

**STATEMENT OF  
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BEFORE  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS  
COMMITTEE ON VETERANS' AFFAIRS  
UNITED STATES HOUSE OF REPRESENTATIVES  
ON  
ENDOSCOPY PROCEDURES AT THE VA:  
WHAT HAPPENED, WHAT HAS CHANGED?  
June 16, 2009**

## **INTRODUCTION**

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to testify today on endoscopy reprocessing errors by VA that placed veterans at risk of viral infections as a result of endoscopy procedures performed at several VA medical centers (VAMC). The VA Secretary, the Chairmen and Ranking Members of our oversight committees, and other Members of Congress requested the Office of Inspector General (OIG) review VA's procedures at those facilities as well as nationwide. Our report, *Healthcare Inspection, Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*, was published today.<sup>1</sup> I am accompanied by three members of my staff: George Wesley, M.D., Director, Medical Consultation and Review, Office of Healthcare Inspections; Jerome Herbers, M.D., Associate Director, Medical Consultation and Review, Office of Healthcare Inspections; Limin (Lin) Clegg, Ph.D., Director, Biostatistics Division, Office of Healthcare Inspections. As I have previously stated in testimony before this Subcommittee, I believe that VA provides high quality health care to veterans; however, I am concerned that the controls are not in place to ensure the delivery of a uniform, high quality medical benefit.

## **BACKGROUND AND FINDINGS**

VA medical facilities have not complied with multiple directives to ensure endoscopes are properly reprocessed. Unannounced OIG inspections on May 13 and 14, 2009, found that medical facilities:

- Have the appropriate endoscope Standard Operating Procedures (SOPs) available 78 percent of the time.
- Have documented proper training of staff 50 percent of the time.
- Are compliant with both recommendations 43 percent of the time.

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<sup>1</sup> <http://www.va.gov/oig/publications/reports-list.asp>

The impact of improper high level disinfection of reusable endoscopes places veterans at risk of infection from viruses including Hepatitis B, Hepatitis C, and human immunodeficiency virus (HIV). Medical research has shown Hepatitis B and Hepatitis C infections have been transmitted through endoscopes. There has not been a documented case of HIV transmission with colonoscopes.

As a result of the improper reprocessing of colonoscopes, 6,387 veterans were notified by the Murfreesboro, Tennessee, VAMC, and 3,260 veterans were notified by the Miami, Florida, VAMC, that they were at risk of these viral infections. Improper processing of ear, nose, and throat (ENT) endoscopes at the Augusta, Georgia, VAMC, resulted in the notification of 1,069 veterans that they were at risk for these same diseases.

There have been multiple notifications to VA medical centers that reprocessing of endoscopes required close attention to detail and compliance with the manufacturers' recommendations for high level disinfection. The responsibility for reprocessing endoscopes is described in VA Handbook, "Supply, Processing, and Distribution (SPD) Operational Requirements."<sup>2</sup> Part 6 of the handbook addresses decontamination and states, in part, "All reusable medical devices used in the medical center should be processed in the SPD decontamination area. If there are other areas of the medical center where decontamination must be done, all procedures listed in this section of the handbook will apply to that area." The handbook also states that staff reprocessing endoscopes "should consult all manufacturers' instructions."

On February 10, 2003, based on problems identified at non-VA facilities, the Olympus Corporation issued a safety alert entitled "Reprocessing of Auxiliary Water Channel on Olympus EXERA<sup>TM</sup> Gastrointestinal Endoscopes." This notice reminded customers that "the auxiliary water channel must be reprocessed each time the endoscope is used."

On February 13, 2004, the VA National Center for Patient Safety (NCPS) issued an alert related to "an incorrect connector being used to link cleaning solution to endoscopes during reprocessing."<sup>3</sup> The alert required VA medical facilities to: (1) provide in-service training consistent with manufacturers' instructions for reprocessing specific models of gastrointestinal (GI) endoscopes, and (2) incorporate knowledge of proper handling and reprocessing of GI fiberoptic endoscopes into the Joint Commission competence assessment requirements for individuals tasked with this assignment.

Based on a January 2006 event involving the reprocessing of prostate biopsy devices, the Veterans Health Administration (VHA) conducted a national review in September 2006 to assess compliance with reprocessing standards. All VHA facilities conducted

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<sup>2</sup> VA Handbook 7176, issued in 2002.

<sup>3</sup> NCPS Alert, *Proper Connectors for Sterilization of all Gastrointestinal Fiberoptic Endoscopes*, February 13, 2004.

self-assessments and the aggregated results were published in 2007. Facilities were directed to create local policies based on manufacturers' instructions, including requirements for demonstration of competence in performing reprocessing.

On December 22, 2008, in response to events at the Murfreesboro VAMC, NCPS issued a Patient Safety Alert regarding the incorrect tube/valve combination and the frequency of reprocessing auxiliary water system accessories.<sup>4</sup> The alert emphasized the importance of following manufacturers' instructions. The alert also required facilities to have SOPs available to all personnel who reprocess endoscopes and accessories and that staff be evaluated for reprocessing competence. Facilities were directed to certify compliance with these action steps by January 7, 2009. Sixteen facilities reported that they were not in compliance with the manufacturers' instructions for reprocessing endoscopes.

On February 4, 2009, the Principal Deputy Under Secretary for Health (PDUSH) and the Deputy Under Secretary for Health for Operations and Management (DUSHOM) sent a memorandum to all VA medical facilities announcing "Endoscopy Step-Up Week" for March 8-14 requiring that facilities ensure they have:

- Locally-developed device-specific SOPs meeting manufacturers' requirements for set-up and reprocessing of all endoscopes.
- Evaluations of model-specific competence for appropriate personnel who set up and/or reprocess endoscopic equipment.
- Assured accountability for reprocessing procedures in all areas and at all levels of the organization.

The memorandum did not require reporting or certification of compliance. On February 9, 2009, VHA issued Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*. This Directive formalizes the requirements specified in the February 4 memorandum.

On May 12 and 13 of this year, the OIG conducted unannounced inspections of VA medical facilities to test the medical facility's compliance with VHA's leadership memorandum of February 4, 2009, establishing an "Endoscopy Step Up Week" March 8-14, 2009, and the February 9, 2009, VHA issued Directive 2009-004. For each colonoscopy reprocessing location, we classified that reprocessing unit as "SOP compliant" if model-specific reprocessing SOPs were present for applicable colonoscopes; as "competence compliant" if at least one demonstrated model-specific competence record existed for each applicable endoscope; and as "compliant" if it was both "SOP compliant" and "competence compliant."

From the sampling of colonoscopy reprocessing units, the OIG projects that 78 percent of VHA colonoscopy reprocessing units were in compliance with SOPs. We estimate that only about one out of two VHA colonoscopy reprocessing units (50.2 percent) is in

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<sup>4</sup> VHA Patient Safety Alert AL09-07, *Improper Set-up and Reprocessing of Flexible Endoscope Tubing and Accessories*, December 22, 2008.

compliance with competency. The compliance with both SOPs and competency is estimated at 42.5 percent.

The results of the unannounced inspections led to the conclusion that serious management issues need to be addressed by VA with respect to the management of industrial processes such as the reprocessing of endoscopes. The OIG report recommends that VA:

- Ensure compliance with relevant directives regarding endoscope reprocessing.
- Explore possibilities for improving the reliability of endoscope reprocessing with VA and non-VA experts.
- Review the VHA organizational structure and make the necessary changes to implement quality controls and ensure compliance with directives.

### **Clinical Risk Assessment Advisory Board (CRAAB)**

VHA Directive 2008-002, *Disclosure of Adverse Events to Patients* (January 18, 2008), provides guidance for disclosure of adverse events related to clinical care to patients or to their personal representatives. Adverse events are defined as “untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other VHA facility.”

VHA Directive 2008-002 describes three adverse event scenarios and their corresponding notification processes:

- *Clinical Disclosure of Adverse Events.* This disclosure category pertains to disclosure of an adverse event to a single patient at the local level. Generally, such events referred to in this subdivision are of a relatively minor nature.
- *Institutional Disclosure of Adverse Events.* This type of disclosure focuses on “cases resulting in serious injury or death, or those involving reasonably expected serious injury, or potential legal liability.”
- *Large Scale Disclosure of Adverse Events.* This type of disclosure is defined as “involving a large number of patients, even if at a single facility.” Authority and responsibility for large scale disclosures resides with VHA’s PDUSH. Often the issues will be clear and the PDUSH will proceed according to the facts and available medical science. However, if the issues are unclear, the PDUSH can request that the DUSHOM convene the CRAAB, an ad hoc consultative board.

CRAABs have permanent voting members that include representatives from the Office of the National Center for Ethics in Health Care, Office of Quality and Performance, National Center for Patient Safety, Office of Patient Care Services, and Office of Public Health and Environmental Hazards. Additionally, individuals knowledgeable about the case at hand, subject-matter experts, and stakeholders affected by the decision may be asked to participate.

Key issues that the CRAAB is expected to address include the number of veterans exposed or potentially exposed; the probability that the adverse event will cause harm; the nature, magnitude, and duration of the potential harm; and the availability of treatment to prevent or ameliorate harm.

VHA Directive 2008-002 recognizes that although it is difficult to weigh all benefits and harms, situations prompting a decision whether to conduct large scale disclosure of adverse events likely involve the following considerations:

- Are there medical, social, psychological, or economic benefits or burdens to the veterans, resulting from the disclosure itself?
- What is the burden of disclosure to the institution, focusing principally on the institution's capacity to provide health care to other veterans?
- What is the potential harm to the institution of both disclosure and non-disclosure in the level of trust that veterans and Congress would have in VHA?

The CRAAB may choose to recommend notification if “one patient or more in 10,000 patients subject to the event or exposure is expected to have a short-term or long-term health effect that would require treatment or cause serious illness if untreated.”

With respect to the colonoscopy reprocessing issues at the Murfreesboro VAMC and the Miami VAMC, the CRAAB unanimously voted for patient notification. The CRAAB was charged with addressing the Augusta VAMC ENT reprocessing incident, but as the facts became clear, notification proceeded without requiring formal CRAAB meetings.

As a result of the National Patient Safety Alert of the December 22, 2008, 16 VA facilities (other than Murfreesboro) reported reprocessing problems with tubing that connects to the auxiliary water line of colonoscopes. The CRAAB, over a series of meetings, and after reviewing scientific literature and conducting further evaluations, voted unanimously to recommend that veterans not be notified of these reprocessing issues as the risk of cross contamination of patients was so small as to be clinically insignificant.

## **CONCLUSION**

The OIG’s review of these issues concludes that the CRAAB has been an effective mechanism for providing guidance to VHA leadership on disclosure of adverse events to veterans. However, the results of our unannounced inspections led to the conclusion that serious management issues need to be addressed by VA with respect to the management of industrial processes such as the reprocessing of endoscopes.

Mr. Chairman, this concludes my statement and we would be happy to answer any questions that you or other Members of the Subcommittee may have.