STATEMENT OF
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U.S. DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
HEARING ON
"SACRED OBLIGATION: RESTORING VETERAN TRUST AND PATIENT SAFETY"
MAY 3, 2011

Mr. Chairman and Members of the Committee, thank you for this opportunity to testify on aspects of patient safety that are critical to the delivery of quality medical care to veterans. My statement and comments are based on reports by the Office of Inspector General (OIG).

While the subject of this hearing is on substantive performance gaps where the Department of Veterans Affairs (VA) needs to improve, I want to clearly state that from the body of work conducted by the OIG's Office of Healthcare Inspections, it is clear that VA provides veterans with high quality medical care that has the support of veterans and employees as measured by satisfaction surveys and is rated with the best health care plans in the country. That being said, VA has had several high profile and highly publicized incidents that naturally would shake the faith of those who receive care from VA. Some of the incidents were the result of improper reprocessing of complex medical equipment and others were the result of leadership failing to act when presented information of serious breaches of infection control protocols.

REUSABLE MEDICAL EQUIPMENT

The reprocessing of reusable medical equipment (RME) is categorized based on the associated risk of and the level of cleaning required to prevent infection. Devices that enter normally sterile tissue, including joints and the vascular system, require sterilization to eliminate all forms of microbial life. Other devices, including many endoscopes, examine intact mucous membranes and do not ordinarily penetrate sterile tissue. For these devices, which are often constructed of materials and mechanisms that are unable to withstand exposure to the high temperatures or chemicals required for sterilization, high-level disinfection (HLD) is appropriate. HLD eradicates all micro-organisms "except for small numbers of bacterial spores."[1]

[1]W.A. Rutala, D.J. Weber, and the Healthcare Infection Control Practices Advisory Committee, Centers for Disease Control and Prevention, *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*.

OIG Reports on RME

Healthcare Inspection – Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities (June 16, 2009) and Healthcare Inspection – Follow-Up Colonoscope Reprocessing at VA Medical Facilities (September 17, 2009)

In June 2009, we reported on difficulties in reprocessing colonoscopes at the Miami, Florida, VA Medical Center (VAMC) and the Murfreesboro, Tennessee, VAMC, which led to the notification of 2,531 veterans at Miami and 6,805 veterans at Murfreesboro that they were at risk of developing the blood borne infections of hepatitis B, hepatitis C, and HIV. The same report details defects in reprocessing ear-nose-throat endoscopes that resulted in 1,069 Augusta, Georgia, veterans being notified of their risk of contracting blood borne viral illnesses.

The report includes the results from an unannounced inspection of VA medical centers that found more than half did not have appropriate standard operating procedures (SOPs) and documented evidence of employee training for the colonoscopes in use at the medical center. In a follow up inspection of 129 VA medical centers that reprocessed colonoscopes, we found that all had the appropriate SOPs for reprocessing colonoscopes and one did not have adequate documentation of employee training to reprocess the scopes.

Healthcare Inspections – Patient Safety Issues VA Caribbean Healthcare System San Juan, Puerto Rico (March 16, 2010)

The OIG received allegations regarding quality of care and patient safety related to RME reprocessing at the VA Caribbean Healthcare System (the system) in San Juan, Puerto Rico. The complainant provided more than 137 pieces of evidence to support these allegations. In our March 2010 report, we substantiated multiple allegations:

- For approximately 2 years, endovaginal transducers at the Mayaguez Outpatient Clinic (OPC) were not submitted to high-level disinfection as required after each patient procedure.
- Leak testing was not performed on colonoscopes in the Operating Room for at least 9 months, leak testing was not performed on laryngoscopes in Radiotherapy and at the Ponce OPC for 9 months and 3 years respectively.
- Pre-cleaning was improperly performed on the laryngoscopes in Radiotherapy.
- One of the laryngoscopes had a leak while it was in service during this time.
- The system inaccurately certified compliance with RME reprocessing procedures and training on three occasions.
- Senior system leadership and responsible managers were aware of these issues but took no action to assess the risk to patients.

As a result of our review, issue briefs (IB) on each area were discussed on pre-Clinical Risk Assessment Advisory Board (CRAAB) conference calls. Based on information provided by the system, the risk to patients was determined to be negligible. An Administrative Investigation Board (AIB) was completed after our visit to address management responsiveness. We recommended that the Veteran Integrated Service

Network (VISN) Director follow up on all recommendations from the AIB and take appropriate administrative action.

Healthcare Inspection – Alleged Endoscope Reprocessing Issues St. Louis VA Medical Center St. Louis, Missouri (April 21, 2010)

This review was conducted to determine the validity of allegations regarding ongoing issues in the Supply, Processing, and Distribution (SPD) department related to endoscope reprocessing and communication at the St. Louis VA Medical Center, St. Louis, Missouri.

We substantiated:

- Endoscope reprocessing issues have been ongoing. We reviewed documentation related to three contaminated gastrointestinal (GI) endoscopes, which were identified prior to patient use. We also reviewed documents notifying managers that damage and repairs to endoscopes had increased. We requested the 2009 repair log and associated costs from SPD and found that a majority of the scopes that were damaged or needed repair belonged to the GI service.
- Breakdowns in communication of adverse events and outcomes existed. We found minimal documentation as well as communication failures for two of the three adverse event reports (AER) reviewed.

In addition, we conducted an unannounced inspection of the SPD area. We identified several items related to reusable medical equipment reprocessing and staff safety that needed improvement as required by Veteran Health Administration (VHA) policies.

We recommended that the AER reporting process is clearly defined, timely, and well-documented and that implemented action plans are monitored for compliance to eliminate ongoing endoscope damage and reprocessing issues. We also recommended that SPD meet VHA policy and is monitored for compliance.

The VISN and Medical Center Directors agreed with the findings and recommendations. We closed this report on February 17, 2011, based on evidence submitted by the VAMC that action had been initiated to implement our recommendations.

Healthcare Inspection – Reprocessing of Dental Instruments, John Cochran Division of the St. Louis VA Medical Center, St. Louis, Missouri (March 7, 2011)

The purpose of this review was to determine the sequence of events involving alleged improperly cleaned and sterilized dental RME; errors in reprocessing or sterilization; actions taken to correct deficiencies; and decisions related to patient notification of breaches in dental equipment reprocessing or sterilization.

The dental RME reprocessing issues at the John Cochran Division (JCD) were a long-standing problem that went unrecognized and unaddressed by VISN and VAMC managers. VHA self-identified the deficiencies and took actions to correct them; however, those actions did not always resolve the issues. Responsible managers did not verify the adequacy of RME reprocessing practices, nor did they assure that

corrective actions were consistently implemented in response to VHA guidance and the Infectious Disease Program Office (IDPO) report. As a result, SOPs were not developed in a timely manner for the reprocessing of dental RME, SOPs did not always match manufacturers' instructions, and Dental Clinic staff had not received training on dental RME pre-treatment or reprocessing.

We concluded that the occurrence of a patient-to-patient transmission of a blood borne infectious disease at the JCD was unlikely. Nevertheless, the Clinical Risk Board adhered to the process outlined in VHA Directive 2008-002, *Disclosure of Adverse Events to Patients* (January 18, 2008), when it recommended disclosure to 1,812 patients potentially affected by breaches in the cleaning and sterilization processes. We concluded that the VAMC promptly set-up and staffed its Dental Review Clinic, made appropriate efforts to contact identified patients, and provided adequate support and follow-up to patients.

We recommended that the VISN Director require the VAMC Director to monitor the facility's compliance with all appropriate elements of RME reprocessing, SOPs, staff training, and staff competencies as defined in relevant VHA guidance; ensure that the VISN SPD Management Board provides monitoring to ensure that SOPs based on manufacturers' instructions are in place and that staff training and competencies are current; and take appropriate administrative actions based on the findings of the Administrative Board of Investigation and IDPO report. The VISN and Medical Center Directors agreed with the findings and recommendations

Combined Assessment Program Review Results

Despite the fact that VA leadership issued clear guidance to facilities on standards for reprocessing RME and that Congress held hearings on reprocessing failures at these sites, the OIG continues to find non-compliance with VA directives. Because of the persistence of deviations from expected performance by staff at VA facilities, a review of RME reprocessing practices was included in the OIG's Combined Assessment Program (CAP) reviews from January 1, 2010, through September 30, 2010[2]. Facility results were reported at the time of the inspection and rolled up to present a representative view of the system. We found that 87 percent of the reprocessing SOPs were consistent with manufacturers' instructions and 92 percent were located within the reprocessing areas. In our observations of employees reprocessing equipment, the SOPs were followed 87 percent of the time. Documented annual training was found for 82 percent of the employees and item specific competencies were documented 87 percent of the time. Proper protective equipment was worn by employees 89 percent of the time. VA requires that RME activities (e.g. validation of staff competency, compliance with established SOPs, results of infection prevention and control monitoring, and risk management activities) be reported to the Executive Committee of the Medical Staff (ECMS). Of the 45 facilities inspected in this CAP cycle, 37 (82 percent) had documented ECMS discussion of all required elements. Compliance with

[2] *Combined Assessment Program Summary Report – Evaluation of Reusable Medical Equipment Practices in Veterans Health Administration Facilities Report,* March 14, 2011.

these standards at the 82 percent to 92 percent level is not sufficient to ensure proper patient safety.

Recommendations

A zero defects culture is essential at all VA medical facilities to ensure patient safety and promote patient confidence. Employees and managers must establish a climate of trust to ensure that RME is only presented for patient use when it is in the appropriate condition.

Reprocessing high technology equipment and endoscopes can be complex. The methods available to report that proper reprocessing has occurred are not as clear as those used to indicate proper sterilization has occurred. Users of devices that require reprocessing must work with regulators and manufacturers to produce equipment that reduces the likelihood of reprocessing errors. VA must consider a variety of novel strategies from the method of procurement to the support of applicable basic scientific research in its quest to insure providers have equipment in the proper condition when patient care is delivered.

VA's Disclosure of Adverse Events[3] policy was one of the Nation's earliest efforts to systematically address the issue. A recent article in the medical literature*, The Disclosure Dilemma — Large-Scale Adverse Events*,[4] highlights some of the issues faced by institutions as they struggle to deal with the application of the limits of science and proper public policy. I believe it is time to have a national body advise VA on potential changes to this policy in light of the broad national experience with these complex issues.

LEADERSHIP ISSUES

Leadership failures may endanger patients' lives. There have been two recent occasions[5] when facility staff deviated from RME reprocessing standards resulting in VA CRAAB reviews. Failure to comply with accepted infection control policies in the Dayton, Ohio, VAMC Dental Clinic resulted in the notification to 535 veterans that dental care may have put them at risk of acquiring blood borne viral infections.

In our recent report on the Dayton VAMC Dental Clinic, we concluded that the subject dentist did not adhere to established infection control guidelines and policies, and multiple dental clinic staff had direct knowledge of these repeated infractions. These violations of infection control policies placed patients at risk of acquiring infections including those that are blood borne.

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[3] VHA Directive 2008-002*, Disclosure of Adverse Events to Patients, January 18, 2008*.

[4] Denise M. Dudzinski, Ph.D., Philip C. Hebert, M.D., Ph.D., Mary Beth Foglia, R.N., Ph.D., and Thomas H. Gallagher, M.D., *New England Journal of Medicine, The Disclosure Dilemma — Large-Scale Adverse Events*, Volume 39, September 2, 2010.

[5] *Healthcare Inspection Patient Safety Issues VA Caribbean Healthcare System San Juan, Puerto Rico,* March 16, 2010; *Healthcare Inspection – Oversight Review of Dental Clinic Issues Dayton VA Medical Center Dayton, Ohio*, April 25, 2011.

In our report on the VA Caribbean Healthcare System RME issues, we substantiated multiple allegations including that senior system leadership and responsible managers were aware of these issues but took no action to assess the risk to patients.

In these instances, VA local leaders did not perform to the expected standard and placed veterans' health at risk. It is imperative that leaders take the appropriate actions to ensure compliance with policies designed to ensure patients are not placed at risk of preventable disease in the normal course of the delivery of patient care.

Recommendations

Just as physicians have access to senior facility leaders via clinical department leaders and nurses have access through the Chief Nurse, VA clinical leaders should strive to receive unfiltered information from the many technicians who are critical to the daily delivery of quality medical care. Current lines of communication may not be adequate to get the technicians' concerns to facility leaders. Ongoing discussions between the facilities' leadership and technicians may provide important data necessary to improve quality care.

Some successful organizations recognize that the rotation of individuals through leadership positions or positions of special responsibility provide a periodic check for the organization on its adherence to policy. VA should consider how this management tool might improve performance at network offices and at medical centers.

CONCLUSION

Clearly VA can perform better regarding RME reprocessing. Attention from Congress and VA senior leadership has improved processes but continuous attention to this issue at the medical center level will go a long way to easing veterans' concerns about the safety of medical procedures and easing anxiety about having routine preventive tests such as colonoscopies and regular dental check-ups.

Mr. Chairman, thank you for this opportunity and I would be pleased to respond to any questions that you or other Members of the Committee have.