GERALD M. CROSS, MD, FAAFP, ACTING UNDER SECRETARY FOR HEALTH, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF
GERALD M. CROSS, MD, FAAFP
ACTING UNDER SECRETARY FOR HEALTH,
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BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE
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Mr. Chairman, Ranking Member Burr, and members of the Committee: thank you for providing me this opportunity to discuss the Department of Veterans Affairs' (VA) quality management and safety programs, as well as the facts and circumstances surrounding recent gaps in the reprocessing of endoscopes and how VA's quality management programs responded to this situation. I am accompanied today by Dr. William E. Duncan, M.D., Ph.D., MACP, Associate Deputy Under Secretary for Health for Quality and Safety; Juan Morales, Director of the Tennessee Valley Healthcare System; Rebecca Wiley, Director of the Charlie Norwood (Augusta) VA Medical Center; and Mary Berrocal, Director of the Miami VA Healthcare System.

Before reviewing the details of the recent shortfalls in VA's endoscope reprocessing at several of its medical centers, I will review the quality management organizations and activities in place. Quality management is fundamental to VA health care, which exists solely to serve our nation's Veterans. Professional publications and the mainstream media have recognized and lauded our accomplishments in providing the best integrated health care in the country. These achievements are possible because of VA's ability to link four fundamental elements of health care delivery: access by eligible Veterans, regardless of pre-existing condition or ability to pay; systems of care, such as primary care and community-based long term care coordination that focuses on the whole patient; a comprehensive electronic health record that follows the patient throughout the continuum of care; and systems of performance measurement that ensure consistently safe, high-quality health care. Despite caring for patients that are, on average, sicker, older, and less affluent, VA health care compares favorably with the best U.S. health care systems.

VA maintains broad and robust quality management and safety programs that incorporate multiple components, including improvement activities, patient safety reporting and analysis, internal and external reviews including accreditation by recognized professional groups, performance management, close monitoring of patient care experiences, evidence-based clinical guidelines, utilization management, risk management activities, and a systematic approach to process improvement and redesign. VA tracks more than 250 measures and monitors that are routinely used to evaluate processes and outcomes of care, as well as to hold its senior administrative and clinical leaders accountable. Some examples of these measures include breast and cervical cancer screening, diabetes exams, hypertension screening, smoking cessation counseling, immunizations and the use of beta blockers after a heart attack. Based upon standard benchmarks from other Federal systems and the private sector, the Veterans Health

Administration (VHA) has consistently improved its performance annually for the past decade on nearly every measure and VHA's performance equals or exceeds the average for commercial health plans, Medicare and Medicaid. Veterans' perceptions of care provided by VHA likewise equal or exceed those in the community on standard measures of patient satisfaction. VA provides this information online (www.qualityofcare.va.gov/home.cfm). This Web site provides information on 10 quality measures at the facility, Veterans Integrated Service Network (VISN), and national levels and compares VA's performance with other providers; on all 10 measures, VA outperforms its counterparts.

My testimony today will describe how VA has centralized quality and safety management, how it turns measurement into action, and discuss in detail how VA identified problems in some of its facilities concerning the reprocessing of endoscopic equipment, including how VA began and continues to notify patients, and what remedies it has adopted in response to these incidents.

Centralizing Quality and Safety Management

VA has long been a leader in measurement of quality and performance. Our current Performance Measurement System began as the External Peer Review Program in 1992, focusing primarily on compliance with evidence-based guidelines for inpatient and outpatient care. Even prior to that, the Continuous Improvement in Cardiac Surgery Program (founded 1987) and the National Surgical Quality Improvement Program (1991) developed some of the first tracking systems for risk-adjusted surgical mortality and morbidity to provide VA a comprehensive quality assurance program for surgical services.

VA established the Office of Quality and Safety on November 16, 2008, to better align and integrate ongoing quality and safety activities and to provide senior leaders with trustworthy analysis of quality data and monitors from multiple sources in order to drive improvement and transformation throughout VHA. This new Office also provided a mechanism to ensure that quality and safety indicators across multiple measurement approaches were being routinely analyzed and trended. This Office consists of three units: the National Center for Patient Safety, the Office of Quality and Performance, and the Quality and Safety Analytics unit.

VA's National Center for Patient Safety (NCPS) has been in existence since 1999. NCPS takes a systems approach to patient safety that is adapted from known high reliability organizations such as aviation or nuclear power. These system-level interventions include safety engineering tools (e.g., Root Cause Analysis, Healthcare Failure Mode and Effect Analysis), checklist and template-driven approaches to standardizing care processes (e.g., Patient Daily Plans, Universal Protocols to Ensuring Correct Surgery and enforce Hand Hygiene guidelines), and leadership training (e.g. Medical Team Training). High reliability organizations align all their activities to create an organizational mindfulness of safety. VA accomplishes this through a national, externally validated, organizational safety culture survey. NCPS utilizes reports of adverse events and "close calls" from facilities to identify vulnerabilities that require intervention. "Close calls" are those events that did not result in significant harm but identified vulnerabilities that, under other circumstances, might have resulted in harm. One measure of the dissemination of safety-mindedness is the continued growth in self- reported adverse events and close calls. Since its inception, NCPS has conducted Aggregated or Individual Root Cause Analyses that targeted over 425,000 adverse events and close calls. Dozens of countries around the world recognize this

system of analysis and monitoring as a benchmark and have adopted it for their own health care systems.

VA's Office of Quality and Performance has, since the 1990s, been responsible for assessing patient experiences and satisfaction; measuring, analyzing and reporting on VA's performance; identifying and promoting evidence-based practices; monitoring accreditation of facilities and programs, physician credentialing and privileging, peer review and risk management; and supporting utilization management. Since 2006, VA has used the Survey of Healthcare Experiences of Patients to track patient satisfaction. This year, VA selected a new contractor and a new instrument, the Consumer Assessment of Healthcare Providers and Systems (CAHPS), to measure patient satisfaction. The Agency for Healthcare Quality and the Centers for Medicare and Medicaid Services developed the CAHPS, which has been widely adapted by other health systems. VA made this shift because the CAHPS is a shorter survey, has a wealth of research already available, will improve turnaround reporting of fully adjusted and weighted satisfaction information to the field, and allows benchmark comparisons with private and other Federal health care organizations. Early results suggest VA is outperforming the private sector. Similarly, the American Customer Satisfaction Index has shown VA performance to be superior for hospital and outpatient care in each of the last 5 years.

VA's newest organization, the Office of Quality and Safety Analytics, compiles and analyzes quality and safety data from multiple sources and supports education and training of quality management professionals across all of VHA. This unit is the outgrowth of a national Inpatient Evaluation Center (IPEC) program begun in 2005 to measure and report risk-adjusted medical or surgical care outcomes, including length of
stay, use of intensive care units, and rates of complications such as central-line associated bloodstream infections, ventilator associated pneumonia, and venous thromboembolism. IPEC staff generates quarterly reports for all facilities and are available to facilitate onsite quality improvement efforts.

The Office of Quality and Safety seeks input from both internal and external subject matter experts. Many of the country's leading experts on these issues are VA clinicians, who serve on an internal advisory committee. VHA also recently participated in the Institute for Healthcare Improvement's "5 Million Lives" Campaign.

From Measurement to Action

VA has set the national standard for quality measurement and transparency, but measurement alone is not enough – action is also needed. Last year, VA issued Quality Management Program Directive 2008-061, which emphasized the critical responsibility of facility, VISN, and national leadership to ensure health care is safe, effective, patient-centered, timely, efficient and equitable. It designated that leaders must have accountability structures in place, must understand and be able to articulate the flow of quality management within their organizations, and must take responsibility for identifying, prioritizing, and coordinating improvement activities within their organization. VISNs were tasked with doing an annual evaluation of the Quality Management Programs at their facilities, developing action plans for identified deficiencies and tracking these until they have been corrected. Networks and facilities are held accountable for these measures in their performance plan; the Deputy Under Secretary for Health for Operations and

Management conducts quarterly reviews with Network Directors to review their progress. Additional interventions may be triggered by
specific circumstances – for example, the appointment of any VHA physician who meets identified malpractice triggers is subject to mandatory review by the VISN Chief Medical Officer. Facilities with special concerns can also undergo a detailed Analytic Site Review coordinated through the VISN office and conducted by staff from the Office of the Associate Deputy Under Secretary for Health for Quality and Safety. These comprehensive assessments attempt to identify areas of concern by linking and analyzing over a thousand quality metrics in multiple domains. Follow up site visits by teams of experts are often initiated as a result.

VA is committed to improving systems and redesigning them when necessary to improve the care delivered to patients by engaging front line staff in productive and meaningful changes. A national approach to process improvement and redesign, known internally as Systems Redesign, is adapting approaches such as Six Sigma, Lean Thinking, and International Standards Organization (ISO) Quality Management Systems, all of which are proven tools in highly complex and high reliability organizations, to tackle some of the most challenging problems in health care, including optimizing use of staff and beds to avoid delays in emergency rooms, operating rooms, and intensive care units; ensuring critical laboratory values are brought to the attention of clinicians responsible for the care of patients immediately; and making care transitions and handoffs – such as when a patient transfers between hospital units, or is discharged home – as safe as possible. We are hiring systems improvement professionals and aligning them with our executives because quality improvement can only be sustained if it is supported by top leadership. We are also establishing our first four Veterans Engineering Resource Centers because these partnerships with the nation's leading schools of engineering will bring critical insights from disciplines not typically used in health care settings. These perspectives have particular value in analyzing complex, recurring processes such as the sterile reprocessing of medical and diagnostic devices.

High quality care also demands attention to everyday activities, such as improving hand hygiene practices to reduce health care associated infections and other efforts to prevent the spread of Methicillin-Resistant Staphylococcus Aureus (MRSA) in hospitalized patients. VA's MRSA prevention program has had a significant impact on infection rates, transmission rates, and has been recognized as a national model. Falls and pressure ulcers are among the most common inpatient adverse events, particularly for older patients, and have the potential to greatly extend a hospital stay. VA is deploying special programs to assess and reduce the risk of falls and skin breakdown in hospitals across the country.

Another routine task is the process of verifying the training, licensure, and employment of all licensed, registered and certified health care professionals in VHA, including nearly 55,000 licensed independent practitioners and 70,000 non-independent professionals. VA continually improves its process for credentialing and privileging health care providers to ensure VHA clinicians meet the highest possible standards. Last year, VHA enrolled all licensed independent practitioners in the National Practitioner Data Bank – Health Integrity and Protection Data Bank Proactive Disclosure Service, which ensures immediate notification of medical malpractice payments and adverse actions. To ensure VA is aware of any actions taken against a physician for all current and previously-held licenses, we monitor physician licensure through the Federation

of State Medical Boards' Disciplinary Alert Service. We also obtain confirmation from the Federation of all licenses currently or previously held by all physicians who work for VHA (employees and contractors).

VA has an exceptional program for ensuring patients receive the right medication, in the right dose, at the right time through its patient-centric electronic health record (EHR). VA's EHR is supported by the Computerized Patient Record System (CPRS), electronic medication order entry, and direct prescription into Pharmacy Vista and the Bar Code Medication Administration (BCMA), which has become the model for the private sector and foreign countries alike. The EHR also automatically checks for allergies or possible drug interactions, further improving patient safety and care. VA's Center for Medication Safety (VAMedSAFE) is a national, comprehensive pharmaco-vigilance program that emphasizes the safe and appropriate use of medications. VAMedSAFE utilizes different methods and tools, including passive and active surveillance, to continuously monitor for potential adverse drug reactions. In many instances, VAMedSAFE directly and promptly notifies providers across VA's health care system if patients are at risk. VA has a Memorandum of Understanding with the Food and Drug Administration (FDA) that allows close collaboration on specific post-marketing surveillance efforts and other drug and vaccine safety projects. These efforts are conducted through FDA's newly established Sentinel Initiative and the Office of Surveillance and Epidemiology's Center for Drug Safety and Epidemiology Research. Medications and prescriptions are essential to effective health care management, but inaccuracies can have severe repercussions. In 2008, VA provided approximately 130 million prescriptions to more than 5 million patients. Our error rate for these prescriptions is less than 1 in every 294,000, significantly better than the private sector.

Endoscope Reprocessing

Legitimate questions have been raised about the overall quality and safety of VA's care due to inadequate reprocessing of fiber-optic endoscopic equipment at some of its facilities. VA's number one priority is the well being of our Nation's Veterans, and we deeply regret these incidents occurred. Our Veterans were willing to make the ultimate sacrifice and they deserve the best possible care, at every facility that we operate. We have an obligation to provide them a safe environment in which to receive medical
care. Veterans and their families need to feel confident that when they come to VA they are in good hands and that they are being provided consistently safe, high-quality health care. As this incident shows, however, we must consistently challenge ourselves to remain diligent stewards of leading health care initiatives and services.

Leaders in health care quality have long recognized the challenges of maintaining high reliability across complex activities such as endoscope reprocessing in the face of production pressure. Although we are not able to provide comparison rates for reprocessing discrepancies in non-VA health systems, it is important to emphasize that a cornerstone of VA's quality and safety programs is a commitment to identifying problems, identifying any patients at risk, disclosing any problems to them, and offering appropriate testing, counseling and treatment. The reprocessing issues identified at our facilities were identified by VA employees committed to quality and safety, and we have kept Veterans Service Organizations, the media, and Congress informed about this issue as new facts become available.

Secretary Shinseki has made accountability and transparency top priorities for VHA and for the entire Department. It is unacceptable that this has happened and the Secretary directed aggressive action to inform, test and support our patients. We will use this unfortunate experience to understand how we can transform our Department. VA is a results-driven organization that learns from its mistakes. Everyday we need to push ourselves to better serve and care for our clients – Veterans.

The Secretary has demanded that we continue to rigorously monitor this situation. Our next step is to utilize the findings of these investigations to implement necessary corrective actions in a firm, responsible fashion. We will do this while continuing to maintain an environment that encourages all staff to identify concerns that impact the care and safety of our Veterans.

In relation to the inadequate processing of endoscopes, that is, those steps taken to disinfect at a high level endoscopic equipment and prepare it for further use, VA has taken local and national actions to better understand how this could happen and to ensure it does not happen again. We are committed to an open and honest assessment of our policies and procedures. While we never want to worry patients unnecessarily, we believe patients have a right to know about important information that could potentially affect their health. VA's policy requires disclosure to patients of any adverse events related to their health care that causes or may potentially cause harm. VA has notified patients about even those events that may not be obvious or severe or those that pose only a minimal risk to a patient's health. The probability that anyone was harmed as a result of our inadequate reprocessing at these four facilities is very low.

The disclosures we are making to Veterans are based on the very small potential for harm. At present, there is no definitive evidence to suggest that the positive tests we have found so far are the result of inadequate reprocessing of endoscopy equipment. In this country, many adults who are infected with Human Immunodeficiency Virus (HIV), Hepatitis B and C have not been tested and would not be aware that they are infected. In recent weeks VA has been testing many patients who have never been tested before. As a result, we would expect some of these patients would test positive. No matter how low the likelihood that any disease occurred due to suboptimal scope disinfection, VA will care for patients regardless of the source of infection.

There were other facilities where there was inadequate reprocessing of endoscopes but, after review, it was determined that the risk of harm to patients at these facilities was so remote that it did not justify informing patients.

Background
Endoscopes are small diameter devices that allow a physician to see internal organs through external orifices by utilizing a system of optics. There are many different types of flexible and rigid endoscopes. The endoscopes discussed below are inserted either through the nose or mouth to visualize the esophagus, nasal passages, lung, stomach and upper part of the small intestine, or they are inserted through the rectum to visualize the colon. Some of these endoscopes used for colonoscopies have an internal tube that allows the physician to inject a stream of water through the endoscope to flush away any material that might obstruct adequate visualization of the colon. Flexible endoscopes are complex devices that need to be reprocessed before they can be used again safely. Reprocessing procedures are defined by the endoscope manufacturer and generally involve careful cleaning of the entire external and internal surfaces with an appropriate cleaner,

brushing any interior channels, and subjecting the entire scope to high level disinfection or sterilization as recommended in the manufacturer's instructions.

Discovering the Problems

On Monday, December 1, 2008, at the Tennessee Valley Health Care System, Alvin C. York (Murfreesboro) VA Medical Center (VAMC) in Tennessee, VA staff observed during the third endoscopic colonoscopy of the day a discoloration in the tubing that supplies water to flush the colonoscope. They immediately realized that this presented a potential problem to the patient and investigated further. Over the next 2 days, staff determined they were not using a water irrigation tube with a check valve designed to prevent contaminated fluid from the patient from flowing back into the scope and irrigation water tubing. As they investigated further, the staff discovered the Auxiliary Water Tube (MAJ-855) had been altered with a different connector that was not a one- way valve. In the process of examining the procedures for the use and reprocessing of the colonoscope, the Murfreesboro staff discovered that they were not changing and reprocessing the MAJ-855 in accordance with the manufacturer's instructions.

The Murfreesboro staff reported these problems to the facility Patient Safety staff on December 4, 2008, and the next day, to VA's National Center for Patient Safety (NCPS). NCPS conducted fact finding by evaluating the equipment and procedures used at Murfreesboro and by closely working with the endoscope manufacturer.

Based on this work, a Patient Safety Alert (AL09-07) was issued to the entire VA system on December 22, 2008. This alert requested that all facilities determine they were using the correct valve and also stressed that the manufacturers' instructions for all endoscopes were to be exactly followed regardless of the brand. All facilities were directed to determine if manufacturers' instructions were followed in the use or reprocessing of flexible endoscope tubing and accessories and to report any deviations to VA Central Office by January 7, 2009. As a result of this alert, in early January 2009, 16 additional facilities reported they had in some way not reprocessed their endoscope water flushing systems in accordance with the manufacturers' instructions.

It must be emphasized that failure to follow a manufacturer's instructions does not necessarily result in significant additional risk of cross contamination because the equipment is designed to have redundant safety features. With this in mind, NCPS contacted the manufacturer, which conducted tests to clarify what additional clinical risk might accrue from the failure to follow its instructions. As a result of these clinical and lab-based tests, the VHA Clinical Risk Assessment Advisory Board (CRAAB) determined there was no appreciable additional risk of cross-contamination if the only
practice was incorrect reprocessing of the MAJ-855 between patients. This determination was made on February 6, 2009, following receipt of results of the manufacturer's clinical tests. The CRAAB is a multidisciplinary committee that makes recommendations to the Principal Deputy Under Secretary for Health (PDUSH) as to clinical risk and whether large scale notifications (disclosure) should be made to Veterans.

The CRAAB concluded there was a very small risk of cross-contamination if the MAJ-855 was not reprocessed between patients and either (1) the proper check valve was not attached to the MAJ-855; or (2) the clinician did not prime the MAJ-855 with water prior to initiating the

examination. Following the February 6, 2009, meeting, the CRAAB, therefore, recommended disclosure only where either of these two circumstances existed in addition to improper reprocessing of the MAJ-855. Of the 17 VAMCs reporting noncompliance with manufacturers' instructions, these circumstances existed only at Murfreesboro and thus, the CRAAB only recommended disclosure to patients at this facility.

VA has a formal process to evaluate clinical risks to patients when a risk, and hence the need for disclosure, is not clear. The CRAAB weighs the nature of the harm, the probability, severity, magnitude and duration of the harm, and courses of action, and balances these factors against the potential medical, social, psychological or economic benefits or burdens to Veterans resulting from the disclosure itself.

On January 26, 2009, the Augusta VAMC informed VA Central Office of a problem it discovered with reprocessing of its Ear, Nose and Throat (ENT) scopes. These scopes are different from the colonoscopes used at Murfreesboro. As a result of a personnel change in January 2008, ENT scopes were not reprocessed in accordance with the manufacturer's instructions. After reviewing the circumstances, the PDUSH decided that potentially exposed patients should be informed.

To ensure all VHA facilities were reprocessing endoscopic medical equipment correctly, on January 28, 2009, the Deputy Under Secretary for Health for Operations and Management issued a memorandum requiring all VAMCs performing any endoscopic procedures to conduct a review of the set up and reprocessing of these devices. On February 9, 2009, the Under Secretary for Health instructed all medical centers to conduct a safety Step-Up Week from March 9 through 13, 2009, to focus facilities on retraining staff on the proper use of all endoscopy equipment, establishing easily tracked accountability chains for instrument cleaning, and training all appropriate staff about standard operating procedures.

On February 24, 2009, Mountain Home VAMC reported that ENT endoscopes were not reprocessed in accordance with manufacturer's instructions. On February 27, 2009, after reviewing the facts with the facility and a group of experts, the PDUSH decided that disclosure to patients was required. The facility notified its local congressional delegation, local Veterans Service Organizations, and Veterans at potential risk.

On March 4, 2009, in preparation for the Step-Up Week, staff at the Miami VA Medical Center discovered they had erroneously reported in January they were in compliance with the manufacturer's instructions. Miami staff found that the water irrigation tubing was not correctly reprocessed and that it was not consistently primed and flushed prior to the start of the patient examination. While either one of these omissions by themselves would not have resulted in increased risk to patients, both practices together created a slightly increased potential for cross contamination between patients. The CRAAB recommended disclosure to affected Veterans, and the PDUSH agreed.

The official policy of VHA is that "VHA facilities and individual VHA providers have an ethical and legal obligation to disclose to patients adverse events that have been sustained in the course of their care, including cases where the adverse event may not be obvious or severe, or where the harm may only be evident in the future."

As a result of increased scrutiny of the reprocessing of medical equipment within VHA, 10 VA medical centers, in addition to the 17 originally identified, have found reprocessing practices that were not in compliance with manufacturer's instructions. At each facility where we found a problem, we evaluated the situation to determine if notification was required.

Local Response

Each of the four medical centers mentioned above took prompt action to notify possibly affected Veterans; to offer testing, counseling and needed treatment; and to identify and implement necessary procedural changes to ensure the issues would not develop again. Other changes varied among medical centers and are discussed below. Specifically, each VAMC:

• Identified Veterans who received endoscopic colonoscopies or esophageal studies during the applicable date range and sent them letters by regular or certified mail, return receipt requested. The letters informed the Veteran they were potentially at risk and offered testing for Hepatitis B, C, and HIV infection. Hepatitis B, C and HIV were identified as the significant viral conditions which have the potential to be transmitted via endoscopic cross-contamination. The letter provided a toll-free telephone number to call to answer questions or schedule testing.
• Established and staffed call centers to respond to questions from Veterans.
• Established systems to track Veterans who were notified and tested.
• Established clinics to provide, on a priority basis, testing and treatment as appropriate.
• Instituted changes in staffing and processes as necessary to ensure endoscopic equipment would be properly reprocessed according to manufacturer's instructions.

At the Murfreesboro campus, staff identified 6,805 Veterans in initial reports as having received colonoscopies between April 2003, when VA first began using the affected equipment, and December 2008, when VA discovered the issue. After conducting an intensive medical record review to ensure all potentially affected Veterans were identified, VA added 418 patients to the list for notification. VA completed certified mailings to the first group by February 13, 2009, while the second group was notified by certified letters sent May 8, 2009. Murfreesboro VAMC continues to search for Veterans whose letters have been returned. The staff is using additional databases and general Internet searches. VA is closely monitoring the results of this outreach, and the records will continue to be updated. My oral statement will include the most current information. As part of its participation in the national Step-Up week in March 2009, the Murfreesboro VAMC conducted an intensive review of the procedures for reprocessing of all reusable medical equipment (RME), ensuring they complied with manufacturers' reprocessing instructions. It also conducted a Root Cause Analysis to identify and understand all components of this issue, validated standard operating procedures (SOPs), confirmed training of all clinical and support staff, and verified staff competencies.

At the Mountain Home VAMC, staff identified 297 Veterans as possibly affected by improper scope reprocessing that was not in strict compliance with the manufacturers' instructions. All scopes are now reprocessed by the facility's Supply, Processing and Distribution (SPD) program. The facility has updated policies to require better coordination among departments when RME is purchased and SOPs are written. All staff members responsible for handling RME are trained and certified. Training is noted in each competency checklist prior to actual operations. Supervisors are responsible for maintaining competency checklists and periodically validating adherence to standards. All facility SOPs are aligned with the manufacturers' written

instructions.
At the Augusta VAMC, staff identified 1,069 Veterans who received ENT procedures between January and November 2008. VA completed an initial mailing of letters to these Veterans by February 10, 2009. Additionally, VA released public service announcements with the help of local media to further increase awareness among Veterans and family members. VA staff called Veterans who had not contacted the VAMC in response to the initial mailing. At the end of March 2009, VA sent 137 certified letters to patients who still had not made contact in response to the initial mailing or who could not be reached by phone. Of those letters, 128 were successfully delivered, one was declined, and six were returned. Of the six returned letters, one was identified as not deliverable because the patient was deceased. As of May 29, 2009, all but five of the 1,069 patients in the risk pool have received mail notification, and we are continuing to attempt to locate these five patients.

Augusta VAMC also conducted a Root Cause Analysis and, based on its findings, took the following steps to improve medical equipment reprocessing. First, reprocessing of RME was consolidated into the SPD function. Construction also began on a new SPD station near the gastrointestinal endoscopy suite. A multidisciplinary task force ensured the ready availability of manufacturers' instructions for reprocessing and that SOP and staff competency checklists matched those instructions, revising where needed. VA re-trained all staff involved in RME reprocessing and evaluated them using competency checklists. Finally, the facility also increased use of the SPD Observational Assessment Tool from once per year, as nationally required, to once a month to ensure continued compliance with all requirements.

At Miami VAMC, VA identified a total of 2,609 Veterans through medical record searches and reviews as having been possibly at risk for cross contamination. VA began mailing notifications to all affected Veterans March 23, 2009. After checking other databases for address updates or changes, the facility sent a second certified mailing to Veterans whose first letters were returned as undeliverable. Miami has a particularly mobile population, so the facility undertook additional efforts to locate Veterans who could not be notified by mail. These measures included searches for alternate addresses on other VA databases and commercial Web sites and multiple visits to homeless shelters in the Miami area. The facility continues to attempt to locate and notify remaining potentially affected Veterans.

Miami also reorganized its SPD program and realigned executive leadership and line managers to make them accountable for reprocessing activities. The facility added a

Clinical Nurse Specialist to enhance clinical knowledge in the line management function. It also reviewed and revised competency definitions for all employees assigned to the gastrointestinal clinic or to SPD to address proper equipment handling, maintenance, use, and cleaning. VA conducted extensive training for gastrointestinal technicians and nurses in proper equipment set-up and pre-cleaning practices. Some of this training was done by manufacturers' representatives, while some was done by sending staff to other VAMCs. Facility leadership verified the competencies of all SPD staff responsible for endoscope cleaning by April 7, 2009. Beyond this, the facility established a continuing education plan, including professional certification activities. By enhancing quality management committees and establishing a VISN-level team

responsible for conducting unannounced inspections, VA continues to exercise effective oversight of facilities and to preserve patient safety.

VA's National Response

VA has taken a number of steps nationally to identify and correct shortfalls with the proper set up, use, reprocessing, and maintenance of reusable endoscopy equipment at all other VAMCs.

The Safety Step-Up Week and the series of communications to the field (including memoranda, the patient safety alert, and reminders on national calls and at national meetings) alerted all facilities about potential problems with endoscope processing and training. Facilities have been given an opportunity during national calls to inform other facility leaders about what they have learned concerning the discovery of problems, patient disclosures, or best practices.

VHA developed, published and implemented a national directive (Veterans Health Administration Directive 2009-004, dated February 9, 2009, "Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities"). Cornerstones of the directive are:

• Assigning responsibilities, especially at the front line level with Network and Facility Directors, but also with key staff within each medical facility;

• Requiring oversight programs be established, including unannounced site audits and quality assurance processes;

• Requiring through policy that manufacturers' instructions for the use, reprocessing, and maintenance of RME must be obtained and followed. These instructions must be used to develop local standard operating procedures and have them available for use by staff; and

• Requiring staff training and assessing staff competency to ensure manufacturers' instructions are being followed correctly.

VA's national SPD program has developed several training courses to increase the professionalism and education of field SPD employees. For example, VHA has developed a 5-day course, which includes a National SPD Certification Test, for new SPD staff, particularly front-line technicians. SPD Chiefs, Assistants and Supervisors can take a three-day seminar, and managers who supervise Chiefs of SPD can take a different three-day class. A new 3-day class is available for new SPD Chiefs and Assistant Chiefs. The VHA National Infectious Diseases Program and Employee Education System have produced one educational video for reprocessing endoscopes, distributed it to medical facilities and is completing the production of another video. Oversight of SPD is accomplished by both internal and external mechanisms. First, a National SPD Self-Evaluation involves each facility analyzing its SPD-related activities twice a year. A facility's performance is judged in part on the results of this evaluation. Second, the National SPD Quality Management Observational Assessment Tool (SPD Tool) was conducted in fiscal years (FY) 2007 and 2008 and is being repeated this
fiscal year. VA distributed the SPD Tool to VISNs and facilities in May for completion. The SPD Tool requires a four-person team at each medical facility to directly observe staff members reprocessing cytoscopes, colonoscopes, bronchoscopes, and upper GI endoscopes. Low outliers identified by this SPD Tool are scheduled for special site visits. One of the recommendations of the FY 2008 SPD Tool was to establish and fill Assistant Chief of SPD positions at all

Complexity Level 1 facilities.1 All Complexity Level 1 and 2 facilities have been directed to establish these positions, and facilities are working to establish and fill them. These positions will assist with the oversight of reprocessing activities that occur both inside and outside of SPD. Finally, the National SPD Site Review Program also sends a site review team each year to one-third of VHA facilities. Areas reviewed by the site review team include the SPD department and areas outside SPD where medical equipment reprocessing occurs.

Future Actions

VA has several initiatives underway to improve SPD and ensure it becomes a high reliability production environment. We are working to develop and deploy a systems- based approach that will become the standard for quality management systems for SPD. In addition, a workgroup continues to investigate ways to standardize the brands and models of endoscopes used in a particular facility, which will simplify reprocessing protocols and training needs. The workgroup is also evaluating leasing options that will provide repair, maintenance and training services. VA has issued a request for information (RFI) for a software solution for SOP management that can also be used for competency verification and document control. VA expects such software will facilitate automatically transmitting any changes to the manufacturers' instructions to users and verifying receipt of these changes. We are also developing a new directive that will align SPD at each medical center under the facility Chief of Staff. Standardizing organizational alignment will simplify communication lines from VA Central Office to the field and vice versa. It will also enhance clear lines of authority and responsibility for the SPD function.

To better understand any possible connection between newly discovered chronic blood borne infections and reports of possible improper reprocessing of endoscopy equipment, VA has assembled a team of subject matter experts to conduct a detailed epidemiologic investigation, starting with an extensive review of electronic medical records. The review encompasses all recent and prior testing for HIV, Hepatitis B, and Hepatitis C, as well as other relevant laboratory test results (e.g. liver function tests); medical histories and risk factors for each of the three viral infections; and details of the actual procedures. The team will also review the sequence of patients receiving endoscopic exams, to assess whether a Veteran previously diagnosed with one of the three viruses preceded a newly-diagnosed Veteran on a daily examination schedule. It is very important to note that, even when completed, this study will not be able to demonstrate causality. However, it will be able to answer the following questions:

- Have all positive test results for HIV, Hepatitis B and C been confirmed? Are there any false positives?
- Is there evidence that any Veteran with a positive post-endoscope test was infected prior to their endoscopic procedure, but never diagnosed?
- Can we identify whether a patient who was previously diagnosed with HIV or Hepatitis had an endoscope procedure the same day as a Veteran who is now newly diagnosed with these viruses?

It is expected that the first phase of this investigation will take several weeks, to permit review of relevant charts and completion of any additional blood work. We will share the results with the Committee when it is available. Additional analyses will need to be performed after the remaining patients exposed have been tested.

Very limited information exists in the medical literature that could elaborate or quantify the known risks associated with reprocessing of endoscopy equipment. One long-term review (1970 through 2003) examined health care associated infections related to gastrointestinal endoscopy and found 281 transmitted infections.2 Major reasons for endoscope-related infections from this study were inadequate cleaning, improper selection of a disinfecting agent, failure to follow recommended cleaning and disinfection procedures, and flaws in endoscope design or automated endoscope reprocessors. Failure to follow established reprocessing guidelines has continued to result in infections associated with gastrointestinal endoscopes.

Flexible endoscopes are particularly difficult to disinfect and easy to damage because of their intricate design and delicate materials. Meticulous cleaning must precede any sterilization or high level disinfections of these instruments. Failure to perform thorough cleaning can result in sterilization or disinfection failure, and outbreaks of infection can occur.4 Because of the large variety of types and models of endoscopic equipment, a single, standard process for reprocessing all reusable endoscope equipment does not exist. This equipment is also constantly being updated, improved, and changed. Our responsibility for effective maintenance and disinfection is further complicated by the growing plethora of equipment, as each type of equipment or each piece and component requires unique reprocessing techniques. The leasing option described above is one approach to improving SPD and should help address this concern.

A recent article summarized the information available in the scientific literature about endoscopy-related exogenous infections (an infection having a cause from outside the body) or pseudo-infections (where patients may have a positive test result but do not develop clinical symptoms). The article identified 140 outbreaks during the period 1974 through 2004, roughly half of which occurred in the United States and half elsewhere.5 Overall, the risk of infection due to inadequate endoscope reprocessing is reported as very low.6

Conclusion
Quality is a journey without end. Our quality monitoring systems continue to be refined and, by objective measures of performance, indicate that VHA continues to set the pace for health care in the country. Nonetheless, the recent troubling revelations regarding endoscope reprocessing show just how hard it can be to ensure that care is safe and effective 100 percent of the time. We do feel, however, that these revelations validate our effort over the past several years to develop a culture of transparency in which staff are not afraid to raise issues and concerns and in which we share with our Veterans and other stakeholders our success and our shortcomings. This allows us to re-think and re-design our systems of care and create additional tools and measures to strengthen quality management.

Mr. Chairman, quality remains a priority at VA. Our Veterans are the finest America has to offer and they deserve the best care possible, and because of our quality and safety programs, I can state VA is answering that call. Thank you again for the opportunity to testify. My colleagues and I are prepared to answer your questions.