



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities

To Report Suspected Wrongdoing in VA Programs and Operations

**Telephone: 1-800-488-8244 between 8:30AM and 4PM Eastern Time,
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Executive Summary

Introduction

The VA Office of Inspector General received requests from the Secretary, Chairmen and Ranking Members of VA oversight committees, along with individual members of Congress, regarding the reprocessing of endoscopic equipment at several specific VA medical centers (VAMCs), and to assess the extent of related problems throughout the Veterans Health Administration (VHA). The purpose of the review is to describe the pertinent events at VAMCs where problems were reported, assess VHA's response to the events, and conduct a system-wide evaluation of current reprocessing practices.

Results

We visited the facilities which had been the subject of considerable media attention: the Bruce W. Carter VAMC (Miami) in Miami, FL; the Tennessee Valley Healthcare System-Murfreesboro campus (Murfreesboro); and the Charlie Norwood VA Medical Center (Augusta) in Augusta, GA. We reviewed applicable regulations, policies, procedures, and guidelines. Furthermore, 26 inspectors conducted unannounced onsite visits for the total of 42 probability-based randomly selected VHA facilities to examine pertinent endoscope reprocessing documentation.

Because of the unannounced nature of the inspections and for cost-efficiency, a stratified clustering sample design was employed to maximize the number of facilities that could be inspected in a single day. Two probability-based random samples of VHA endoscope reprocessing facilities were selected from the study populations for the unannounced onsite inspection: one for colonoscopy reprocessing and another for ENT endoscope reprocessing. With probability sampling, each unit in the study population has a known positive probability of selection. This property of probability sampling avoids selection bias and allows use of statistical theory to make valid inferences from the sample to the study population.

Conclusions and Recommendations

Facilities have not complied with management directives to ensure compliance with reprocessing of endoscopes, resulting in a risk of infectious disease to veterans. Reprocessing of endoscopes requires a standardized, monitored approach to ensure that these instruments are safe for use in patient care.

The failure of medical facilities to comply on such a large scale with repeated alerts and directives suggests fundamental defects in organizational structure.

The Clinical Risk Assessment Advisory Board has been an effective mechanism for providing guidance to VHA leadership on disclosure of adverse events to veterans.

Recommendation 1: We recommended that the Acting Under Secretary for Health ensure compliance with relevant directives regarding endoscope reprocessing.

Recommendation 2: We recommended that the Acting Under Secretary for Health explore possibilities for improving the reliability of endoscope reprocessing with VA and non-VA experts.

Recommendation 3: We recommended that the Acting Under Secretary for Health review the VHA organizational structure and make the necessary changes to implement quality controls and ensure compliance with directives.

Comments

The Acting Under Secretary for Health concurred with the findings and recommendations. See Appendix D (pages 41–43) for the full text of his comments. He stated his commitment to resolve the urgent management and clinical issues involved. VHA will provide its detailed plan of corrective action in July 2009.

We will follow up on the corrective actions until all recommendations have been fully implemented.

(original signed by:)
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Introduction

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections (OHI), received requests from the Secretary, Chairmen and Ranking Members of our oversight committees, along with individual members of Congress, to evaluate concerns regarding the reprocessing of endoscopic equipment at several VA medical centers (VAMCs), and to assess the extent of related problems throughout the Veterans Health Administration (VHA).

The purpose of this review is to describe the pertinent events at VAMCs where problems were reported, assess VHA's response to the events, and conduct a system-wide evaluation of current reprocessing practices.

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

Background

Endoscopy

Endoscopy is a minimally invasive diagnostic procedure that is used to assess the interior surfaces of an organ. Endoscopic instruments have rigid or flexible tubes which allow visual inspection and photography; they also enable biopsy of tissue and removal of foreign objects.

Although Hippocrates described endoscopic examinations 2,400 years ago, the modern era of endoscopy began less than 60 years ago with the development of flexible instruments and adequate light sources.¹ Capability for examination of the entire colon was developed in the 1970s and colonoscopy came into widespread use thereafter. Today, specialists throughout the range of medical and surgical practice employ both rigid and flexible endoscopes for diagnosis and treatment. In addition to upper and lower gastrointestinal (GI) applications, flexible fiberoptic endoscopy encompasses laparoscopy (for the abdomen and pelvis), bronchoscopy (lower airways), cystoscopy (urinary tract), arthroscopy (joints), and rhinolaryngoscopy (upper airways), and others. Endoscopic procedures are carried out in specially equipped endoscopy suites, operating rooms (ORs), and intensive care units.

Endoscopes vary substantially in length and complexity. Some rhinolaryngoscopes are less than 12 inches long and have no internal channels, while GI endoscopes may be more than 6 feet long and have three internal channels for application of suction, delivery

¹ Lau WY, Leow CK, Li, AKJ. *History of endoscopic and laparoscopic surgery*. World J Surg. 1997;21:444-453.

of air or water, and for biopsy and other operative procedures. This review addresses issues related to the use and reprocessing of flexible fiberoptic endoscopes (FfEs). Rigid endoscopes and FfEs used exclusively in sterile OR environments are not considered.

Reprocessing of Reusable Medical Equipment

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 FfEs, 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 microorganisms “except for small numbers of bacterial spores.”²

Endoscopes must be decontaminated after each use to remove potential sources of infection. Individual manufacturers publish specific reprocessing instructions for each endoscope and related accessory items (tubing, pumps, etc.). FfE reprocessing includes basic cleaning steps and HLD of the instrument and accessories using manual or automated processes. Some facilities use automatic endoscope reprocessors designed to wash and disinfect FfEs. Whether manual or automated, reprocessing requires the following five steps:

1. Pre-cleaning to remove body fluids and debris from internal and external surfaces. This step is typically completed near where the procedure is performed, typically by a nurse or technician who brushes each internal channel and flushes each channel with water.
2. Disinfection by immersion in a disinfecting liquid and perfusion of the disinfectant into all accessible channels.
3. Rinsing of all surfaces and channels with sterile, filtered, or high-quality potable water to remove the disinfectant.
4. Flushing of the channels with alcohol to assist in drying the interior channels, followed by forced-air drying.
5. Storage in a dry and well-ventilated environment in accordance with the manufacturer’s instructions and hung vertically with control valves and biopsy inlet cap removed to facilitate air movement.

² Rutala WA, Weber DJ, and the Healthcare Infection Control Practices Advisory Committee, Centers for Disease Control and Prevention. *Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008. http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed May 28, 2009.

Leak testing and steps 2–4 can occur in a facility’s Supply, Processing, and Distribution (SPD) decontamination area or in a designated and appropriately equipped reprocessing site near where endoscopy is performed. While access to SPD decontamination areas is limited to SPD staff, either SPD or clinic staff can reprocess FFEs at reprocessing sites in clinical areas.

Manufacturers of endoscopic equipment and accessories publish detailed instructions for equipment set-up, pre-cleaning, and reprocessing. When a new endoscope is introduced, manufacturer representatives typically provide initial training to staff, and some provide annual or on-demand refresher training. For the most commonly used endoscopes, manufacturer websites are replete with product information, user manuals, and other customer-focused documents.

FFE reprocessing has been shown to have a narrow margin of safety, and any deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection. Endoscopy-related outbreaks of infectious diseases have clearly resulted from failures to comply with reprocessing guidelines.

Although there is no requirement to report failures in the reprocessing of reusable medical equipment and no compilation of occurrences nationwide, media descriptions suggest that incidents at non-government hospitals are not rare. For example, in 2004 a California hospital sent letters to more than 2,000 patients who had undergone endoscopies after a reprocessing machine was found to have malfunctioned,³ and in 2005 a hospital in Pennsylvania notified 200 patients when colonoscopes were discovered to have been inadequately disinfected.⁴

Endoscopy-Related Infection

Infections associated with GI endoscopy have been estimated to occur at a rate of 1 in 1.8 million procedures.⁵ Although various types of microorganisms can be implicated, viruses have been of concern for the greatest numbers of patients because viral infections may take months or years to become manifest. The three viruses most often considered after lapses in endoscope disinfection are hepatitis B, hepatitis C, and the human immunodeficiency virus (HIV). Each of these viruses is readily killed when recommended disinfection practices are followed. Proven cases of transmission through endoscopy have occurred for hepatitis B and hepatitis C, and have invariably been associated with deficiencies in the use or reprocessing of endoscopes or accessories, or

³ Torassa U. *Endoscopy hygiene a growing problem*. San Francisco Chronicle, September 10, 2004.

⁴ Fahy J, Spice B. *Monroeville hospital urges 200 colonoscopy patients to get checked for hepatitis, HIV*. Pittsburgh Post-Gazette, March 31, 2005.

⁵ Schembre DB. *Infectious complications associated with gastrointestinal endoscopy*. *Gastrointest. Endosc. Clin. N. Am.* 2000;10:215-32.

with other lapses in infection control. There are no reported cases of transmission of HIV by endoscopes.⁶

Endoscopy in VHA

Endoscopic procedures are frequently performed in VA medical facilities, usually in outpatient settings. Table 1 depicts common outpatient endoscopic procedures, excluding those performed only in operating rooms (e.g., laparoscopy, arthroscopy).

Table 1: Number of selected outpatient endoscopic procedures performed at VHA facilities in FY09 through May 23, 2009, by type of endoscopy.	
GI Endoscopy	191,701
Colonoscopy	142,472
ENT Endoscopy	48,606
Cystoscopy	49,453
Bronchoscopy	5,163
<i>Data Source: VHA Medical SAS Outpatient data file generated May 24, 2009, based on CPT-4 codes (See Appendix A).</i>	

Inpatient procedures in fiscal year (FY) 2009 (through May 29, 2009) included 599 colonoscopies and 167 ear, nose, and throat (ENT) endoscopy procedures.⁷

Responsibility for reprocessing endoscopes is described in the VA Handbook, “Supply, Processing, and Distribution (SPD) Operational Requirements.”⁸ Part 6 of this document 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.”

⁶ Nelson DB, Muscarella LF. *Current issues in endoscope reprocessing and infection control during gastrointestinal endoscopy.* World J Gastroenterol. 2006;12:3953-64.

⁷ VHA Medical SAS inpatient data file generated May 30, 2009, based on ICD-9 codes. See Appendix A.

⁸ VA Handbook 7176, 2002.

In recent years, several VHA medical facilities have been found to deviate from recommended procedures in the reprocessing of endoscopes, in some cases necessitating patient recalls. Pertinent events and actions from 2003 through 2007 are detailed below.

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™ 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.”⁹ The alert required VHA medical facilities to: (1) provide in-service training consistent with manufacturer instructions for reprocessing specific models of GI endoscopes, and (2) incorporate knowledge of proper handling and reprocessing of GI fiberoptic endoscopes into JCAHO competence assessment requirements for individuals tasked with this assignment.

Based on a January 2006 event involving the reprocessing of prostate biopsy devices, VHA conducted a national review in September 2006 to assess compliance with reprocessing standards. All VHA facilities conducted 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. VHA also planned a re-assessment in FY 2008.

Disclosure and the Clinical Risk Assessment Advisory Board

VHA Directive 2008-002 provides guidance for disclosure of adverse events related to clinical care to patients or to their personal representatives.¹⁰ The directive includes instances “where the adverse event may not be obvious or severe, or where the harm may only be evident in the future.” It was developed based on VHA’s National Center for Ethics report “Ethical Leadership: Fostering an Ethical Environment and Culture,”¹¹ which notes:

Within the Veterans Health Administration (VHA), there is a presumptive obligation to disclose adverse events that cause harm to patients. However, in the case of an adverse event that has the potential to affect dozens or

⁹ NCPS Alert, *Proper Connectors for Sterilization of all Gastrointestinal Fiberoptic Endoscopes*, February 13, 2004.

¹⁰ VHA Directive 2008-002, *Disclosure of Adverse Events to Patients*, January 18, 2008.

¹¹ 2007, p. 34.

even thousands of patients, a public health response also requires a determination of the probability and magnitude of harm resulting from the adverse event as well as a weighing of additional factors, including, but not limited to salient ethical principles; risk of harm to veterans and identifiable third parties; benefit and burden of disclosure to veterans including medical, psychological, social or economic, impact on the institution's perceived integrity and its capacity to provide care and treatment for all veterans; as well as applicable policy and relevant precedent.¹²

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:

1. *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. An example is a medication error that did not result in harm or injury.
2. *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.” In these instances, the need for institutional disclosure is recognized, often with detailed clinical counseling and advisement of legal options accompanying patient notification. However, like “Clinical Disclosure of Adverse Events,” described above, “Institutional Disclosure of Adverse Events” refers to disclosure to a single patient of an adverse event and its related issues.
3. *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.”¹³ Authority and responsibility for large scale disclosures resides with VHA’s Principal Deputy Under Secretary for Health (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 Deputy Under Secretary for Health for Operations and Management (DUSHOM) convene the Clinical Risk Assessment Advisory Board (CRAAB), an ad hoc consultative board.

¹² *National Center for Ethics Report on Ethical Leadership: Fostering an Ethical Environment and Culture, 2007*

¹³ Attachment A of VHA Directive 2008-002 recognizes that adverse events with a known risk of serious future health consequences may be associated with an “extremely small” risk.

CRAAB members include representatives from the Office of the Deputy Under Secretary for Health for Operations and Management, 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:

- a. Are there medical, social, psychological, or economic benefits or burdens to the veterans, resulting from the disclosure itself?
- b. What is the burden of disclosure to the institution, focusing principally on the institution's capacity to provide health care to other veterans?
- c. 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.”

In 2008 the CRAAB has addressed a variety of issues involving a potential need for large scale adverse event disclosures. These are briefly summarized:

- In March the CRAAB convened due to problems with the reprocessing of endoscopy biopsy valves at a VAMC. The CRAAB minutes note that 714 patients who underwent endoscopic procedures may have been exposed to potential harm due to incomplete reprocessing of biopsy valves. The CRAAB recommended to the PDUSH that these patients be notified for follow-up and testing.
- In June the CRAAB convened due to problems with prostate brachytherapy at a VAMC.¹⁴ CRAAB minutes noted that up to 63 patients may have received lower radioactive doses than prescribed. The CRAAB recommended that the patients be notified of possible radiation therapy under dosage. In October the CRAAB reconvened to further explore the issue of radiation under dosing after problems at

¹⁴ Brachytherapy is a form of radiotherapy in which a radioactive source is placed inside or next to the area requiring treatment.

other VA facilities were identified. The CRAAB met to track the issue in November and December and again in April 2009.

- The CRAAB convened in July to address the issue of improperly reprocessed ENT endoscopes at a VAMC. The CRAAB recommended that the VAMC disclose to 159 affected patients the possibility that the ENT endoscopes may have been improperly disinfected.
- Also in July, the CRAAB examined “the events surrounding an issue with apparent reuse of syringes for heparin infusion in the cardiac catheterization lab” at a VAMC. In this instance, the CRAAB concluded that “a population-based notification is not supported when applying the risk guidelines suggested in Directive 2008-002,” and so informed the PDUSH.

Section I – Recent Events Involving Endoscope Use and Reprocessing

Scope and Methodology

We visited the Bruce W. Carter VAMC (Miami) in Miami, FL, and the Tennessee Valley Healthcare System-Murfreesboro campus (Murfreesboro) during the week of April 13-17, and the Charlie Norwood VA Medical Center (Augusta) in Augusta, GA, on May 5-6, 2009. We interviewed facility directors; Chiefs of Staff, Chiefs of Surgery, Chiefs of Medicine, Chiefs of Supply, Processing, and Distribution (SPD), and the Chiefs of Infectious Disease; gastroenterologists and other GI staff; Infection Control nurses; and other clinical and administrative personnel knowledgeable about the issues. We also interviewed the CRAAB chairman and CRAAB members; the VHA National Director for Infectious Diseases; the Director and staff of the VA National Center for Patient Safety, Food and Drug Administration (FDA) officials; and representatives of endoscope manufacturers.

We reviewed the Administrative Investigation Board (AIB) from Miami and Root Cause Analyses (RCAs) from Murfreesboro and Augusta, VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities* (February 2009), memoranda regarding endoscopy issues from medical facilities to VA Central Office, CRAAB minutes and correspondence, internal investigation documents from facilities and NCPS, SPD self-assessments, inventory reports, standard operating procedures (SOPs), incident reports, and follow-up actions after NCPS Alerts and memoranda from PDUSH and DUSHOM.

Findings

A. Colonoscopy

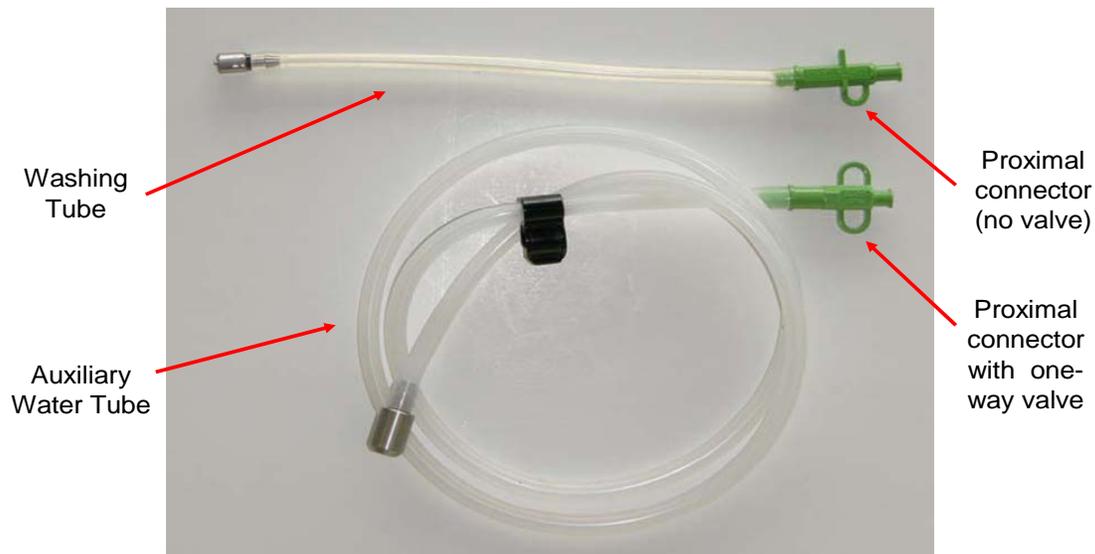
Tennessee Valley Healthcare System – Alvin C. York (Murfreesboro) Campus

Tennessee Valley Healthcare System comprises two campuses, the Alvin C. York VAMC (Murfreesboro) and the Nashville VAMC. On December 1, 2008, a patient underwent a colonoscopy at Murfreesboro. His was the third and last procedure of the day. During this procedure, clinicians noted blood in the tubing of the auxiliary water system, which is used during procedures for irrigation. Concerned about equipment failure, staff notified the manufacturer and took the equipment out of service. On December 4, the Patient Safety Manager (PSM) initiated an investigation, and on December 5, the Veterans Integrated Service Network (VISN) leadership was notified. On December 8 facility managers ordered an RCA.

The PSM determined that there was no equipment failure, but that a required one-way valve had been absent during the procedure. The PSM also found that two components

of auxiliary water system tubing were not being disinfected or discarded according to the manufacturer's instructions. The first piece of tubing, the auxiliary water tube (AWT), connects to the colonoscope, is four feet long, and has a one-way valve which prevents backflow of bodily fluids into the tube. The second piece of tubing, the washing tube, is less than a foot long and has a connector for use during reprocessing of endoscopes. The PSM discovered that the AWT was attached to the connector of the washing tube, although it was unclear when the switch occurred. Both the one-way valve and the connector are light green in color and are roughly the same size and shape. While the one-way valve has two "wings," the connector has only one wing. See Figure 1.

Figure 1. Connectors switched at Murfreesboro.

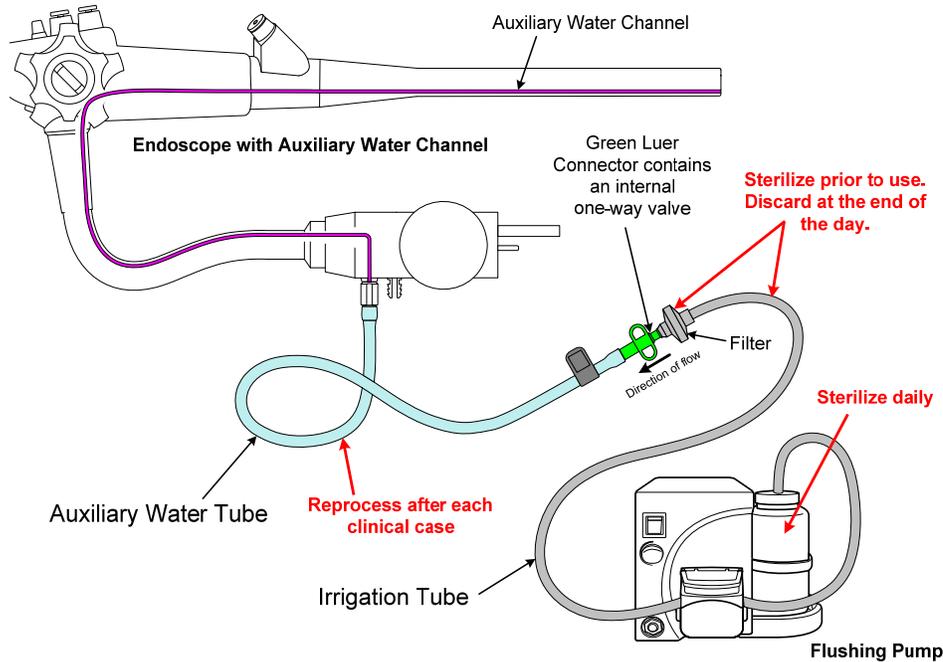


The manufacturer delivers the AWT with tubing and connector attached. These components are not meant to be disconnected for any reason, including reprocessing. We were unable to determine when or why the switch occurred, nor could we trace the action to a specific location or employee. While colonoscope reprocessing is documented and can be tracked through the instruments' serial numbers to a specific technician or nurse, the reprocessing of auxiliary tubing and other accessories is not documented.

In addition to the problem with switched connectors, it was also found that, while the colonoscopes themselves were undergoing appropriate reprocessing, AWTs were reprocessed at the end of the day rather than after each patient. Further, irrigation tubes,

another component of the auxiliary water system, were not discarded at the end of each day in accordance with manufacturer instructions. See Figure 2.

Figure 2. Auxiliary water system and reprocessing requirements for components.



SPD staff received training in July 2008 specific to the reprocessing of FFEs; however, GI nursing staff (who reprocessed colonoscopes until December 1) did not receive this training. Further, we found no evidence that GI nursing staff had demonstrated competence to clean and reprocess FFE and related accessories.

On December 12, the Chief of Infectious Disease and GI physicians were tasked with completing a risk assessment; on December 15, the risk assessment, which recommended notification of the patients who received colonoscopies on December 1, was submitted to VISN and NCPS officials. Murfreesboro managers anticipated that VACO would decide about notifying these patients. On January 7, 2009, two patients who received colonoscopies on December 1 were notified.¹⁵

¹⁵ The first of the three patients who had colonoscopy on December 1 can be excluded because colonoscopes and accessories are clean for the first use each day. If colonoscopes and tubing/accessories are not properly cleaned between patients, cross contamination is possible for subsequent patients receiving procedures that day.

Murfreesboro managers could not determine with certainty how long the auxiliary water tube which had no one-way valve had been in use. Consequently, they decided to notify all patients who had undergone colonoscopy from the date that colonoscopes were originally received from the manufacturer (April 23, 2003). On February 9 letters were sent to 6,387 patients advising them of the potential exposure and offering testing for viral diseases.

National Center for Patient Safety Alert and Subsequently Reported Problems

On December 22, in response to events at Murfreesboro, NCPS issued a Patient Safety Alert regarding the incorrect tube/valve combination and the frequency of reprocessing auxiliary water system accessories.¹⁶ The Alert emphasized the importance of following manufacturer's 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 VHA facilities responded that they had not been compliant with reprocessing guidelines. Thirteen facilities were reprocessing the AWT at the end of each day or less often rather than after each patient. Ten facilities reported that irrigation tubes were being reprocessed weekly or less often instead of being discarded at the end of the day. The NCPS conducted an onsite assessment of one of the 16 facilities. Based on findings from that evaluation and on issues identified at other sites, the NCPS issued an analysis of systemic problems with reprocessing throughout VHA (see Appendix B).

CRAAB Response to Murfreesboro Event

The December 1, 2008, incident at Murfreesboro raised concerns about possible patient exposure to microbial pathogens via contaminated medical equipment. Several questions arose, including which patients, if any, should be notified, what information to convey, and what patients should be advised to do.

On December 15, the DUSHOM requested, "that the CRAAB be convened as soon as possible to review issues related to appropriateness of cleaning endoscopes...The group should review the appropriateness of cleaning endoscopes and determine the number of patients who may have been affected by this process. There also may be a need to determine the scope of this problem on a national level."

The CRAAB met January 9, 12, and 15, and February 6, 2009. At the first meeting, two main issues were identified. The first was that of the incorrect connector which had been attached to the AWT at Murfreesboro. The second involved the 16 facilities reporting non-compliance in response to the December 22 NCPS Alert.

¹⁶ VHA Patient Safety Alert AL09-07, *Improper Set-up and Reprocessing of Flexible Endoscope Tubing and Accessories December 22, 2008.*

The CRAAB established that Murfreesboro was the only VAMC facility with this problem. The facility could not immediately determine if other patients had undergone colonoscopy with the incorrect connector attached. The type of colonoscope used on December 1 had been in use at Murfreesboro campus since approximately May 2003.

At the time of its first meeting on January 9, the CRAAB felt that the risk to patients was “small but not zero.” However, the CRAAB noted that a Murfreesboro RCA which began on December 8th was due to be completed on January 16, 2009. It deferred further conclusions and requested that the RCA include “an assessment of how likely it would be for the wrong connector to go unnoticed or undetected, when was the washing tube...first used at the Murfreesboro campus?” and whether it was “possible to date when the incorrect connector was added to the [auxiliary water tube]...?”

CRAAB Response to 16 Facilities Reporting Problems After NCPS Alert

The CRAAB also discussed in its January 9 meeting the 16 VA facilities (other than Murfreesboro) that reported reprocessing problems following the NCPS alert. The CRAAB noted that at ten facilities accessories “upstream of the one-way check valve were being reprocessed incorrectly,” and that different reprocessing instructions for components of the auxiliary water subsystem “creates confusion.” The CRAAB concluded that even if components are not properly reprocessed, “when the correct anti-backflow valve is used, the risk of cross contamination of patients was so small as to be clinically insignificant.” The CRAAB “voted unanimously to not require notification of patients involved with the incorrect use or reprocessing of components upstream of the one way check valve.”

The CRAAB also discussed the finding that VAMCs had reported “the AWT was being reprocessed at the end of each day, instead of after each patient as required by the manufacturer's instructions.” The Board concluded that, “To cause possible cross contamination of patients by blood borne viruses, viral particles would have to passively diffuse 6–7 feet through the auxiliary water channel of the endoscope” in order to contaminate the AWT.¹⁷ This was felt to be virtually impossible. Nevertheless, before dismissing the issue of patient notification, the CRAAB elected to further consider the issue at a subsequent meeting.

The CRAAB determined that the incorrect connector was probably switched sometime after the equipment was delivered in 2003. Furthermore, only one of multiple Murfreesboro AWTs had the incorrect connector. With regard to the issue of the AWT being reprocessed at the end of each day instead of after each patient, the board unanimously recommended that because the risk is “clinically insignificant...disclosure would not be beneficial to patients.”

¹⁷ The internal diameter of the AWT is 1 millimeter.

The CRAAB limited its considerations to “viral illnesses that resulted from cross contamination,” and even more specifically, hepatitis B, C and HIV. The CRAAB noted that it would take a prolonged time period, e.g., months to years for such infection to become apparent. In contrast, the CRAAB noted, “bacterial cross contamination would result in illness within days of the endoscopy.”

Other engineering issues were discussed, and the CRAAB received a report about the NCPS’s discussions with the colonoscope manufacturer, as well as microbiological testing that the manufacturer had performed to assess worst case scenarios of hepatitis B, hepatitis C, and HIV infection.

The CRAAB queried the 13 VAMCs that were not reprocessing the AWT after each patient to ascertain their practices with respect to use of the auxiliary water system. The CRAAB’s concern was that if the AWT is not changed after each patient and is not connected prior to the procedure and water flushed through the endoscope (or becomes disconnected anytime during the procedure), it could be contaminated by back flow.

Also in this CRAAB meeting, bacterial cross contamination was discussed further. The CRAAB “decided that we should not deal with this issue because any clinical adverse bacterial event would have already occurred within days of the procedure and it would be impossible to determine if the bacterial infection resulted from the patient's colonic flora or from cross contamination. The risk of bacterial infection would not be expected to have serious or long-term consequences for the patient and therefore would not seem appropriate to disclose to the patient so far after the event had occurred.”

On February 6 the CRAAB evaluated data provided by the colonoscope manufacturer demonstrating that the AWT one-way valve prevents backflow when used properly.

In light of continued uncertainty as to precisely when the connectors were switched – despite multiple explorations of this issue both at by Murfreesboro and the NCPS – the CRAAB “voted unanimously to recommend disclosure to all patients” who had colonoscopy at Murfreesboro from April 23, 2003 to December 1, 2008. The CRAAB indicated that, “These patients should be offered serologic testing for Hepatitis B & C and HIV.” However, the CRAAB noted that, “This recommendation does not apply to ... patients who had the first colonoscopy of each day.” The CRAAB concluded that patient notification was not warranted at the 13 VAMCs performing incorrect reprocessing of AWTs because none of these facilities reported connecting the AWT to the colonoscope after the procedure had begun.

Step-Up Week

On February 4, 2009, the PDUSH and 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 to the DUSHOM.

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.

Bruce W. Carter VA Medical Center, Miami, Florida

Miami managers responded to NCPS Alert 09-07 on January 5, 2009, indicating no problems with endoscopy equipment. At this facility, colonoscopy reprocessing was done by an SPD technician (tech) assigned to the GI procedure area. The SPD tech reported to the Chief of SPD, who in turn reported to the Chief of Acquisition and Materiel Management Service (A&MMS).

The Chief, A&MMS, coordinated the Alert response and asked the Chief of SPD to certify compliance. The SPD Chief searched inventory files and concluded that the AWT had never been purchased. The SPD tech responsible for reprocessing colonoscopes in the GI area reported that he had never seen the AWT. While the Chiefs of A&MMS and SPD told us that GI reported they did not use AWT, GI staff told us that they only reported they were in compliance with the Alert because their AWTs had the proper one-way valve attached. GI staff told us that they did not realize that the second page of the Alert addressed reprocessing issues.

On February 11, a manufacturer representative visited the GI clinic and recommended use of disposable tubing in place of the AWT. Without proper approval, the GI staff put the sample tubing into trial use. On March 4, 2009, a GI nurse requested that SPD purchase the disposable tubing, and the Chief, A&MMS, thereby learned that the AWT was in fact in use at the time of the Alert.

In preparation for Step-Up Week, a facility team evaluated the equipment used in the GI suite and also found that the AWT was being used. The team discovered that procedures for set-up, use, and reprocessing of colonoscopes were not in accordance with manufacturer's recommendations. The AWT was not reprocessed after each patient, but rather was only flushed or rinsed with sterile water and never sent to SPD for sterilization.

On March 5 the VISN was notified and on March 6 a memorandum was forwarded to the DUSHOM. Use of disposable tubing was discontinued on March 12, and all auxiliary water system pumps were removed. On March 16 the medical director of the Infection Control Program conducted a risk assessment and concluded that “while the consequence of transmission of disease was clinically significant, the probability of transmission is substantially less than 1 in 10,000.” It was estimated that the number of potentially affected veterans was somewhere between 5,000 and 10,000. However, it was noted that this estimate included all patients who underwent colonoscopy with irrigation capacity, even though not every patient had irrigations done or the tubing connected.

At the request of the DUSHOM, on March 16, 2009, the CRAAB met to review issues at Miami; findings included:

- The AWT and other accessories were not sterilized prior to initial use.
- The AWT was not reprocessed between patients.
- None of the irrigation components had been changed or reprocessed since May 2004 when the equipment arrived onsite.

Further, it was found that at this facility clinicians connected the auxiliary water system to the colonoscope after the procedure was already in progress in approximately half of all procedures. The committee believed that this practice, when combined with the absence of AWT reprocessing, posed a low but significant risk for cross contamination of blood borne pathogens.

On March 17, the CRAAB unanimously recommended disclosure to all Miami patients who had colonoscopy with use of the AWT between May 2004 and February 12, 2009. The PDUSH directed disclosure, and the medical center mailed 3,260 letters to veterans determined to be at risk, advising them of their potential exposure and offering serologic testing for hepatitis B, hepatitis C, and HIV.

On March 26, 2009, a manufacturer’s representative, in the course of providing training on the AWT, found debris in the auxiliary water channel while flushing a colonoscope presumed to be clean. Other colonoscopes presumed to be clean were tested with the same result. All GI endoscopic procedures were discontinued pending review by the VHA Infectious Diseases Program Office (IDPO). On March 27, the IDPO recommended that colonoscopy without use of the auxiliary water channel be resumed, but that colonoscopes with the auxiliary water channel not be placed back into use until the manufacturer validated their safety.

The VISN 8 Network Director chartered an AIB to review the issues at Miami. The AIB found serious problems with inventory control, oversight, supervision, training, communication, and competence assessment related to endoscopy equipment. On

April 2, the AIB reported that endoscope reprocessing is “incomplete and not according to device-specific manufacturer’s instructions.”

A team from another VAMC provided training and verified competence of Miami SPD staff responsible for colonoscopy reprocessing. Manufacturer’s representatives provided additional training. The IDPO returned to the MVAMC on April 8 for a follow-up site visit and found that SPD technicians were properly cleaning the endoscopes.

During our site visit April 15-16, we reviewed both SPD and GI staff training records and did not find device-specific competencies. We subsequently received copies of certification of competence for reprocessing staff.

B. ENT Endoscopy

Charlie Norwood VA Medical Center, Augusta, Georgia

On November 4, 2008, a patient in the ENT clinic at the Augusta VAMC questioned the method by which a nurse was cleaning a laryngoscope. The patient, who had already had his endoscopic procedure, read instructions on the box of disposable sanitizing cloths being used by the nurse. The instructions stated that they should not be used as a means to clean equipment that comes in contact with mucous membranes. At the time of the event, ENT endoscopes were cleaned in the ENT clinic by nursing staff; they were not undergoing HLD.

An ENT physician reported the patient’s concern to the Chief of Surgery, who then notified the medical center’s epidemiologist and Chief of SPD. On November 5 the Chief of Surgery closed the ENT clinic pending completion of a preliminary investigation. The ENT clinic resumed seeing patients on November 12 following staff training.

The medical center began an investigation into the issue on November 21. Following an extensive review and consultation with experts, recommendations and an action plan regarding patient notifications were finalized January 20. On January 28, the DUSHOM requested that a CRAAB review Augusta’s “failure to follow recommended disinfection and sterilization guidelines for cleaning endoscopes...” in the ENT clinic. After consideration of the facts, the PDUSH concluded that notification was warranted and CRAAB involvement unnecessary. On February 9 notification letters were sent to 1,069 affected ENT patients.

The investigation revealed that a nurse assigned to the ENT clinic from 1999 to January 2008 had been properly cleaning endoscopes per manufacturer’s guidelines. In January 2008, that nurse transferred to another position in the medical center and a nurse with no experience working with endoscopes was assigned to ENT. The new nurse told us that she received 2-3 days of orientation from the outgoing nurse, and that she was

specifically told to use the sanitizing cloths to clean laryngoscopes. She did not observe a laryngoscope being cleaned. This nurse further stated that, after asking staff from the Medical College of Georgia how laryngoscopes were cleaned there, expressed concerns to the ENT Clinic Chief and Chief of SPD in June or July 2008.

In addition to an epidemiologist's investigation, medical center managers also directed the Risk Manager and Quality Manager to investigate staff actions, and chartered a Root Cause Analysis (RCA) team to evaluate system and process issues that could have contributed to the event. Those reports were submitted on February 11 and March 4, respectively.

Prior to the November 4 event, FFE reprocessing SOPs had not been updated since 2001; in addition, staff responsible for FFE reprocessing did not have adequate documentation of competence assessments. When we visited Augusta in May 2009, the facility still did not have documentation of device-specific competence, which was the standard used in this national assessment.

Section II – National Assessment of Reprocessing Practices in VHA

Scope and Methodology

We reviewed applicable regulations, policies, procedures, and guidelines. Twenty-six inspectors conducted unannounced onsite visits for the total of 42 probability-based randomly selected VHA facilities to examine pertinent endoscope reprocessing documentation.

To prepare for the unannounced onsite inspection, we emailed a request to the directors of VHA facilities for information on colonoscopy and ENT endoscopy on April 27, 2009. This request asked for the following information: (1) a list of the manufacturer and model number for each colonoscope in active use at each procedure location and reprocessing location, including clinics, (2) reprocessing locations for ENT endoscopes, including clinics, and (3) the administrative section responsible for completing performance evaluations for HLD staff at each reprocessing location.

Study Populations

The study population for colonoscope (or ENT endoscope) reprocessing consisted of all colonoscope (ENT endoscope) HLD reprocessing units in VHA facilities as of April 27, 2009. A VHA facility may have more than one endoscope reprocessing location, and each of the reprocessing units was counted. For example, a facility may reprocess colonoscopes both in its GI procedure suite/room and at its OR, and thus two HLD reprocessing units would be counted for that facility. In addition, a facility may send its

endoscopes to another facility for HLD reprocessing; no reprocessing unit would be counted for the sending facility.

To identify the study populations, we first ascertained all VHA facilities that performed colonoscopy and ENT endoscopy. We extracted two (self-reported) lists of VHA facilities from the facility responses to the information request email of April 27: one for facilities that reported performing colonoscopy, another for the ENT endoscopy. A facility that reported performing both endoscopies would be on both lists. Independently, we generated the (workload) lists of facilities from the FY 2009 VHA outpatient medical SAS data file where colonoscopy and/or ENT endoscopic procedures were performed, based on CPT-4 codes (see Appendix A). The self-reported and the workload facility lists for each endoscopy were compared and the discrepancies between the lists were resolved to ensure the completeness of ascertainment of VHA colonoscopy and ENT endoscopy facilities.

We established the study populations by including the distinct endoscope HLD reprocessing units within colonoscopy and ENT endoscopy facilities. The distinct reprocessing locations, separately for colonoscopes and ENT endoscopes within each endoscopy facility, were determined by the self-reported information from facility responses to the email request. For example, if a facility performed colonoscopy both in its GI procedure suites and its OR, and the facility reprocessed all colonoscopes in a central SPD location, then the facility would be counted as having only one reprocessing location (SPD).

Sample Design

Separate, detailed onsite inspections were conducted at Miami, Murfreesboro, and Augusta. Therefore, these facilities and their associated hospitals and clinics were excluded from our sample selection for the unannounced onsite inspection. We also excluded the VA Maryland Healthcare system (Baltimore and Perry Point VAMCs), where we conducted exploratory information gathering, and the Alaska VA Healthcare System because of its geographic distance.

Because of the unannounced nature of the inspections and for cost-efficiency, a stratified clustering sample design was employed to maximize the number of facilities that could be inspected in a single day. Two probability-based random samples of VHA endoscope reprocessing facilities were selected from the study populations for the unannounced onsite inspection: one for colonoscopy reprocessing and another for ENT endoscope reprocessing. With probability sampling, each unit in the study population has a known positive probability of selection. This property of probability sampling avoids selection bias and allows use of statistical theory to make valid inferences from the sample to the study population.

After identifying endoscope reprocessing facilities, we first combined associated facilities into a cluster of facilities that includes the VAMC and associated clinics (if any) where endoscopes are reprocessed. In addition to sharing the same administrative leadership, facilities within a cluster are generally close geographically, making feasible same-day site visits within a cluster.

We then categorized each cluster of facilities into one of the following three strata:

- The “colonoscopy” stratum of facilities performing only colonoscopy.
- The “ENT endoscope” stratum of facilities performing only ENT endoscopy.
- The “both” stratum of facilities performing both colonoscopy and ENT endoscopy.

A facility cluster is classified into the “colonoscopy” (or “ENT endoscope”) stratum if all facilities within a cluster performed only colonoscopy (or ENT endoscopy), and classified into the “both” stratum if otherwise. For example, if a VAMC performs only colonoscopy and one of its clinics performs only the ENT endoscopy, the cluster of the VAMC and its clinics is classified as “both.”

Because of the distance from the Fort Harrison VAMC (Montana) to its Billings clinic, we grouped Fort Harrison only with its clinic in Missoula as one cluster, and paired the Billings clinic with the Sheridan VAMC (Wyoming) as another cluster for sampling. This intentional splitting and pairing permitted one inspector to conduct site visits at Fort Harrison and Missoula and another inspector to visit Sheridan and Billings all on the same day.

We randomly selected 26 clusters of facilities from the strata, with unequal probability of selection. The facility clusters that performed both endoscopic procedures and had more than two facilities were over sampled to maximize the number of facilities visited on the same day. A total of 42 (28.4 percent) VHA facilities were selected for inspection from among 148 VHA facilities engaged in endoscopy. Among the 42 sampled facilities, 9 facilities performed only colonoscopy, 6 only ENT endoscopy, and 27 both.

This complex sample design included stratification, clustering, and unequal probabilities of selection.

Site Visits for Document Examination

Twenty-six healthcare inspectors trained for this project conducted unannounced site visits on May 13, 2009, at the 42 sample facilities to examine pertinent documentation. Up to three facilities were visited by each inspector; six inspectors conducted a third site visit on May 14.

At each reprocessing location within a facility, the inspector asked for all model-specific SOPs and competence records for colonoscopy reprocessing (if the facility performed only colonoscopy), for ENT endoscopes (if only ENT), or both if applicable. For the colonoscopy reprocessing, the inspector checked the located SOPs and competence records against each model listed for that reprocessing location. The reprocessing location model list was compiled before the site visit based on information provided in response to our email request.

After completing the inspection at each facility, the inspector briefed the facility director or designee on whether the inspector found (or did not find) model-specific instructions and model-specific competence records for reprocessing endoscopes.

Presence of Endoscope Reprocessing SOPs

During the unannounced site inspection, inspectors verified whether SOPs for each model of colonoscopes were readily accessible at the colonoscopy reprocessing location. At ENT endoscope reprocessing location, we verified whether there was at least one model specific reprocessing SOP for any ENT endoscope, regardless of the number of model types. SOPs in printed or electronic formats were acceptable. SOPs were considered absent if they were not in the immediate area or were in a locked space (e.g., someone's room or desk).

Presence of Endoscope Reprocessing Competence Records

At each colonoscopy reprocessing location, we determined the presence or absence of at least one reprocessing competence record dated May 1, 2008, or later for each of the specific models of colonoscopes reprocessed there. At each ENT endoscope reprocessing location, we verified whether there was at least one model specific reprocessing competence record for any ENT endoscope, regardless of the number of ENT endoscope model types. If competence records were not accessible during our visit, the facility was instructed to fax the records to us within 24 hours. If records were not received, we counted the competence records as absent.

Statistical Analysis

For manufacturers other than Olympus, we considered the colonoscopy reprocessing SOP to be present at a reprocessing location if any manufacturer model-specific SOP was accessible to reprocessing staff. For example, if a Pentax 70K series colonoscopy SOP was present at a reprocessing location, we counted the SOP as present for all Pentax models.

The presence or absence of an auxiliary water channel is an additional reprocessing issue for many colonoscopes. The 180-series and some 160-series colonoscopes include an auxiliary water system. We therefore classified the model-specific SOP as "present" for

all Olympus models (with or without the auxiliary water system) reprocessed at a reprocessing location if any model-specific SOP for Olympus colonoscopes with auxiliary water channel was present. However, the presence of SOPs for colonoscopes without auxiliary water counted only for Olympus models that do not use the auxiliary water system.

The following is a list of all 160- and 180-series Olympus colonoscopes with an auxiliary water system sold in the U.S.: CF-Q160L, CF-Q160I, CF-Q160AL, CF-Q160AI, CF-Q180AL, CF-Q180AI, PCF-Q180AL, PCF-Q180AI, CF-H180AL, CF-H180AI, PCF-H180AL, and PCF-H180I.¹⁸ We used this list to classify all Olympus colonoscopes as with or without auxiliary water.

Therefore, we categorized each colonoscope into one of the following five types for the purpose of this review:

- Olympus with an auxiliary water system.
- Olympus without an auxiliary water system.
- Pentax.
- Fujinon.
- Storz.

For each colonoscope reprocessing location, we classified that reprocessing unit as “SOP compliant” if all 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.” Note that if the SOP (competence record) for an Olympus colonoscope with an auxiliary water system was present at a reprocessing location, it was also counted as the SOP (competence record) for Olympus colonoscopes without an auxiliary water system, but not vice versa.

For each ENT endoscope reprocessing location, we classified the reprocessing unit as “SOP compliant” if any model-specific reprocessing SOP was present, as “competence compliant” if at least one demonstrated model-specific competence record was present, and “compliant” if both “SOP compliant” and “competence compliant.”

We estimated the percentage of “SOP compliance,” “competence compliance,” and “compliance” for all reprocessing units in VA medical facilities, separately for colonoscope and ENT endoscope reprocessing. Horvitz-Thompson sampling weights, which are the reciprocal of sampling probabilities, were used to account for our unequal probability sampling. To take into account our complex sample design with stratification and clustering, the jackknife replicate-based method was employed to obtain the sampling errors for the estimates.

¹⁸ Communication with representative of Olympus America, Inc., May 22, 2009.

We present a 95 percent confidence interval for the true compliance (parameter) of the study population. A confidence interval gives an estimated range of compliance values (being calculated from a given set of sample data) that is likely to include an unknown population parameter. The 95 percent confidence interval indicates that among all possible samples we could have selected of the same size and design, 95 percent of the time the population parameter would have been included in the computed intervals.

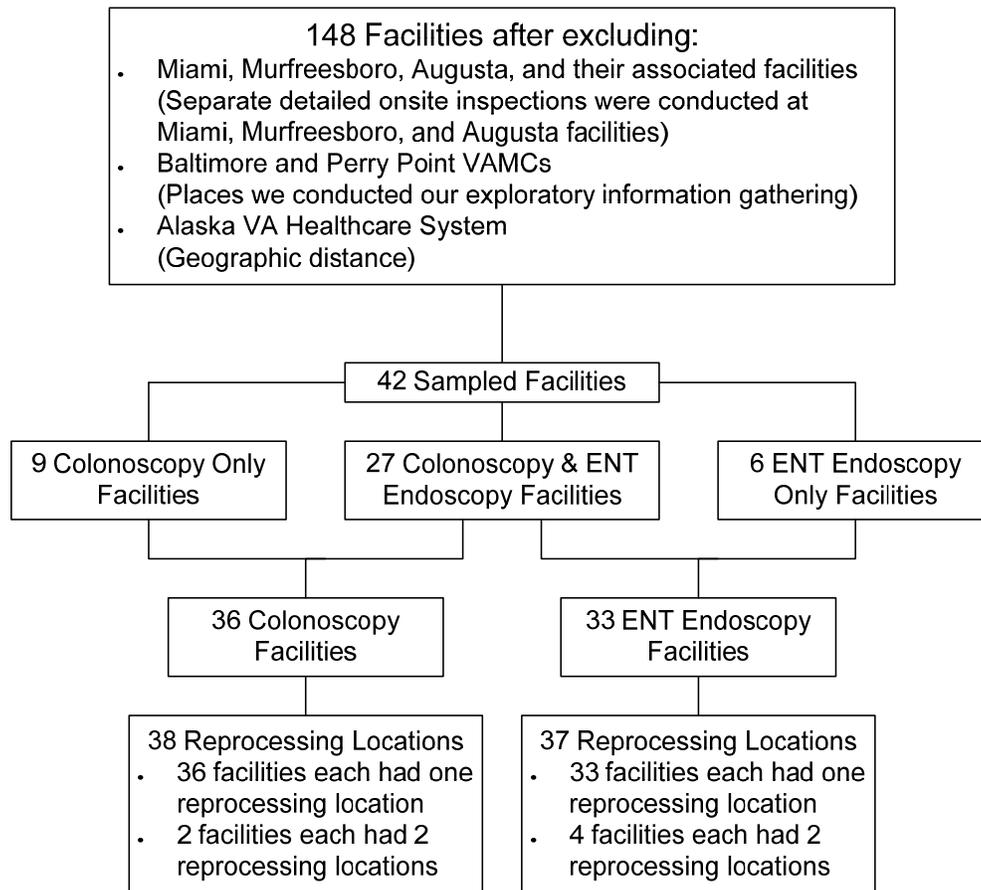
Percentages can take only positive values from zero to 100, but their logits have an unrestricted range; hence, the normal approximation can be used to estimate the parameters. We thereby calculated the confidence intervals for percentages on the logit scale and then transformed them back to the original scale to ensure that the calculated confidence intervals contained only the proper range of zero to 100 percent.

All data analyses were performed using SAS statistical software (SAS Institute, Inc., Cary, NC), version 9.2 (TS1M0). Maps were produced using ArcGIS software (Environmental Systems Research Institute, Redlands, CA), version 9.2.

Findings

As of April 27, 2009, 156 VA medical facilities were performing colonoscopy and/or ENT endoscopy. After excluding facilities associated with Miami, Murfreesboro, Augusta, and the Alaska and Maryland Healthcare Systems, we randomly selected 42 (28.4 percent) VHA facilities from among the remaining 148 VHA facilities engaged in endoscopy using probability-based stratified clustering sampling for our unannounced inspections (Figure 3). Two of the 36 colonoscopy-only facilities each reprocessed their colonoscopes at two different locations, and four of the 33 ENT-only endoscopy facilities each reprocessed their endoscopes at two different locations. Therefore, 38 HLD colonoscopy reprocessing units and 37 HLD ENT endoscope reprocessing units were subject to our unannounced onsite documentation inspection.

Figure 3. Sampling pathway for unannounced onsite inspections at VHA colonoscopy and ENT endoscopy facilities.



Appendix C lists the 42 sample VHA facilities where we conducted unannounced inspections. Figure 4 depicts geographically the 42 facilities we inspected and the 106 VHA endoscopy facilities that were included for review but were not selected for inspection. It shows that we visited 16 of the 21 Veterans Integrated Service Networks

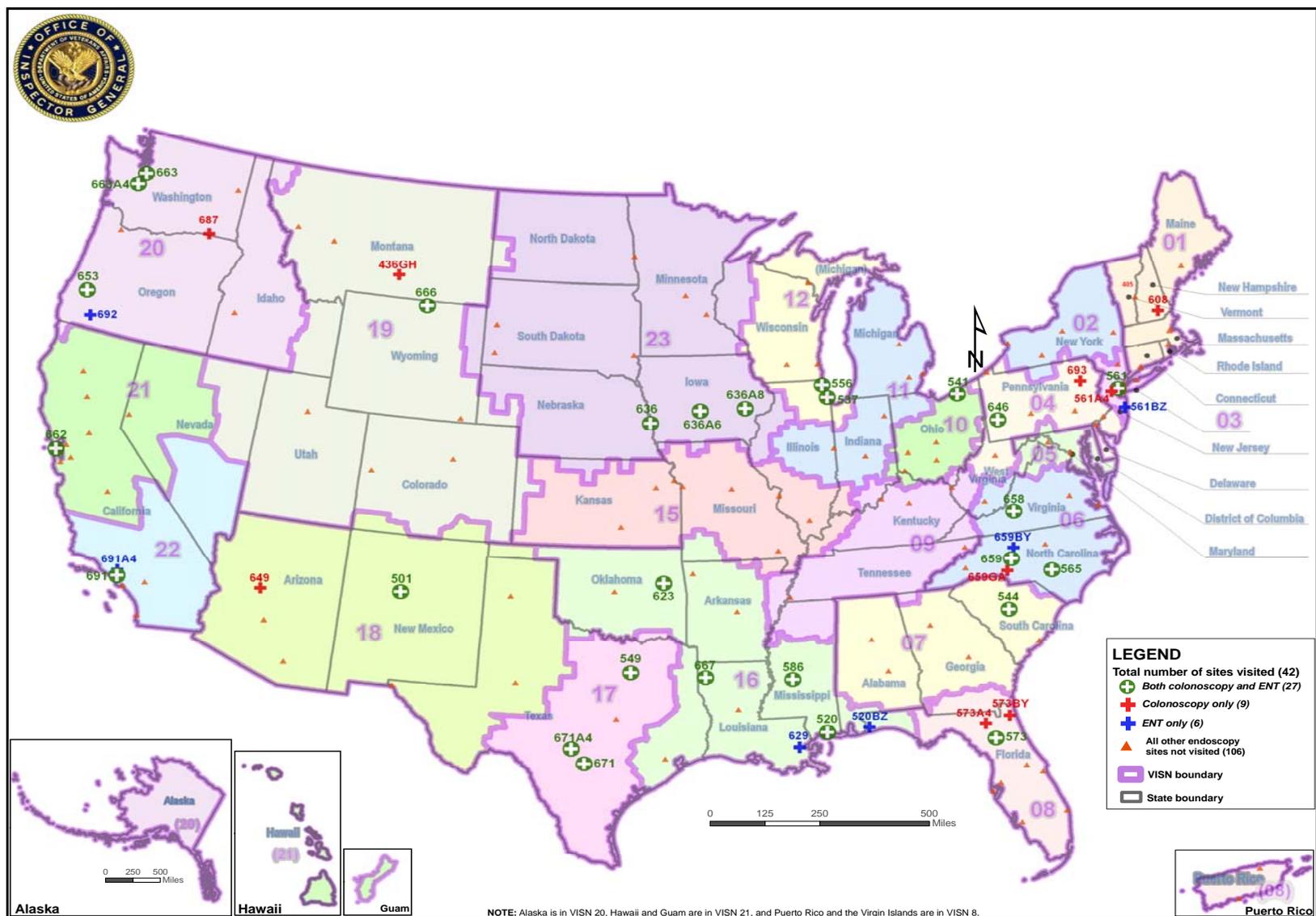


Figure 4. VHA Endoscopy facilities included in unannounced onsite inspections.

Excluded were Miami, the Tennessee Valley Healthcare System, Augusta, and their associated facilities because separate detailed inspections were conducted at Miami, Murfreesboro, and Augusta. Also excluded were the Maryland Healthcare System, where we conducted exploratory information gathering, and the Alaska Healthcare System, because of its geographic distance.

A. Responsibility for Reprocessing Endoscopes in VHA, Based on Facility Self-Reported Information

We sent an email request to the directors of VHA facilities for information on colonoscopy and ENT endoscopy on April 27, 2009, including the administrative section responsible for completing performance evaluations for HLD staff at each reprocessing location. Analyses included data from facilities excluded from sample inspections.

Table 1 illustrates the distribution of 159 colonoscopy reprocessing locations within the 145 VA medical facilities engaged in colonoscopy as of April 27, 2009, based on facility self-reported information. It shows that 131 (90 percent) of the 145 VHA colonoscopy facilities used one colonoscopy reprocessing location and about two out of three (68 percent) were at a GI procedure suite/room. Among the 14 facilities that reprocessed their colonoscopes at two different locations, 5 (36 percent) facilities reprocessed at a procedure room and at SPD, while 8 (57 percent) facilities processed both at a procedure room and at an OR.

Table 1. Distribution of 159 colonoscopy reprocessing locations within 145 VHA colonoscopy facilities.

131 facilities with a single reprocessing location	Procedure Room	90
	SPD	37
	OR	4
14 facilities with two reprocessing locations	Procedure Room + SPD	5
	Procedure Room + OR	8
	OR + Mobile	1

Table 2 tabulates reprocessing supervisory responsibility by colonoscopy reprocessing location. Overall, SPD staff supervised about 41 percent of VHA reprocessing units where colonoscopes were reprocessed. In terms of reprocessing locations, reprocessing units located at SPD were more likely to be supervised by SPD staff (81 percent), while reprocessing units located at procedure suite/room were more likely to be supervised by non-SPD staff (76 percent: 53 percent by nursing staff and 23 percent by GI staff).

Table 2. Distribution of reprocessing supervisory responsibility by colonoscopy reprocessing location.

HLD reprocessing location	Reprocessing staff supervision			Total
	SPD	Non-SPD		
		Nursing	GI	
	65 (40.9%)	69 (43.4%)	25 (15.7%)	159 (100%)
Procedure Room	24 (23.3%)	55 (53.4%)	24 (23.3%)	103
SPD	34 (81.0%)	8 (19.0%)	0 (0.0%)	42
OR	6 (46.2%)	6 (46.2%)	1 (7.7%)	13
Mobile	1 (100.0%)	0 (0.0%)	0 (0.0%)	1

Note: Percentages may not add to exactly 100% due to rounding.

Table 3 tabulates the distribution of 144 ENT endoscope reprocessing locations within the 125 VHA ENT endoscopy facilities. In contrast to colonoscopy reprocessing, most of the facilities reprocessed ENT endoscopes at SPD locations. Among the 125 facilities, 106 (85 percent) facilities reprocessed its endoscopes at one location and 69 percent of them were at SPD. Among the 19 facilities that reprocessed their endoscopes at two different locations, all of them included a procedure room and 16 (84 percent) included SPD.

Table 3. Distribution of 144 ENT endoscope reprocessing locations at 125 VHA ENT endoscopy facilities.

Facilities with a single reprocessing location	Procedure Room	31
	SPD	73
	OR	2
Facilities with two reprocessing locations	Procedure Room + SPD	16
	Procedure Room + OR	2
	2 Different Procedure Rooms	1

Table 4 gives the distribution of reprocessing supervisory responsibility by ENT endoscope reprocessing location. In contrast to colonoscopy reprocessing, overall, SPD staff supervised 60 percent of locations where ENT endoscope were reprocessed. As with colonoscopy reprocessing, reprocessing units located at SPD were more likely to be supervised by SPD staff (85 percent), while reprocessing units located at procedure suite/room were more likely to be supervised by non-SPD staff (82 percent: 65 percent by nursing staff and 18 percent by GI staff).

Table 4. Distribution of reprocessing supervisory responsibility by ENT endoscope reprocessing location.

HLD reprocessing location	Reprocessing staff supervision			Total
	SPD	Non-SPD		
		Nursing	ENT	
	87 (60.4%)	47 (32.6%)	10 (6.9%)	144 (100%)
Procedure Room	9 (17.6%)	33 (64.7%)	9 (17.6%)	51
SPD	76 (85.4%)	12 (13.5%)	1 (1.1%)	89
OR	2 (50.0%)	2 (50.0%)	0 (0.0%)	4

Note: Percentages may not add to exactly 100% due to rounding.

B. Compliance with VHA Directive 2009-004 Based on Unannounced Onsite Inspection

VHA Directive 2009-004 (February 9, 2009), *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*, requires (page 3) that “device-specific SOPs for set up and reprocessing of RME are posted in any area where these devices are reprocessed.” It defines (page 1) competence as “the assurance that an individual has received the appropriate training and has demonstrated an achieved skill level required to independently and appropriately perform an assigned reprocessing task or responsibility” and calls for “documented” initial and continued staff competence at least annually (pages 2–3). We checked for the presence of all five applicable model-specific SOPs and competence records at each colonoscopy reprocessing location and any model-specific SOPs and any competence records at each ENT endoscope reprocessing location that were sampled for unannounced onsite inspection.

Issue 1. Absence of Colonoscopy Model-Specific Reprocessing SOPs and/or Competence Records

Table 5 reports the compliance of the 38 reprocessing locations at the 36 colonoscopy facilities we inspected (two of the 36 facilities each had two reprocessing units). It also gives the estimated compliance of VHA reprocessing units based on our sampled data. As indicated in the Statistical Analysis section, we classified the reprocessing unit as “SOP compliant” if all applicable model-specific reprocessing SOPs were present at its location; as “competence compliant” if at least one demonstrated model-specific competence record existed for each type applicable model-specific endoscopes; and “compliant” if both “SOP compliant” and “competence compliant.”

Table 5. Sample and VA estimates of compliance with standard operating procedures and competence in accordance with VHA directive 2009-004: Colonoscope Reprocessing.

Compliance	Sample (38 units) Compliance	VA Estimates	
		Compliance	(95% Confidence Interval)
Standard Operating Procedure	81.6%	77.9%	(59.5%, 89.4%)
Competence	52.6%	50.2%	(31.6%, 68.8%)
Compliance With Both SOP & Competence	47.4%	42.5%	(26.7%, 60.1%)

Of the sampled colonoscopy reprocessing units, 82 percent were in compliance with SOPs, 53 percent with competence, and 47 percent were in compliance with both SOPs and competence. After taking into account our complex sample design, we estimated that 78 percent of VHA colonoscopy reprocessing units were in compliance with SOPs, and we are 95 percent confident that the true compliance value was somewhere from 59.5 percent to 89.4 percent. We estimated that only about one out of two VHA colonoscopy reprocessing units (50.2 percent) was in compliance with competence and we are 95 percent confident that the true compliance value varied somewhere from 31.6 percent to 68.8 percent. The compliance with both SOPs and competence was estimated at 42.5 percent with the 95 percent confidence interval from 26.7 to 60.1 percent.

Issue 2. Absence of ENT Endoscope Model-Specific Reprocessing SOPs and/or Competence Records

Table 6 shows the compliance of the 37 ENT endoscope reprocessing units at the 33 facilities we inspected (four of the 33 facilities each had two reprocessing units). It also gives the estimated compliance of VHA reprocessing units based on our sampled data. Note that we classified an ENT endoscope reprocessing unit as “SOP compliant” if any model-specific reprocessing SOPs was present at its location; as “competence compliant” if at least one demonstrated model-specific competence record existed; and “compliant” if both “SOP compliant” and “competence compliant.”

Table 6. Sample and VA estimates of compliance with standard operating procedures and competence in accordance with VHA directive 2009-004: ENT Endoscope Reprocessing.

Compliance	Sample (37 units) Compliance	VA Estimates	
		Compliance	(95% Confidence Interval)
Standard Operating Procedure	73.0%	76.9%	(58.9%, 88.6%)
Competence	56.8%	54.7%	(34.9%, 73.2%)
Compliance With Both SOP & Competence	48.6%	47.3%	(28.9%, 66.5%)

Of the sampled 37 ENT endoscope reprocessing units, 73 percent were in compliance with SOPs, 57 percent with competence, and 49 percent with both SOPs and competence. After taking into account our complex sample design, we estimated that 77 percent of ENT endoscope reprocessing units were in compliance with SOPs, and we are 95 percent confident that the true compliance value was somewhere from 58.9 percent to 88.6 percent. We estimated that 55 percent of VHA ENT endoscope reprocessing units were in compliance with competence and we are 95 percent confident that the true compliance value varied somewhere from 34.9 percent to 73.2 percent. The compliance with both SOPs and competence was estimated at 47 percent with the 95 percent confidence interval from 28.9 to 66.5 percent.

Issue 3. Compliance and Responsibility for Reprocessing Endoscopes

Tables 7 and 8 detail the estimated compliance of VHA reprocessing units (based on our sample data), separately for colonoscopy and ENT endoscope, by the facility self-reported administrative section responsible for completing performance evaluations for HLD staff at reprocessing locations. Although not statistically significant, the data suggest that VHA colonoscopy reprocessing units supervised by GI were in somewhat better compliance than units supervised by SPD or Nursing, and for ENT reprocessing units supervised by Nursing and ENT were in somewhat better compliance than units supervised by SPD.

Table 7. Estimated VA colonoscope reprocessing compliance with standard operating procedures and competence in accordance with VHA directive 2009-004 by supervisory staff.

Supervisory Staff	SOP Compliance		Competence Compliance		Compliance With Both SOP & Competence	
	(95% Confidence Intervals)		(95% Confidence Intervals)		(95% Confidence Intervals)	
SPD (10 sampled reprocessing units)	56.2%	(19.3%, 87.3%)	54.6%	(17.2%, 87.4%)	40.0%	(10.3%, 79.4%)
Nursing (19 sampled reprocessing units)	86.3%	(55.8%, 96.9%)	38.2%	(16.6%, 65.7%)	38.2%	(16.6%, 65.7%)
GI (9 sampled reprocessing units)	84.6%	(29.2%, 98.6%)	69.1%	(31.7%, 91.5%)	53.7%	(23.5%, 81.3%)

Table 8. Estimated VA ENT endoscope reprocessing compliance with standard operating procedures and competence in accordance with VHA directive 2009-004 by supervisory staff.

Supervisory Staff	SOP Compliance		Competency Compliance		Compliance With Both SOP & Competence	
	(95% Confidence Intervals)		(95% Confidence Intervals)		(95% Confidence Intervals)	
SPD (22 sampled reprocessing units)	77.6%	(52.9%,91.5%)	49.1%	(24.8%,73.9%)	39.8%	(18.8%,65.3%)
Non-SPD (15 sampled reprocessing units: 13 supervised by Nursing and 2 by ENT staff)	75.8%	(45.0%,92.3%)	64.2%	(38.6%,83.7%)	60.0%	(33.6%,81.7%)

Conclusions and Recommendations

Facilities have not complied with management directives to ensure compliance with reprocessing of endoscopes, resulting in a risk of infectious disease to veterans. Reprocessing of endoscopes requires a standardized, monitored approach to ensure that these instruments are safe for use in patient care.

The failure of medical facilities to comply on such a large scale with repeated alerts and directives suggests fundamental defects in organizational structure.

The Clinical Risk Assessment Advisory Board has been an effective mechanism for providing guidance to VHA leadership on disclosure of adverse events to veterans.

Recommendation 1. We recommend that the Acting Under Secretary for Health ensure compliance with relevant directives regarding endoscope reprocessing.

Recommendation 2. We recommend that the Acting Under Secretary for Health explore possibilities for improving the reliability of endoscope reprocessing with VA and non-VA experts.

Recommendation 3. We recommend that the Acting Under Secretary for Health review the VHA organizational structure and make the necessary changes to implement quality controls and ensure compliance with directives.

CPT and ICD-9 Codes

Gastrointestinal Endoscopy: Total

CPT: 43200-2, 43204-5, 43215-17, 43219-20, 43226-8, 43231-2, 43234-51, 43255-65, 43267-69, 43271-2, 44360-1, 44363-66, 44369-70, 44372-3, 44376-80, 44382-3, 44385-6, 44388-44394, 44397, 45300, 45303, 45305, 45307-9, 45315, 45317, 45320-1, 45327, 45330-5, 45337-42, 45345, 45355, 45378-87, 45391-2, 3130F, 3132F, 3140-1F.

Gastrointestinal Endoscopy: Colonoscopy

CPT: 44388-44394, 44397, 45300, 45303, 45305, 45307-9, 45315, 45317, 45320-1, 45327, 45330-5, 45337-42, 45345, 45355, 45378-87, 45391-2.

ICD-9: 45.23, 45.25, 45.41-3

ENT Endoscopy

CPT: 31231, 31233, 31235, 31237-40, 31267, 31276, 31287-88, 31290-94, 31505, 31510, 31515, 31520, 31525-31, 31535-6, 31540-1, 31545-6, 31560-1, 31570-71, 31575-9, 92511, S2342, S2344.

ICD-9: 21.21, 22.11, 22.19, 29.11, 31.41-4.

Cystoscopy

CPT: 52000-1, 52004-5, 52007, 52010, 52214, 52224, 52235, 52240, 52250, 52260, 52265, 52270, 52275-7, 52281-3, 52285, 52290-1, 52301, 52305, 52310, 52315, 52320, 52325, 52327, 52330, 52332, 52334, 52341-6, 52351-5, 52400, 52402.

Bronchoscopy

CPT: 31615, 31620, 31622-5, 31628-33, 31635-8, 31640-1, 31643, 31645-6, 31656.

National Center for Patient Safety Review of Reprocessing Issues

Endoscope Reprocessing Autopsy

National Center for Patient Safety

17 April 2009

Purpose

Identify vulnerabilities, especially systems-based vulnerabilities, in our processes related to flexible endoscope reprocessing.

Background

Organizations with well functioning safety programs are ones where staff are willing to report unsafe products and processes that could impact the safety and health of veterans. In VHA patient safety issues that are reported, found to be of high enough priority, are actionable, and found to have system implications are disseminated using the VHA Patient Safety Alert and Patient Safety Advisory process. As vulnerabilities are addressed through the Alert and Advisory process they often elicit additional reporting from the field on similar topics. It is important to note that more reports do not necessarily mean that more events are occurring.

The first Patient Safety Advisory on reprocessing medical devices was issued March 6, 2003, reaffirming to the facilities that the auxiliary water channel on Olympus EXERATM Gastrointestinal Endoscopes needed to be reprocessed (cleaned and highly disinfected, or sterilized) each time the endoscope was used. On February 13, 2004, a Patient Safety Alert was issued directing facilities to ensure that the correct connectors were being used when reprocessing Gastrointestinal Fiberoptic Endoscopes. Since February 13, 2004, there have been eleven additional VHA Patient Safety Alerts and Advisories issued on the topic of medical device and equipment reprocessing with the most recent issued on December 22, 2008 regarding endoscopes.

Findings of Systemic Issues

Based on NCPS site visits, meetings with manufacturers, and review of VHA data including over 24 Issue Briefs covering numerous facilities, NCPS has identified a variety of causes that underlie the improper reprocessing of flexible endoscopes.

While any procedure can be improved to reduce ambiguity, the current manufacturers reprocessing instructions were not felt to be a significant vulnerability that required correction. Similarly, the design of the equipment was not thought to be the pivotal cause

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of the problems that were encountered. This was discussed in detail with the FDA. However, NCPS is continuing to work with device manufacturers to improve their designs and reprocessing instructions as appropriate.

Common system issues that have been identified across VHA are listed below. Several that have particular application to the direct causation of the current Miami situation but all are potentially applicable in a more general sense.

- Oversight Issues. There is a lack of routine oversight of the medical product and device reprocessing process by Supply, Processing and Distribution (SPD), Infection Prevention and Control, and Quality Improvement staff. Periodic visits are not being conducted in all areas involved in reprocessing outside of the SPD area (i.e. pre-cleaning and post clinical procedures) to ensure that the approved SOPs are being followed.
- Incongruous SOPs. Facility developed Standard Operating Procedures (SOPs) for endoscope reprocessing lacked device specific information or information of sufficient detail to facilitate staff meeting manufacturers reprocessing requirements. Departures from manufacturer's instructions had been inappropriately based upon verbal input from sales representatives. No process has been established to periodically review and update SPD SOPs to confirm that they meet the manufacturer's current instructions.
- New Technologies. There is no mechanism or system in place to capture manufacturer equipment reprocessing instructions in the SOPs as new devices are introduced or as outdated equipment or expendables are replaced.
- Adulteration of Equipment. GI scope auxiliary equipment was found to be adulterated at more than one facility. This was not a factor in the Miami event. Staff, both clinical and technical, demonstrated a lack of awareness that any change to medical equipment should be an exception and only undertaken by qualified individuals.
- Facility Equipment Committee. SPD Service is generally not represented on the facility Equipment Committee (or its equivalent). This committee has a significant role in purchasing new devices and their associated single or multi-use expendable products and representation would permit SPD to

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learn of new purchases and prepare reprocessing Standard Operating Procedures.

- Communication. The lack of a daily dialog between staff in SPD and GI Lab staff reconciling the number of consumables (e.g., MAJ-855) to expect that day needing reprocessing. While both services may have access to the daily schedule, changes may occur due to missed appointments or emergent procedures, if SPD knows this information it will permit them to confirm that the correct number of MAJ-855s are received from GI and reprocessed. Such a process would provide a greater robustness through increased fault tolerance.
- Competencies for GI Lab. Competencies for GI Lab (or other services involved in any aspect of reprocessing devices and equipment) and SPD staff assigned endoscope reprocessing duties do not contain specific requirements for the equipment being used.
- Clinical staff knowledge. Clinical staff do not have any requirement to be familiar with and comply with manufactures instructions. In the Miami case the instructions to prime the flushing circuit prior to starting the procedure with the patient were frequently not followed. This failure to prime the flushing circuit together with not changing the MAJ-855 tubing for years, instead of between each patient, necessitated notifying thousands of patients about the potential risk of infection.
- Organizational alignment. Currently the SPD function does not report to the same entity when comparing one VHA facility to another. This variability (e.g., nursing, surgery, logistics, pharmacy) makes it difficult to communicate clearly and consistently throughout the organization and in some cases establishes an inherent conflict of interest (working for the individuals who may be violating policy and procedure). This variability in organizational alignment when combined with inadequate Quality Control and Quality Improvement mechanisms virtually guarantees the lack of standardization on consistency of performance across VHA.
- Quality Control Issues. Quality control is testing against standards and specifications with the objective to block the release of defective products. In the case of SPD processes this could include parameters such as time, temperature, and sterilant contact, to ensure that processes are operating within specified control limits. Quality control activities were found to be limited in scope; for example, in SPD quality control involved the number

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of processed loads, load biological monitoring, sterilant chemical monitoring, and the number of rejects in SPD due to failed biological indicators. Of specific applicability with regard to Miami, as well as other facilities that have been identified, is the use of additional monitors such as the number of MAJ-855s being reprocessed vs. the number of scopes being reprocessed and the number of flushing fluid containers (7501352) being processed vs. the GI Lab daily schedule.

- Quality Assurance Issues. Quality Assurance is improving and stabilizing processes through observation, assessment, and measurement so that defects don't occur in the first place. With the notable exception of the clinical laboratories, health care employs minimal quality assurance processes. This is certainly the case with respect to the reprocessing and use of flexible endoscopes. These activities should include: oversight to ensure that appropriate, detailed, current SOPs that follow current manufacturer guidelines exist for all medical devices and products that are being reused; that SOPs are being implemented in all areas where reprocessing activities take place; that staff (both SPD and clinical) competencies are current; and monitors (e.g., the number of returns to SPD for reprocessing from the using service due to contamination) are in place.

Summary/Conclusions

There were numerous reports from facilities that identified failure to comply with manufacturers reprocessing instructions. The failure to follow the instructions stemmed from many significant factors but ambiguity of the manufacturer instruction themselves was not a factor. For example, virtually all facilities with identified problems did not change the MAJ-855 auxiliary water tube between each patient, a requirement that is mentioned multiple times in multiple places in the reprocessing instructions. Failure to comply with this instruction has its roots in a culture in medicine that does not always appreciate the need to adhere to the details of instruction and routinely tolerates or encourages personal preference based actions. When this is combined with a lack of organizational components that provide robust quality control and quality assurance mechanisms it is likely that less than perfect performance can result.

Unlike many areas in healthcare where the expectation of 6 sigma performance is unrealistic due to the extreme variability among patients this constraint does not apply when it comes to the reprocessing of endoscopes. This is because the reprocessing of scopes is a hardware related activity that has discrete and well

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characterized tasks. The analog for endoscope reliability would be commercial or military aviation maintenance. To achieve similar levels as in aviation, health care needs to use similar approaches to deal with the issues we have identified. This means that the organizational structure and appropriate quality control and assurance mechanisms, such as ones to address the vulnerabilities identified above, must be created and implemented.

VHA Facilities Sampled for Unannounced Inspections*

OHI did unannounced inspections of the following 42 VHA facilities:

New Mexico VA Health Care System – Albuquerque, NM
VA Gulf Coast Veterans Health Care System – Biloxi, MS
Jesse Brown VA Medical Center – Chicago, IL
Louis Stokes VA Medical Center – Cleveland, OH
Wm. Jennings Bryan Dorn VA Medical Center – Columbia, SC
VA North Texas Health Care System, Dallas VA Medical Center – Dallas, TX
North Chicago VA Medical Center – North Chicago, IL
VA New Jersey Health Care System, East Orange Campus – East Orange, NJ
Fayetteville VA Medical Center – Fayetteville, NC
Malcom Randall VA Medical Center, North Florida/South Georgia Veterans Health
System – Gainesville, FL
G.V. (Sonny) Montgomery VA Medical Center – Montgomery, AL
Manchester VA Medical Center – Manchester, NH
Jack C. Montgomery VA Medical Center – Muskogee, OK
Southeast Louisiana Veterans Health Care System – New Orleans, LA
VA Nebraska Western Iowa Health Care System – Omaha, NE
VA Pittsburgh Healthcare System, University Drive Division – Pittsburgh, PA
Northern Arizona VA Health Care System – Prescott, AZ
VA Roseburg Healthcare System – Roseburg, OR
Salem VA Medical Center – Salem, VA
W.G. (Bill) Hefner VA Medical Center – Salisbury, NC
San Francisco VA Medical Center – San Francisco, CA
VA Puget Sound Health Care System – Seattle, WA
Sheridan VA Medical Center – Sheridan, WY
Overton Brooks VA Medical Center – Shreveport, LA
South Texas Veterans Health Care System – San Antonio, TX
Jonathan M. Wainwright Memorial VA Medical Center – Walla Walla, WA
VA Greater Los Angeles Healthcare System – Los Angeles, CA
VA Southern Oregon Rehabilitation Center & Clinics – White City, OR
Wilkes-Barre VA Medical Center – Wilkes-Barre, PA
Billings VA Outpatient Clinic – Billings, MT
VA Gulf Coast Veterans Health Care System, Pensacola Outpatient Clinic –
Pensacola, FL
Lyons Campus of the VA New Jersey Health Care System – Lyons, NJ

VHA Facilities Sampled for Unannounced Inspections*

James J. Howard VA Community Clinic – Brick, NJ
Lake City VA Medical Center, North Florida/South Georgia Veterans Health System –
Lake City, FL
Jacksonville VA Outpatient Clinic – Jacksonville, FL
VA Central Iowa Health Care System, Des Moines Division – Des Moines, IA
Iowa City VA Medical Center – Iowa City, IA
Winston-Salem VA Satellite Outpatient Clinic – Winston-Salem, NC
Charlotte VA Outpatient Clinic – Charlotte, NC
VA Puget Sound Health Care System, American Lake Division – Tacoma, WA
Kerrville VA Medical Center – Kerrville, TX
Sepulveda VA Ambulatory Care Center – North Hills, CA

* The following facilities were excluded from selection for the unannounced onsite inspection:

- Miami, Murfreesboro, Augusta, and their associated facilities, because separate detailed onsite inspections were conducted at there.
- VA Maryland Healthcare System (Baltimore and Perry Point), where we conducted exploratory information gathering.
- Alaska VA Healthcare System, because of its geographic distance.

Acting Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: June 11, 2009

From: Acting Under Secretary for Health (10)

Subject: **OIG Draft Report, *Healthcare Inspection, Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*, Project No. 2009-01784-HI-0106 (WebCIMS 432508)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report, and I concur with the recommendations and findings. Your report's conclusion that VHA facilities have not complied with management directives regarding the reprocessing of endoscopes, resulting in a risk of infectious disease to veterans, is an urgent management and clinical issue, and I am committed to making the necessary changes to correct this lack of compliance.

2. As your report accurately states, despite repeated attempts to address this issue, VHA has had a persistent challenge with ensuring the reliability of endoscope reprocessing in our medical facilities. This is partly because reprocessing of reusable medical equipment has complex characteristics, as described in this report, that present a formidable challenge for all types of medical facilities, whether they be in the government or the private sector. However, I also realize that there are deficiencies specific to VHA that we need to target and address as an organization in order to ensure that instruments are safe for use in patient care.

3. One of these specific requirements is the need for VHA to apply a standardized approach to ensure the reliability of endoscope reprocessing in all of our applicable facilities, and monitor the system to continuously ensure expected performance. In response to this need, VHA issued Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities* on February 9, 2009, which

VHA Facilities Sampled for Unannounced Inspections*

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OIG Draft Report, *Healthcare Inspection, Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*, Project No. 2009-01784-HI-0106 (WebCIMS 432508)

provides systematic guidance and policy for the set up, proper use, reprocessing, and maintenance of all RME used in VHA facilities. To ensure that facilities are compliant with and adhering to specific guidelines in this Directive, the Deputy Under Secretary for Health for Operations and Management (DUSHOM) recently required all VISN and Medical Center Directors to certify compliance by June 9, 2009. Furthermore, the DUSHOM is requiring that VISN staff conduct random site visits of facilities with the goal of visiting every facility that does any type of endoscopic procedure by July 31, 2009. The VISN Director must confirm completion of these site visits with the DUSHOM, along with any identified issues and a timeframe for resolution.

4. Additional components that VHA will specifically evaluate and address include organizational structures and systems in order to ensure reusable medical equipment is reprocessed according to manufacturers' instructions with high reliability, and to document facility compliance with recommended standard operating procedures as well as with implementation of appropriate responses to alerts and directives impacting reprocessing. VHA will take several measures to ensure this:

- a. VHA will implement systems to ensure that all individuals engaged in reprocessing reusable medical equipment will have device-specific competencies documented and demonstrated at a minimum on an annual basis.
- b. VHA will implement measures to ensure that device and procedure specific standard operating procedures (SOPs) are uniformly available, are updated as required, and are reviewed at least annually.
- c. VHA will coordinate the implementation of quality management systems and ensure that robust quality control is implemented and appropriately documented in all VHA facilities where reprocessing occurs.
- d. VHA will standardize equipment at the facility level where ever possible to ensure uniformity in the setup, use and reprocessing of equipment.
- e. VHA will negotiate national contracts to ensure standardization of equipment and leverage its ability to maximize added value from the vendors, including support of maintenance, repair and training.

VHA Facilities Sampled for Unannounced Inspections*

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5. Thank you for the opportunity to review the report and provide comments. Due to the short time allotted for reviewing this report, VHA will prepare its detailed plan of corrective action and present them to you at a later time. I would be pleased to discuss any concerns or comments you may have about this response. If you have any questions, please have a member of your staff contact Margaret Seleski, Director, Management Review Service (10B5) at (202) 461-8470.

(original signed by:)

Gerald M. Cross, MD, FAAFP

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