA NCPS posted an alert on its website on April 3, 2006, with instructions on how to properly clean and sterilize a reusable transrectal ultrasound transducer assembly that was in use at VHA facilities. Having determined that sterilization and cleaning procedures in use at the VA medical center were not sufficient, VHA employees worked with the NCPS to correct this problem within VHA. VHA is now in the process of notifying those exposed to the improperly cleaned and sterilized transrectal ultrasound transducer that they may be at risk of serious illness.

It is time for VHA to review all aspects of the processes required to ensure that physicians performing procedures are provided with the proper equipment in the proper state of sterilization and cleanliness. The task is now probably too complex to expect that the technicians in every VHA facility should have to identify from non standard instruction sets the sterilization routine for each of the many items that are used in procedures at a hospital every day. The processes involved in assuring that properly cleaned and sterilized instruments, supplies, and prosthetics are delivered to the operating room needs review and modification to lessen the chance that patients are placed at risk.

Other Quality of Care Issues

Patient safety is improved when management provides the required oversight to ensure that otherwise routine activities are properly conducted. As a result of a March 16, 2004, incident in which the San Juan VA[7] Medical Center ran out of oxygen as the result of breakdowns in routine procedures, the OIG reviewed selected aspects of oxygen management during the CAP process. The OIG made recommendations at 15 of 23 sites reviewed by the CAP process in FY 2005[8] to emphasize the importance of following routine and appropriate procedures to ensure each hospital had adequate supplies of this necessary commodity.

[7] *Audit of Medical Oxygen Supply Management Practices VA Medical Center San Juan, Puerto Rico,* Report No. 04-01901-19, November 3, 2005.
[8] *Summary report of Combined Assessment Program Reviews at Veterans Health Administration Medical Facilities October 2004 through September 2005*, Report No. 06-01754-123, March 31, 2006.

Patient safety, quality of medical care, and economy often improved when VHA has in place effective policies that standardize medical care. The prevention and management of pressure ulcers is one area in which quality medical care is likely to decrease the average length of stay at VA facilities. The OIG reported on VHA pressure ulcer management[9] and encouraged VHA to develop and implement a policy to address the management these patients. Aspiration pneumonia is a common problem in the hospital setting that has significant quality of care and financial implications. The OIG issued a report on VHA practices regarding the management of patients with feeding and swallowing disorders[10] who are at risk for aspiration pneumonia. VHA agreed with our findings and is making improvements in the management of patients with this condition. The OIG has in a similar fashion reviewed sedation practices outside the operating room at VA medical facilities, reported our findings[11], and made recommendations for improvements which VHA agreed to implement.

Recent natural and man made disasters have demonstrated the importance of a healthcare system to be prepared for the unexpected. The OIG reviewed, through the CAP process, aspects of medical facilities disaster plans[12] and made recommendations to medical facilities and national leadership to improve compliance with guidance provided in the *Veterans Affairs Emergency Preparedness Act of 2002* (P.L. 107-287). We found that VHA facilities were in general in compliance with the law and we made recommendations to address areas where improvement was needed to include education for employees on emergency procedures and high-risk laboratory safety conditions.

[9] *Healthcare Inspection Management of Patients with Pressure Ulcers in Veterans Health Administration Facilities*, Report No. 05-00295-109, March 22, 2006.
[10] *Healthcare Inspection Evaluation of the Management of Patients with Feeding and Swallowing Problems in Veterans Health Administration Facilities*, Report No. 03-00494-110, March 22, 2006.
[11] *Healthcare Inspection Evaluation of Management of Moderate Sedation in Veterans Health Administration Facilities,* Report No. 04-00330-15, November 1, 2005.
[12] *Emergency Preparedness in Veterans Health Administration Facilities,* Report No. 04-03266-51, January 16, 2006.

VHA has used performance metrics to drive change in clinical areas. As part of a review of VHA clinical outcomes, the OIG evaluated and reported[13] on the VHA performance metric that was designed to improve VHA colon cancer management. This metric, created in 2000, was met if 72 percent of veterans over 51 years of age were screened using standard screening procedures for colon cancer. In our review of patients who were diagnosed with colon cancer, we found that 92 percent of those in the sample were either screened or did not require screening. This is significantly better than the VHA performance metric standard and much better than measures of non-VA populations, where data is available. However, we found that patients who were screened and had a result that indicated that they were at increased risk for colon cancer, were not rapidly provided with the diagnostic evaluations required to make a diagnosis of cancer. Once the diagnosis was made, we found that care was expeditiously provided. As a result of our review, VHA has agreed to review colon cancer management practices and to issue new guidance on the management of this condition by September 30, 2006.

The OIG values and understands the many important contributions that are made to the medical care of veterans by the faculty and trainees at the Nation's medical schools. Important also is the positive interaction that veterans have with young physicians who gain insight into the history of our country from veterans that they have only otherwise read about in books. VHA has policies in place to ensure that veterans receive appropriate medical care independent of the level of training of the members of the treatment team. The OIG will continue to work with VHA to monitor these policies and to ensure that veterans receive proper medical care and trainees receive proper training. The OIG has reported on a number of isolated cases[14] that deal with aspects of this issue and will continue to be vigilant in this area to ensure that VHA standards are upheld.

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[13] *Healthcare Inspection Colorectal Cancer Detection and Management in Veterans Health Administration Facilities,* Report No. 05-00784-76, February 2, 2006.

[14] *Healthcare Inspection Resident Supervision Issues in the Operating Room William Jennings Bryan Dorn VA Medical Center, Columbia, SC,* Report No. 05-03084-135, May 9, 2006; *Resident Supervision in the Operating Room, Birmingham VA Medical Center, Birmingham AL*, Report No. 05-02925-100, March 10, 2006; *Alleged Failure to Supervise Hand Surgery Fellows VA Boston Healthcare System, Boston MA*, Report No. 05-02023-73, February 1, 2006.

Summary

The OIG is committed to working with VHA to insure that veterans receive appropriate, high-quality, healthcare.

Mr. Chairman, thank your again for this opportunity and I would be happy to answer any questions that you or other members of the Subcommittee may have.