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HEARING ON OVERSIGHT OF VA QUALITY MANAGEMENT ACTIVITIES

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

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JUNE 24, 2009

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HEARING ON OVERSIGHT OF VA QUALITY MANAGEMENT ACTIVITIES

WEDNESDAY, JUNE 24, 2009

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 9:31 a.m., in room 418, Russell Senate Office Building, Hon. Daniel K. Akaka, Chairman of the Committee, presiding.

Present: Senators Akaka, Tester, Begich, Specter, Burr, Isakson, and Johanns.

OPENING STATEMENT OF HON. DANIEL K. AKAKA, CHAIRMAN, U.S. SENATOR FROM HAWAII

Chairman AKAKA. The hearing of the Senate Committee of Veterans Affairs will come to order.

Let me say that we know of several instances of poor quality care including the prostate cancer treatment in Philadelphia. The deaths at Marion, Illinois, of course, and at certain facilities which failed to clean endoscopes properly, putting veterans at risk for infectious diseases.

In the case of the cancer treatment, VA contracted with an outside entity for a large sum of money, with the expectation that good care would be provided. Good care was not the result and VA failed to monitor such care. I want to be clear that each of these instances is a breach of our promise to provide the highest quality of care to our veterans.

As I said I would keep my opening statement short, I would like to call on our Ranking Member, Senator Burr, for his opening statement.

STATEMENT OF HON. RICHARD BURR, RANKING MEMBER, U.S. SENATOR FROM NORTH CAROLINA

Senator BURR. Thank you Mr. Chairman. Aloha.

Chairman AKAKA. Thank you.

Senator BURR. Mr. Chairman, I want to thank you for honoring my request from early May and calling what I think is a vitally important hearing about the VA's improper cleaning of its medical equipment. I want to welcome our witnesses today.

There is a human element to this issue that must not be forgotten or overlooked at all. Those affected are all veterans who served their country with honor.

These are people like Michael Priest, a Navy veteran who had a colonoscopy performed at the Murfreesboro VA Medical Center in

June 2007. Mr. Priest was to submit a statement today about his experience, though we haven't gotten it yet, Mr. Chairman.

The VA notified Mr. Priest by telephone that he had tested positive for Hepatitis B and HIV. After he came in for more extensive tests and treatment, they notified him by phone a week later that the first round of tests were inaccurate: he was not infected.

The lack of sensitivity displayed by VA officials in Mr. Priest's case is troubling, to say the least. There was no formal apology issued to him, no phone call from a higher up from the hospital explaining why there was a mix-up, just a single phone call saying, "We got it wrong," as if the detail was trivial and not life-impacting. There was this and clinicians informing his wife, who accompanied him for the second test and was also presumed to be infected, that she was on her own when looking for treatment, that the VA would not necessarily facilitate for her.

Simply put, this is an unacceptable way to treat our veterans or their families. Unlike Mr. Priest, who was ultimately found to be negative for these diseases, 52 of his fellow veterans have tested positive. While it is still unclear if the procedures at VA facilities are responsible for infection, what is clear is that VA's practices opened the door to exposure.

Mr. Priest has abandoned the VA health system and is now seeing a private provider. When veterans lose their confidence in the VA, then we have all failed in our mission to care for those who fought for us.

Although the VA has been working to restore confidence in their services, veterans are still hesitant; and, quite frankly, who can blame them? The more I learn about this issue, the more it seems to be a case of extreme negligence.

With multiple past incidents, multiple warning signs, multiple patient safety alerts, multiple internal VA directives, widespread media attention, an on-going Inspector General's investigation, and pending hearings on the issue, there is no possible justification as to why this has still not been corrected.

I am going to run through a brief timeline, Mr. Chairman.

March 2003. Patient Safety Advisory issued stated that the auxiliary water channels on endoscopies must be cleaned after each use. Again, March 2003. Despite this warning, this was not followed in at least 18 facilities, including Murfreesboro and Miami.

February 2004. Another alert, this time about using the correct connectors. Despite this warning, incorrect connectors were used in Murfreesboro.

Are you noticing a pattern here? I sure am. Since this 2004 February alert, there have been 11 additional Patient Safety Alerts on the topic of medical devices and equipment reprocessing. Eleven.

April 2006. Over 500 Maine veterans are tested due to improper disinfection of biopsy needles. Seventeen facilities in 11 States are found to have the same problem.

March 2008. 714 veterans at an Illinois facility put at risk because of improper cleaning of biopsy valves. VA put out a Patient Safety Alert in response.

July 2008. 159 veterans at a North Dakota facility put at risk because of improper cleaning of the ENT endoscopies, strikingly similar to the problem we saw at the Augusta Medical Center.

As you can see, despite 6 years of warnings about improper cleaning of medical devices, we now arrive at the current problem that has all of our attention.

December 2008. In the wake of improper reprocessing at Murfreesboro, another Patient Safety Alert issued. Again, not new issues, but issues first brought out in 2003 and 2004.

February 2009. VA issues another directive, detailing the proper procedures for the maintenance of equipment. The IG report shows this was ignored by many facilities.

March 2009. VA conducts a "Step-Up Week," in which, according to a VA press release, VA would focus on "retraining, accountability, and training of standard operating procedures." The IG reports that this was also ignored at many facilities.

Mr. Chairman, it is one thing for the VA to discover problems at its facilities and disclose them. But that's only one part of the equation. The other part is learning from mistakes so they are not repeated. That did not happen. It has not happened to date.

The IG conducted unannounced visit to a random sample of hospitals on May 13 and 14, and in these visits, less than 50 percent of the facilities were able to prove they are doing this right. Thirteen and 14 May. Still after all that has happened to shed light on the proper way to do this, they are still not doing it right.

In the wake of Murfreesboro, we were told that all facilities were looking at their procedures and fixing any problems that they had.

The VHA directive on February 9 was supposed to have codified the procedures. The Step-Up Week in early March was supposed to have engaged senior hospital management in personally assuring that the procedures were being done right; then came the IG's findings.

Mr. Chairman, the warning signs were there, but the decision not to focus on them and to take corrective action is what we cannot tolerate. That is the culture that must change.

I look forward to hearing from not only our first panel, but our second panel of VA witnesses. I am not satisfied that the larger problem of patient safety is being adequately addressed. I hope to be convinced today—not for my sake, but the safety of our veterans who trust this medical system as their lifeline.

Mr. Chairman, thank you.

Chairman AKAKA. Thank you very much Senator Burr.

And now I would like to call on our Member, Senator Specter, for his brief statement.

STATEMENT OF HON. ARLEN SPECTER,
U.S. SENATOR FROM PENNSYLVANIA

Senator SPECTER. Thank you very much, Senator Akaka. Thank you Mr. Chairman and Senator Burr for convening this hearing.

I want to speak briefly about a problem which is very similar which has occurred at the Philadelphia Veterans Administration Hospital. According to a *New York Times* article last Sunday, a rogue cancer unit at the Philadelphia VA Medical Center botched 92 of 116 cancer treatments over a span of more than 6 years and kept quiet about it. Ninety-two implant errors resulted from a system-wide failure in which the safeguards were ignored.

The approach is to have seeds the size of a grain of rice permanently inserted into the prostate through needles instead of having an operation. And the insertions were to the wrong area.

I very much appreciate, Mr. Chairman, your authorizing a field hearing in Philadelphia, which we have scheduled for next Monday. I regret that I cannot stay, as we have an extraordinarily busy morning with the live quorum at 10 o'clock and the vote at 11. I think, as most everyone knows, there are many committees meeting simultaneously, so we have to be quadruplets really to make all of the events. We have invited Dr. Cross to come to Philadelphia and I hope he will join us at that time.

I can't see all of the nameplates. Is Dr. Cross in the room? Will you join us on Monday?

Dr. CROSS. Sir, if you need me there I will be there. I have a family wedding to go to, but if need be, I will skip it.

Senator SPECTER. Well, I very much appreciate your willingness to accommodate our schedule. There's a tremendous amount of concern in Philadelphia—really more broadly speaking, but certainly in Philadelphia—where these implants occurred and I think that prompt oversight is something that we ought to do to respond to the public concern.

Thank you very much Mr. Chairman.

Chairman AKAKA. Thank you very much, Senator Specter, for your brief statement. I would now like to call on Senator Begich and then we will hear from Senator Tester afterwards.

STATEMENT OF HON. MARK BEGICH,
U.S. SENATOR FROM ALASKA

Senator BEGICH. Mr. Chairman, because of limited time, I will bypass my opening statement and look forward to the questions.

Chairman AKAKA. Thank you.

Senator Tester.

STATEMENT OF HON. JON TESTER,
U.S. SENATOR FROM MONTANA

Senator TESTER. Thank you, Mr. Chairman. I am going to make my statement very, very brief. First of all, thank you all for being here. I appreciate it and look forward to a good question and answer session.

The material I have gotten is, as I read through it, I can only draw one conclusion and that is there are some things that have been happening that are unacceptable. I think from a medical standpoint you probably know that better than I since I'm not in that profession, yet I guess it. In the testimony that the panel comes forward with, I would just say that I want to know what steps have been taken so it doesn't happen again. I want to know what has been done so that there can be internal reporting without any doubt about it if people see it. Because people in the medical profession, overall—and the VA is no exception—has some pretty competent people. They know what is right and they know what is wrong. And for this to have happened there absolutely was a breakdown in reporting, and there was a breakdown in the overall program; and I want to know how it is going to be fixed to elimi-

nate some of the things that have happened that you guys are going to be talking about today.

With that, Mr. Chairman, I appreciate you having this hearing, as always, and I hope we have an opportunity to ask questions at the end. This is a very, very, very serious situation, as Senator Specter pointed out from his perspective in Pennsylvania. It's the same way across the country. I think that we need to be sure that we have done everything possible to make sure our veterans are treated the way they are supposed to be treated and not put in harm's way because of poor medical practices.

Thank you.

Chairman AKAKA. Thank you very much Senator Tester.

Senator Isakson.

STATEMENT OF HON. JOHNNY ISAKSON, U.S. SENATOR FROM GEORGIA

Senator ISAKSON. Thank you very much, Chairman Akaka. I, too, will be brief because the testimony is far more important from those who came than hearing from us.

The Charlie Norwood VA Center in Augusta is one of the three hospitals where we had, I think, four instances or four cases. Obviously, veterans in Georgia are very concerned and I am very concerned. I have the highest regard for what has been done in Augusta—what they have done regarding seamless transition for the wounded warriors who come back to DOD and transfer to VA—has been tremendous. They have been real leaders.

But this is a very, very serious subject and it is very important that we have a mechanism of accountability to assure our veterans that we are doing everything we can to ensure that all of the equipment and all of the use of equipment is absolutely consistent with the highest forms of hygiene and medical science.

So, Mr. Chairman, I appreciate very much your calling the hearing. I look forward to hearing from the witnesses.

Chairman AKAKA. Thank you very much, Senator Isakson.

I want to welcome the witnesses on our first panel. Dr. Tom Nolan, a distinguished Senior Fellow with the Institute for Healthcare Improvement will begin our discussion of quality management. Also testifying will be Dr. Robert Wise on behalf of the Joint Commission and Ms. Julie Watrous accompanied by Dr. David Daigh and Ms. Vicki Coates on behalf of the Office of Inspector General.

I thank all of you for being here this morning. Your full testimony will appear in the record.

Dr. Nolan will you please begin?

STATEMENT OF THOMAS NOLAN, PH.D., SENIOR FELLOW, INSTITUTE FOR HEALTHCARE IMPROVEMENT

Mr. NOLAN. Mr. Chairman and Members of the Committee, thank you for extending me the privilege of testifying at this hearing on Quality Management on behalf of the Institute for Healthcare Improvement, also known as IHI. I'm a Senior Fellow at IHI. IHI is an independent not-for-profit organization helping to lead the improvement of health care throughout the world.

Although modern approaches to quality management originated and evolved outside of health care, the application of these methods has gained significant traction within health care. Two landmark reports issued by the Institute of Medicine, *To Err Is Human* in 1999 and *Crossing the Quality Chasm* in 2001, highlighted the extent of defects in health care in the United States and the opportunity for improvement. The "Chasm" report declared that the performance of any health care system should be evaluated on six dimensions: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. The authors of the report recognized that these dimensions were an interacting set of qualities that must be pursued together and in balance.

One of the pioneers of quality management was W. Edwards Deming. Deming was one of the first theorists to recognize that most problems of quality and safety arise because of faults of the system rather than because of faults of individuals working in the system.

A simple example illustrates this fundamental principle. Consider how an Automated Teller Machine, or ATM, operates. A customer inserts a bank card, enters the PIN, and then requests an amount of money to be dispensed. In one type of machine, the money comes out first; once the customer removes the money, the bank card comes out. In another type of machine, the bank card comes out first; once the customer removes the card, the money comes out a simple reversal of steps in the process.

The choice between these two designs matters. The customer is far more likely to forget the bank card at the ATM machine if the money comes out first and then the bank card. A directive sent to customers to "please remember your card" will not produce a sustained reduction in cards left at the ATM.

Of course, health care is not banking, but our health care system has thousands of similar opportunities for well-meaning but fallible humans aiming to cure, comfort, or help veterans to make mistakes that harm them. From the viewpoint of quality management, the job of health care executives is to ensure design of systems that both prevent these errors and mitigate the harm when errors do occur.

By what method? Joseph Juran, another pioneer of modern quality management, outlined three key elements of quality management systems: quality planning or system design; quality control in operations; and quality improvement.

How might these apply to the problem that has recently surfaced at VA facilities of contamination in reprocessing of endoscopes? Few systems in the U.S. could produce such thorough and insightful reports as the Inspector General's report on the "Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities" and the "National Center for Patient Safety Review of Reprocessing Issues." Among other things, the Inspector General's report recommended instituting more reliable processes. The National Center for Patient Safety suggested areas of system design that would be needed to accomplish a more reliable overall system.

It is notable, however, that these two reports appear after the fact. If instead they were an input to quality planning and system design, this would help accomplish one of the key goals of quality

management: prevention of defects through design of reliable systems. This is the frontier of quality management in health care.

How would one know at a VA facility if quality management and the resulting high quality were present? One could start by ascertaining how the executives and managers view their role in quality management. They know the trends in the performance of the system through measurement and audit. They invest in improvements to the system. They provide an environment in which everyone in the system can improve the processes in which they work. They promote cooperation between parts of the system, for example, between a hospital and a clinic.

The Veterans Health Administration has been a leader in applying quality control, modern quality control, and quality improvement. We at IHI believe that the VHA could now lead the country into the realm of quality planning and design of a safe system, to prevent these problems from happening in the first place.

Thank you.

[The prepared statement of Dr. Nolan follows:]

PREPARED STATEMENT OF THOMAS NOLAN, PH.D., SENIOR FELLOW ON BEHALF OF THE INSTITUTE FOR HEALTHCARE IMPROVEMENT

Thank you for extending me the privilege of testifying at this hearing on quality management on behalf of the Institute for Healthcare Improvement—also known as IHI. I am Tom Nolan, Senior Fellow at IHI. IHI is an independent not-for-profit organization helping to lead the improvement of health care throughout the world. Founded by a small group of health care leaders in 1991, IHI is based in Cambridge, Massachusetts. We work to accelerate improvement by building the will for change, cultivating promising ideas for improving patient care and safety, and helping health care systems put those ideas into action. IHI employs a core staff of approximately 100 people, along with hundreds of faculty members. We maintain worldwide action- and results-oriented partnerships with thousands of organizations, and tens of thousands of individuals, offering comprehensive programs and maintaining a large research agenda. Our aim is to improve the lives of patients, the health of communities, and the joy of the health care workforce. We believe that, in most settings, this could be accomplished while simultaneously reducing per capita cost.

Although modern approaches to quality management originated and evolved outside of health care, the application of these methods has gained significant traction within health care. Two landmark reports issued by the Institute of Medicine, *To Err Is Human* in 1999 and *Crossing the Quality Chasm* in 2001, highlighted the extent of defects in health care—and the opportunity for improvement. The "Chasm Report" declared that the performance of any health care system should be evaluated on six dimensions: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. The authors of the report recognized that these dimensions were an interacting set of qualities that must be pursued together and in balance.

One of the pioneers of quality management was W. Edwards Deming. Deming was one of the first theorists to recognize that most problems of quality and safety arise because of faults of the system rather than because of faults of individuals working in the system.[1] A simple example illustrates this fundamental principle. Consider how an Automated Teller Machine, or ATM, operates. A customer inserts a bank card, enters the PIN, and then requests an amount of money to be dispensed. In one type of machine, the money comes out first; once the customer removes the money, the bank card comes out. In another type of machine, the bank card comes out first; once the customer removes the card, the money comes out—a simple reversal of steps in the process.

The choice between these two designs matters. The customer is far more likely to forget the bank card at the ATM machine if the money comes out first and then the bank card. The customer knows how to operate the machine—and suffers a loss if he forgets his bank card—but still forgets the bank card if the money comes out first. A directive sent to customers to "please remember your card" will not produce a sustained reduction in cards left at the ATM.

[1] Deming WE. *Out of the Crisis*. Cambridge, MA: MIT Press; 1986.

Of course, health care is not banking, but our health care system has thousands of similar opportunities for well-meaning but fallible humans aiming to cure, comfort, or help patients to make mistakes that harm them. From the viewpoint of quality management, the job of health care executives is to ensure the design of systems that both prevent these errors and mitigate the harm when errors do occur.

By what method? Joseph Juran, another pioneer of modern quality management, outlined the three key elements of a quality management system: quality planning (system design), quality control in operations, and quality improvement.[2]

Quality planning includes:

- Designing processes capable of being executed reliably to meet the needs of customers or produce the desired outcomes;
- Training and certifying people in the skills necessary to do the work. In health care, professional licensure and board certification are ways in which this happens; and
- Understanding the types of defect that are possible in the system and developing a means for the routine tracking of the occurrence of these defects.

Quality control includes:

- Tracking performance during routine operations of key factors in the process or elements of a clinical guideline;
- Identifying failures in operation and mitigating the harm caused to patients; and
- Monitoring defects and the trend in their frequency—for example, are drug overdoses going up, down, or staying the same?

Quality improvement includes:

- Setting priorities for defect reduction;
- Applying design concepts such as simplification, visual controls, and waste reduction; and
- Capturing the learning and spreading it to other locations.

How might this thinking apply to the problem that has recently surfaced in the VA of contamination in reprocessing of endoscopes? Few systems in the US could produce such thorough and insightful reports as the Inspector General's report on the "Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities" and the "National Center for Patient Safety Review of Reprocessing Issues." Among other things, the Inspector General's report recommended instituting more reliable processes. The National Center for Patient Safety suggested areas of system redesign that would be needed to accomplish a more reliable overall system.

It is notable, however, that these two reports appeared after the fact. If instead they were an input to quality planning and system design, this would help accomplish one of the key goals of quality management: prevention of defects through design of reliable systems. This is the frontier of quality management in health care.

How would one know at a VHA facility if quality management—and the resulting high quality—were present? One could start by ascertaining how the executives and managers view their role in quality management:

- They know the trends in the performance of the system through measurement and audit. In a system such as the Veterans Health Care system, this would include knowing the variation in performance among different VHA sites.
- They invest in improvements to the system. These investments range from capital investments to install an electronic medical record, to the investment of clinicians' time to test and implement a protocol for treating heart attack victims effectively, safely, and efficiently.
- They provide an environment in which everyone in the system can improve the processes in which they work. This environment includes the freedom to surface problems in the system without fear of retribution.
- They promote cooperation between parts of the system—for example, between a hospital and a clinic, or between the Department of Defense health care system and the VHA.

The Veterans Health Administration has been a leader in applying quality control and quality improvement. We at IHI believe that the VHA could now lead the country into the realm of quality planning and design of a safe system, to prevent these problems from happening in the first place.

Resources: IHI Website: www.ihi.org

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[2] Juran JM, Godfrey, AB. *Juran's Quality Handbook*. 5th ed. New York, NY: McGraw-Hill; 1999: 2–6.

Chairman AKAKA. Thank you very much, Dr. Nolan. And now we will hear from Dr. Wise.

STATEMENT OF ROBERT A. WISE, M.D., VICE PRESIDENT OF STANDARDS AND SURVEY METHODS, THE JOINT COMMISSION

Dr. WISE. Mr. Chairman, Ranking Member, and Members of the Committee, on behalf of The Joint Commission, thank you for the opportunity to testify at this very important hearing.

The Joint Commission accredits approximately 146 Department of Veterans Affairs organizations, including all of its hospitals. We strive to ensure that our Nation's veterans are receiving high quality and safe care. The Joint Commission accreditation is a risk-reduction process, which is designed to assist health care organizations in reducing the safety risks that are ubiquitous in health care.

Providing health care is fundamentally a human endeavor. The Joint Commission emphasizes to health care organizations the importance of having a systems approach to the delivery of care that requires all staff to work together to create a culture of safety similar to that found in high reliability industries such as nuclear power and commercial aviation.

For example, the systems approach to reducing health care associated infections within health care organizations involves all parts of the organizations and all staff—from physicians and nurses to housekeeping.

This systems approach requires organizations to establish a just culture in which people feel safe to identify and report errors has happened in the VA when problems with cleaning equipment was discovered.

There are five critical components of the hospital accreditation program. First is the need to meet evidence-based standards and National Patient Safety Goals. Second is the ongoing collection of data, such as patient outcomes, complaints, and past survey results. Third is a periodic onsite survey process in which unannounced onsite surveys emphasize the need for organizations to be in continuous compliance with all accreditation standards.

Surveys start with a group of patients and then each patient's experience is traced through the organization. Thus, a surveyor is able to both understand the care directly delivered to these patients and how well the services are integrated to produce good outcomes.

Fourth, hospitals are required to complete an annual self-assessment tool regarding its ongoing compliance with Joint Commission standards. And last is public access to a robust complaint process for families, patients, staff or anyone else who has concerns about the care provided at an organization. Raising the bar.

The Joint Commission helps organizations focus on priority safety issues. Infection prevention remains one of the most challenging issues in the safe delivery of health care. The Joint Commission has worked closely with both government and professional organizations to identify the most effect ways to use scarce resources to reduce the number of HAIs.

The Joint Commission's Infection Prevention Standards require the creation of a hospital-wide program that addresses the specific

risks to the organization, which must be re-evaluated and modified on a yearly basis. Our surveyors examine a sample of disinfection and sterilization processes. While not every type of procedure is reviewed, the overall framework of how the organization manages this portion of its infection prevention program is always part of accreditation.

The Joint Commission's experience with the VA. Because of the way the VA is organized, the opportunities exist to achieve high quality safe care when compared to other health care organizations. Among the VA's attributes are a single medical record for each patient across all care, an integrated health care system allowing coordination of care, and the ability to standardize medical equipment through centralized purchasing. As an example of the positive attributes of the VA system, its sophisticated information system allowed much of the performance measured data required by the Joint Commission to be gathered in an electronic manner, which has resulted in almost uniformly strong performance on measures pertinent to heart attack, heart failure, pneumonia, and surgical infection prevention.

Furthermore, the power of the VA's unique environment was demonstrated when more than a dozen organizations stepped up to describe similar process breakdown in their own facilities. This type of self-disclosure is unusual in an industry that too often is seen hiding these types of problems.

What the Joint Commission is doing to improve safety in health care. The Joint Commission learns lessons from high-risk industries and from other disciplines such as systems engineering that have been successful in creating safe environments as they strive toward high reliability of their processes. To create a high reliability organization an attitude of safety must exist through all levels of an organization. This expectation is essential to the Joint Commission's accreditation process and its message.

The delivery of health care is a complex undertaking that depends on human beings, therefore making it error prone. The Joint Commission began years ago to help organizations become safer organizations by expecting cultures of safety. This direction will remain our top priority.

On behalf of The Joint Commission, I would like to thank you again for this opportunity to testify.

[The prepared statement of Dr. Wise follows:]

PREPARED STATEMENT OF ROBERT A. WISE, M.D., VICE PRESIDENT OF STANDARDS AND SURVEY METHODS, THE JOINT COMMISSION

INTRODUCTION

Mr. Chairman, Ranking Member and Members of the Committee, on behalf of The Joint Commission, I want to thank you for the opportunity to testify at this very important hearing on the Oversight of VA Quality Management Activities. Founded in 1951, The Joint Commission is an independent, not-for-profit organization whose mission is to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.

While The Joint Commission has its roots in hospital accreditation, over the years it has developed evaluation programs for a diverse array of health care settings. Today, The Joint Commission evaluates and accredits approximately 16,000 health care organizations and programs in the United States, including ambulatory care,

behavioral health services, durable medical equipment providers and suppliers, home care, hospices, hospitals, laboratories, and long term care facilities.

The Joint Commission accredits approximately 146 Department of Veterans' Affairs organizations, including all of its hospitals. In partnership with the Veterans Health Administration, the Joint Commission strives to ensure that our Nation's veterans are receiving high quality and safe care. We take situations such as the improper cleaning or reprocessing of colonoscopy equipment at VA medical centers very seriously and are working with the VA to identify the causes that contributed to this problem and to develop solutions so that these problems do not occur again.

THE JOINT COMMISSION'S ACCREDITATION PROCESS

Joint Commission accreditation is a risk-reduction process. The Joint Commission's accreditation process is designed to assist healthcare organizations in reducing the ubiquitous safety risks that are an integral part of the delivery of the high quality health care found in the United States and to then assess the level of the organization's success. While risk will never be completely removed, organizations can be highly successful in substantially reducing, though not eliminating, errors.

The delivery of health care is complex and is fundamentally a human endeavor. The role of The Joint Commission is to help organizations decrease errors through compliance with state-of-the-art standards that focus on a "systems approach" to delivering care. The Joint Commission emphasizes to health care organizations the importance of having all staff work together to create a culture of safety, and establishing and maintaining a strong commitment from leadership to evolve toward high reliability organizations such as those found in the high risk industries of nuclear power and commercial aviation.

Systems Approach and Culture of Safety

Joint Commission efforts to improve patient safety in all types of health care organizations are based upon a recognition of the need for organization leaders and health care practitioners to adopt a "systems approach" to managing risk and keeping inevitable human error from reaching patients. For example, to help reduce the possibility of acquiring and transmitting an infection, organizations need to establish a robust, systematic infection prevention and control program that starts with strong expectations from organizational leadership and emphasizes communication and collaboration among all parts of the organization. Attempting to eliminate healthcare associated infections (HAIs) within health care settings requires attention to the entire care delivery process and involves everyone, from physicians and nurses to housekeeping and receptionists.

This systems approach requires organizations to establish a just culture in which people feel safe to systematically identify and report errors and near misses so that these events serve as important learning experiences for the organization and its staff. The Joint Commission recognizes that the VA is a leader in American medicine in creating such a culture and has spent a great deal of time and effort in creating and maintaining it. A safety-focused learning environment is one in which safety is always top of mind and in which there is constant vigilance by the organization's leaders and staff to identify and eliminate risks. The Joint Commission's standards, survey process, and other quality and safety improvement initiatives are designed to stimulate and facilitate the creation of a culture of safety within accredited organizations.

Accreditation Methods

The Joint Commission has created a framework to enhance patient safety. The critical components needed to achieve lasting improvement in organizational performance include:

- *Evidenced-Based Standards and National Patient Safety Goals:* Standards describe the successful operation of administrative and other critical systems of the health care organization (e.g., medication management, infection control and prevention, and leadership), while National Patient Safety Goals focus on specific high risk processes that directly impact the quality and safety of care delivered to patients (e.g., reduction of central line infections, safe use of anticoagulation medications, reduction of wrong site surgery). These requirements are developed in collaboration with experts and key stakeholders with final review carried out by a Nationwide field engagement.
- *Ongoing Collection of Data:* The Joint Commission initiated the first national standardized data collection program for hospitals. This program has formed the basis for Medicare's current pay-for-reporting program; the VA has been an active participant in this program since its inception. The data collected on each organization reflect the degree to which the organization routinely delivers safe and quality

health care. Data on sentinel events, patient complaints, past survey results, and performance measures are collected on every Joint Commission-accredited healthcare organization and help The Joint Commission focus and drive the onsite assessment.

• *Periodic Onsite Survey Process:* Unannounced onsite surveys emphasize the need for organizations to be in continuous compliance with all accreditation standards. The organization's annual self-assessment augments the onsite survey process. Additionally, the availability of data about the performance of an organization gives the Joint Commission surveyors an informed method to pick patients in the organization whose experience can highlight how the organization is performing in its delivery of quality and safe medical care; this data allows the surveyors to use the important "tracer methodology" tool. By starting with a specially selected patient and then "tracing" that patient's experience through the organization, a surveyor is able to both understand the care directly delivered to patients and the integration of systems within the organization. For example, a patient with a hospital acquired MRSA infection in the ICU will not only reveal how an infectious patient is treated, but will also lead the surveyor to appreciate the healthcare organization's entire infection prevention and control program.

• *Completion of an Annual Self-Assessment Tool:* In addition to being assessed for compliance with standards during the onsite survey, every health care organization is required to complete an annual self-assessment of compliance with all standards. Part of that process is an opportunity to discuss questions and concerns with Joint Commission staff about the organization's approach to compliance with the accreditation requirements.

• *Ready Public Access to a Robust Complaint Process:* As a way to receive ongoing information about the delivery of care at all of the accredited organizations, there exists a toll-free complaint hotline, the confidentiality of which is maintained for those who report concerns about an accredited organization. This hotline is available to patients, families, staff, or anyone else who might have concerns about the care provided at an organization. There is a team that investigates all complaints and has the resources to do an onsite visit if required. Also, this information becomes part of the data used by the Joint Commission to focus the onsite survey.

RAISING THE BAR

The Issue of Infection Prevention and Control

Infection prevention and control remains one of the most important issues challenging the safe delivery of health care, and the approach to eliminating infections is constantly changing and improving. The Joint Commission is aware of this and strives to remain on the cutting edge of initiatives and advancements in this area of health care. Since there are numerous ways in which errors may occur in delivering health care, The Joint Commission helps organizations to focus on priority areas. For example, The Centers for Disease Control and Prevention (CDC) estimates that tens of thousands of central line-associated bloodstream infections occur annually; 12–25% of patients with these infections die. The Joint Commission created a National Patient Safety Goal requiring organizations to implement best practices to prevent central line-associated bloodstream infections. These requirements specify steps an organization must take and are based on evidenced-based national guidelines (*Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals*, found at www.shea-online.org/about/compendium.cfm). A March 2008 GAO report underscores the importance of providing such explicit implementation guidance to hospitals trying to reduce the transmission of infections. For example, the GAO stated that the CDC has over 13 guidelines for hospitals on infection control and prevention containing almost 1200 recommended practices. However, these practices are not framed for easy implementation and in a manner that provides a blueprint for action. The Joint Commission recognizes that many of these practices are vague or framed as contingencies (e.g., if this, then maybe that). To help to address the GAO's concern, The Joint Commission was active in the development of the *Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals*. The Compendium addresses these implementation issues to help hospitals be successful in a complex area.

In regard to the VA's situation pertaining to the use of colonoscopes, because of the complexity of disinfection and sterilization of equipment, the process can be error-prone. Though the number of infections resulting from these processes is not as high as other sources of HAIs, disinfection and sterilization remains a current area of focus.

The need to decrease the number and seriousness of healthcare associated infections remains a focus of Joint Commission accreditation. In the last several years,

The Joint Commission has worked closely with both government (e.g., CDC) and professional organizations (e.g., SHEA, APIC) to identify the most effective way to use scarce resources to mitigate the continuing problem of HAIs. Four infections are responsible for the majority of HAIs. The National Patient Safety Goals identify the most dangerous of those infections and create the expectation that the organization develops processes to significantly lower their incidence in the hospital.

Simply knowing about problems will not immediately remedy the situation, but it is the first step. Usually, an epidemic triggers an investigation and the results of that investigation uncover system failures or process breakdowns. For example, an outbreak of Hepatitis in Nevada led to an investigation which uncovered the reusing of syringes or needles in clinics. In the VA situation, there is no known epidemic; the performance improvement process is working. The VA self-identified a process problem, conducted an investigation, and is implementing improvements. The lapses that happened within the VA system are probably typical of what may be occurring within health care organizations outside of the VA system. The Joint Commission will actively disseminate what is being learned from this situation to other health care organizations.

The Infection Prevention and Control Standards stress the fact that everyone who works in the organization has a role in infection prevention and control; must be given the tools and training necessary to fulfill that role; and must be held accountable for following procedures that minimize risks to patients. In addition, the Infection Prevention and Control Standards require the creation of a program that addresses the specific risks to the organization and which must be re-evaluated and modified on a yearly basis.

A standard part of any infection control and prevention program is the proper processing of equipment, devices, and supplies. This would include all surgical instruments, scopes, and other equipment. While the frequency of infections directly associated with poorly cleaned equipment is not well established (compared to, for example, those associated with the insertion of devices in the body), the control and prevention of HAIs nevertheless remains an integral part of all infection control and prevention programs. The Joint Commission expects organizations to use evidence-based national guidelines when developing infection prevention and control activities. The two widely recognized guidelines pertaining to cleaning, disinfecting, and sterilizing equipment are the Centers for Disease Control and Prevention's Healthcare Infection Control Practices Advisory Committee's *Guideline for Disinfection and Sterilization in Healthcare Facilities* (http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf, and The Society for Healthcare Epidemiology of America's *Multi-society Guidelines for Reprocessing Flexible Gastrointestinal Endoscopes* (http://www.shea-online.org/Assets/files/position_papers/SHEA_endoscopes.pdf).

It is important to emphasize that, as part of every accreditation survey, the surveyors will examine disinfection and sterilization processes. Surveyors are trained to ask health care workers about manufacturer's instructions and how they process medical equipment; observe medical equipment being processed; and review information about parametric, chemical, and biologic indicators. Surveyors are well prepared to review how an organization manages the processing of medical equipment. Surveyors receive ongoing training on the proper management and processing of medical equipment, and they also have access to infection prevention and control experts within The Joint Commission who can guide them while conducting the on-site review.

A combination of cleaning, decontamination, disinfection, and sterilization methods are used in handling medical equipment. Regardless of the methods required, organizations are expected to follow the manufacturer's guidelines. Additionally, organizations are expected to have an on-going quality control process that ensures that proper medical equipment handling protocols are being followed. In a large hospital, there will be many procedures requiring disinfection and sterilization in which many staff are involved. So, while not every type of sterilization procedure is reviewed, the overall process of how the organization manages this portion of its infection control and prevention program is always part of an accreditation survey.

THE JOINT COMMISSION'S EXPERIENCE WITH THE VA

How the VA Differs from Other Health Care Systems

The Joint Commission has been asked to comment on how the VA health care organizations perform in relation to private health care organizations. Because of issues such as confidentiality and limited resources, The Joint Commission does not routinely conduct such data analyses. However, because of the way the VA is uniquely organized (for example, the integration of care for a single episode is gen-

erally unique to the VA system), the opportunity exists to achieve high quality, safe care when compared to other health care organizations. Among the VA's positive attributes are the following:

- A single medical record for each patient across all care settings supporting coordination of care
- A centralized, integrated health care system allowing coordination of care
- A standardized credentialing and privileging process for the appointment of medical staff
- The capability to achieve enhanced epidemiology through the integrated medical record
- The ability to standardize medical equipment through centralized purchasing
- Leadership's commitment to and support of performance improvement and the encouragement of a culture of safety that impacts the entire delivery system

The power of the VA's unique environment was demonstrated through its ability to reach out to the entire hospital membership once the process breakdown in the colonoscopy cleaning process was discovered. That more than a dozen organizations stepped up to describe similar process breakdowns in their own facilities is unusual in an industry that too often is seen as hiding these types of problems. The advantage of the VA's medical record system was demonstrated through the identification of all of the potentially infected veterans and the seeming ease with which the VA contacted those patients with proper next steps.

The Joint Commission's Process with the VA

The Joint Commission's Office of Quality Monitoring is working with the VA to assist with the organizations that are experiencing issues with colonoscope cleaning. According to the responses from the organizations to date, no definitive connection between the equipment and the positive diagnoses found in patients has been made. In addition, prior survey history and prior complaint history were absent any indication of infection control or equipment management problems at any of the three facilities. While the organizations' responses were thorough and credible, ongoing guidance with Joint Commission management and leadership was sought related to whether any alternative approaches should be considered due to the common theme among these events and with the knowledge that the situation was being addressed by the VA at a leadership level. The Joint Commission is continually in communication with the VA regarding this matter, and will ensure through survey and other means that follow-up is successful.

WHAT THE JOINT COMMISSION IS DOING

Complexity of Health Care

There are a number of industries operating within complex environments that have been more successful in avoiding the number and variety of errors that continue to plague the delivery of medical care. Industries such as commercial aviation and nuclear power have had similar types of challenges and have been more successful in creating safe environments known as High Reliability Organizations. While a complete discussion of what constitutes a High Reliability Organization is beyond the scope of this document, it is important to at least list the characteristics that are generally associated with organizations that have achieved such a status. These five characteristics are:

- Preoccupation with failure
- Reluctance to simplify interpretations
- Sensitivity to operations
- Commitment to resilience
- Deference to expertise

For an organization to incorporate these characteristics into its fabric, an attitude of safety must exist through all levels of an organization. While that achievement is quite difficult, at a minimum an expectation that the organization will remain safe through the use of established tools must be solidly part of the leadership's attitudes. The expectation that health care organizations continually move toward achieving this state of high reliability is at the core of The Joint Commission's accreditation process and its components.

The Joint Commission continues to work with the VA in a collaborative and collegial fashion to resolve the VA's infection prevention and control issues. The Joint Commission's pledge to help health care organizations help patients by providing them with useful guidelines and tools (such as the Standards and National Patient Safety Goals) drives The Joint Commission to constantly evolve and grow. In addi-

tion to disseminating all lessons learned through its interaction with the VA, The Joint Commission will:

- Survey health care organizations using state-of-the-art standards;
- Guide and educate these organizations on the most critical of issues through the National Patient Safety Goals;
- Launch the Center for Transforming Healthcare which will allow The Joint Commission to directly partner with the most innovative and advanced organizations in the country to address the most critical health care issues facing the industry today;
- Regularly introduce new initiatives to the health care industry, such as the forthcoming hand hygiene initiative;
- Help health care organizations to reach the same high reliability status as the commercial aviation and nuclear power industries;
- Share with the health care industry all lessons learned;
- Help organizations to provide the highest quality, safest care possible; and
- Serve and protect patients.

CONCLUSION

The delivery of health care is a complex undertaking with numerous intricate and complicated processes that fundamentally depend upon human beings, which tends to make these processes error-prone. The Joint Commission began a number of years ago to help organizations become safer environments for patients and staff by moving organizations toward establishing cultures of safety that are characterized by encouraging the reporting of problems and unsafe practices; prospectively wrapping envelopes of safety systems around high risk processes; and involving all parts of the organization in keeping safety top of mind.

The Joint Commission is pleased that the VA has moved expeditiously in this direction and has spent significant resources on creating the safety infrastructure that can take them into the future. We note that it was a VA employee who identified the risk to patients and the VA leadership took appropriate action to minimize risks for patients being treated at other VA facilities. These types of actions are critical to the evolution of a culture of safety.

On behalf of The Joint Commission, I would like to thank you again for this opportunity to testify. We are firmly committed to working with all of our partners—public and private—to ensure continuous improvement in the delivery of safe, quality health care.

Chairman AKAKA. Thank you very much, Mr. Wise. We have a quorum call at 10, so we're going to recess and be on the floor. Ms. Watrous, when we return we will hear your testimony.

So the Committee stands in recess at the call of the Chair.

[Recess.]

Chairman AKAKA. The hearing of the Senate Committee on Veterans' Affairs will come to order.

Ms. Watrous, will you please begin with your testimony.

STATEMENT OF JULIE A. WATROUS, R.N., M.S., DIRECTOR, COMBINED ASSESSMENT PROGRAM, OFFICE OF HEALTHCARE INSPECTIONS, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY JOHN DAIGH, M.D., ASSISTANT INSPECTOR GENERAL FOR HEALTHCARE; AND VICTORIA COATES, MSW, DIRECTOR, ATLANTA REGIONAL OFFICE

Ms. WATROUS. Mr. Chairman and Members of the Committee, thank you for the opportunity to testify today on a subject that is very important to all of us and to me personally—Quality Management in the VA. I have worked for over 20 years in the VA to manage and improve the quality and safety of health care for our veterans.

I will highlight the results of two reports that we have recently published in this area. I will also briefly discuss our recent report, on the reprocessing of endoscopes.

VHA employs many thousands of care providers who work everyday to provide high quality health care to our veterans and they mostly succeed. VA does some things very well and the quality of care in VHA is generally high. However, the controls need to be improved to ensure the consistent delivery of a uniform medical benefit.

I run the Combined Assessment Program (CAP) with site visits to each VA facility approximately every 3 years. We cover a variety of patient-care administration and quality management topics. We have had findings in environmental issues, medication management, and coordination of care, among others.

In our report, "Evaluation of Quality Management in VHA Facilities Fiscal Year 2008," we summarize our findings from 44 CAP reviews. Quality management programs were generally comprehensive and effective. Two of the 44 facilities had significant weakness in their QM programs, and those were Detroit and St. Louis. Specific recommendations for those two sites addressed peer review, adverse event disclosure, and patient safety among other issues. Both facilities submitted acceptable action plans and we tracked the actions to completion.

In our report, we recommended that patient complaints be critically analyzed and actions taken when trends are identified. Medication reconciliation needed to be actively monitored, medical records needed to be reviewed for inappropriate use of the copy and paste function, and a system-wide fix needed to become a high priority. Compliance with moderate sedation monitoring requirements needed to be reinforced and the length of privileges granted to physicians needed to match the length of the employment association. VHA concurred and submitted an acceptable action plan.

VHA's Patient Safety Program is world renowned and has been copied in other health care systems. However, there is room for improvement. In our report titled "Evaluation of VHA's National Patient Safety Program," we made three recommendations for improvement. All relevant patient data sources needed to be assessed for patient safety significance coordinated across the VA's Quality and Safety Programs and used to drive change.

Organized coordinated oversight of the National Patient Safety Program needed to be systematically provided and VHA needed to develop a plan to systematically review all aspects of the program for efficiency and effectiveness, and revise as needed. VHA concurred and submitted an adequate action plan.

The third report to discuss today is titled "Use and Reprocessing of Flexible Fiberoptic Endoscopes." This review was a reaction to recent events. We reviewed the topic at Murfreesboro, Tennessee, Miami, Florida, and Augusta, Georgia, in detail. We also conducted unannounced visits to 42 other reprocessing sites to assess the extent of related problems across the system. Dr. Daigh testified on this topic before the House Veterans' Affairs Subcommittee on Oversight and Investigation last week.

In our report we concluded that facilities had not complied with directives to ensure appropriate endoscope reprocessing. We also

noted that the Clinical Risk Assessment and Advisory Board has been an effective mechanism for providing guidance on the disclosure of adverse events. We recommended that VHA ensure compliance with relevant directives regarding endoscope reprocessing, explore the possibilities to improve the reliability of endoscope reprocessing, and review the organizational structure and make necessary changes to implement controls that will ensure compliance.

Mr. chairman, thank you again for the opportunity to appear before the Committee. We would be pleased to take your questions.

[The prepared statement of Ms. Watrous follows:]

PREPARED STATEMENT OF JULIE A. WATROUS, RN, MS, DIRECTOR, COMBINED ASSESSMENT PROGRAM, OFFICE OF HEALTHCARE INSPECTIONS OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS

Mr. Chairman and Members of the Committee, thank you for the opportunity to testify today on Quality Management in the Department of Veterans Affairs. I will focus on the results of two reports that we recently published in this area (1) *Healthcare Inspection—Evaluation of Quality Management in Veterans Health Administration Facilities Fiscal Year 2008*; and (2) *Healthcare Inspection—Evaluation of the Veterans Health Administration's National Patient Safety Program*. I will also discuss our recent report, *Healthcare Inspection—Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*. I am accompanied by Dr. John D. Daigh, Assistant Inspector General for Healthcare Inspections, Office of Inspector General (OIG) and Victoria H. Coates, Regional Director of the Atlanta Office of Healthcare Inspections, OIG.

BACKGROUND

The Joint Commission (JC), an accrediting body, describes quality management (QM) as a continuous process that involves measuring the functioning of important patient care processes and services and, when indicated, identifying changes that enhance performance. JC conducts triennial surveys at all Veterans Health Administration (VHA) medical facilities. However, external surveyors typically do not focus on VHA requirements. Also, the JC changed the focus of their survey process in 2004, resulting in a reduction in the JC's onsite attention to those standards that define many requirements for an effective QM program.

Since the early 1970s, VA has required its health care facilities to operate comprehensive QM programs to monitor the quality of care provided to patients and to ensure compliance with VA directives and accreditation standards. Several VHA offices have created programs to evaluate and seek improvement in patient care and safety. Each of these offices has access to comprehensive patient databases and can obtain reports that assess performance against metrics, such as procedure complication rates, surgery waiting times, and patient satisfaction. Some specific programs have developed databases tailored for their patient care review needs, such as the National Surgical Quality Improvement Program (NSQIP), the Inpatient Evaluation Center, and the Cardiac Assessment Reporting and Tracking System.

In 1999, VHA issued the National Patient Safety Improvement Handbook, which established a policy for identifying, reporting, and mitigating vulnerabilities that may result in adverse patient events (such as patient falls and medication errors). VHA facility staff are expected to identify and report actual adverse patient events. Facility patient safety managers (PSMs) prioritize them for severity and probability. A root cause analysis (RCA) may be used by facility staff to determine the reasons why events occurred and to try to prevent future occurrences. The handbook describes two types of RCAs—aggregated and individual. Aggregated RCAs may be used for four events (falls, adverse drug events, parasuicides [actual or attempted suicides], and missing patients) for which data are gathered over time and evaluated annually. Individual RCAs are conducted for more serious events. PSMs enter adverse event information into the National Center for Patient Safety's (NCPS) database. The NCPS has access to all reported patient adverse events, close calls, and RCAs across the VA system.

The OIG is required by Public Law 100–322, Veterans' Benefits and Services Act of 1988, to oversee VHA's QM programs at every level. Oversight is provided through four different approaches:

• Combined Assessment Program (CAP) Reviews—These site visits are scheduled at each VHA facility approximately every 3 years and cover a variety of patient care

administration and QM topics. The QM program review has been a consistent focus during CAP reviews since 1999.

• National Reviews—These system-wide reviews vary by topic and scope but have repercussions for VHA policies and practices. The review of VHA's National Patient Safety (NPS) Program is an example of a national program review.

• Hotline Complaint Inspections—These inspections address complaints made to the OIG Hotline. They may address issues at one facility, several facilities, or may be wider in scope.

• Community Based Outpatient Clinic Reviews (CBOC)—This new program of site visits began in April 2009. The goal is to visit all CBOCs over time. A variety of quality and safety topics will be covered in these reviews.

THE EVALUATION OF QUALITY MANAGEMENT IN VHA FACILITIES

The OIG conducted CAP reviews in 44 VA medical facilities during fiscal year (FY) 2008. To evaluate QM activities, we interviewed facility directors, chiefs of staff, and QM personnel, and we reviewed plans, policies, and other relevant documents. Some of the areas reviewed did not apply to all VHA facilities because of differences in functions or frequencies of occurrences.

The components of a typical QM program are not standardized. For a complete list of the program areas we defined to comprise a comprehensive QM program, please see our report,[1] but some of the areas we chose to include are:

- QM and Performance Improvement (PI) committees, activities, and teams.
- Peer reviews.
- Patient complaints management.
- Disclosure of adverse events.
- Patient safety functions.
- Reviews of patient outcomes of resuscitation efforts.
- Medical record documentation quality reviews.

As a result of our review we made five recommendations, which VHA concurred with:

- Patient complaints needed to be critically analyzed and actions taken when trends are identified.
- Medication reconciliation needed to be actively monitored.
- Medical records needed to be reviewed for inappropriate use of the copy and paste functions and a system-wide fix needed to be made a high priority.
- Compliance with moderate sedation monitoring requirements needed to be reinforced.
- The length of privileges granted to physicians needed to match the length of the employment association.

In addition to these five issues, we expressed concern about the following seven areas and will continue to monitor them:

- Adverse event reporting.
- Utilization management.
- Patient flow.
- Peer review.
- RCA timeliness.
- Implementing and evaluating corrective actions.
- Continuous performance monitoring for physicians.

Although all 44 facilities we reviewed during FY 2008 had established comprehensive QM programs and performed ongoing reviews and analyses of mandatory areas, the St. Louis VA Medical Center and John D. Dingell VA Medical Center, Detroit, Michigan, had significant weaknesses. While facility senior managers supported their QM programs and were actively involved, they needed to implement and/or reinforce efforts to improve action item implementation and evaluation.

EVALUATION OF VHA'S NATIONAL PATIENT SAFETY PROGRAM

On June 18, 2009, we published the results of our evaluation of VHA's NSP Program.[2] We reviewed the *VHA National Patient Safety Improvement Handbook* (VHA Handbook 1050.01, May 23, 2008), reports, training materials, and other relevant documents. We interviewed NCPS staff in July 2008, as well as staff at VA Central Office, at the Veteran Integrated Service Network (VISN) level, and at the facility

[1] *Healthcare Inspection—Evaluation of Quality Management in Veterans Health Administration Facilities Fiscal Year 2008*, May 19, 2009.

[2] *Healthcare Inspection—Evaluation of the Veterans Health Administration's National Patient Safety Program*.

level. Also, we assessed patient safety review results and feedback gathered from VHA facilities during CAP reviews.

It is important to identify as many safety concerns as possible from all available sources in order to understand the magnitude of the concerns and prioritize actions to address them. Many programs under the broad umbrella of quality and safety have the potential to identify safety issues and adverse events. At the facility level, the following programs comprise a partial list:

- Patient incident reporting.
- Patient advocate.
- Peer review.
- Tort claim information system.
- Morbidity and mortality conferences.
- NSQIP.
- Infection control.

While some facility staff may share data from these programs to identify patient safety issues and events, no such sharing is required by directives. Most of these programs require facility data to be entered into databases or sent in reports that are available to the responsible program offices at the VA Central Office level. If these databases were available to all relevant program offices for use in data analysis, it is possible that resulting actions could improve patient care quality and safety. However, quality and safety information is not always well coordinated among VHA entities.

Patient safety could be improved by better coordinating existing data sources in various programs, expanding the identification of patient events through the addition of automated systems, making appropriately identified data available for analysis, and using the data to drive change. High frequency event types should be given appropriate attention.

We found that although the NCPS monitors selected data elements within required processes, it does not provide comprehensive oversight of the NPS Program. It is expected that organized, coordinated oversight of VHA programs be provided to determine whether policies are effective and relevant or in need of revision. Currently, there appears to be redundancy and lack of role clarity between NCPS and VISN staff, resulting in confusion. The NCPS does not document the systematic evaluation of required patient safety processes to determine if revision is needed. It is a general philosophy of any quality review activity to continually assess and seek to improve key processes. We identified the following four areas that would benefit from systematic assessment and possible revision.

- Cumbersome processes and content.
- Follow-up of action items.
- Inter-rater reliability.
- Adverse event disclosure.

As a result of our review, we made three recommendations:

- All relevant patient data sources needed to be assessed for patient safety significance, coordinated across VHA's quality and safety programs, and used to drive change.
- Organized, coordinated oversight of the NPS Program needed to be systematically provided by either the NCPS or another VHA entity.
- VHA needed to develop a plan to systematically review all aspects of the NPS Program for efficiency and effectiveness and make revisions as appropriate.

VHA concurred with our recommendations and provided an implementation plan that is responsive to our recommendations.

USE AND REPROCESSING OF FLEXIBLE FIBEROPTIC ENDOSCOPES AT VA MEDICAL FACILITIES

Based on requests from the VA Secretary, the Chairmen and Ranking Members of our oversight committees, and other interested Members of Congress, we conducted a review of the reprocessing of endoscopic equipment at several specific VA medical centers (VAMCs), and assessed the extent of related problems throughout VHA.[3] We visited the facilities that had been the subject of considerable media attention: the Bruce W. Carter VAMC in Miami, FL; the Tennessee Valley Healthcare System-Alvin C. York Campus in Murfreesboro, TN; and the Charlie Norwood VA Medical Center in Augusta, GA. We reviewed applicable regulations, policies, proce-

[3] *Healthcare Inspection—Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*, June 16, 2009.

dures, guidelines, and conducted unannounced onsite visits at 42 randomly selected VHA facilities to examine pertinent endoscope reprocessing documentation.

We estimated that VA medical facilities:

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

We concluded that facilities did not comply with directives to ensure compliance with reprocessing of endoscopes, resulting in a risk of infectious disease to veterans. Endoscope reprocessing 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.

As a result of our review, we made three recommendations:

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

VHA has concurred with our recommendations and will provide an action plan for implementation within 30 days.

CONCLUSION

The OIG works diligently to provide oversight of quality and safety activities and programs in VA's large and complex health care system. While our reports indicate that VA has a program in place for quality management and patient safety activities, it is important that VHA and facility senior managers strengthen QM programs through increased compliance with existing Joint Commission standards and VHA requirements and continue to improve the NPS Program's effectiveness and oversight.

When internal controls and supervisory monitoring fail, as in the case of endoscope reprocessing, it is essential that appropriate actions are taken to standardize the processes, strengthen the monitoring, and holding staff accountable for performance failures.

Mr. Chairman, thank you again for this opportunity to appear before the Committee. We would be pleased to answer any questions that you or Members of the Committee may have.

Chairman AKAKA. Thank you very much for your testimony.

Senator Johanns if you have any opening statement, you may give it at this time.

STATEMENT OF HON. MIKE JOHANNS, U.S. SENATOR FROM NEBRASKA

Senator JOHANNS. Mr. Chairman, if I might, I would like to give just a very brief opening statement.

First of all, I do want to say I am glad to be here. I really appreciate the Chairman calling this hearing. I am especially interested to have an opportunity to visit with the witnesses. I appreciate your testimony.

I will tell you as a Member of the Committee I was very concerned about the report that was released by the VA Inspector General last week entitled, "Use and Reprocessing of the Flexible Fiberoptic Endoscopes at VA Medical Facilities." It highlighted what I would regard as widespread lapses in a standard of equipment handling. The report was initiated after several deeply troubling instance in various VA facilities, which potentially exposed veterans to deadly viruses: Hepatitis, HIV.

The veterans who had sought treatment at the locations were called back for testing and some of them discovered that they had

been infected. The VA Inspector General decided to conduct a more widespread survey and its findings were nothing to be proud of. Out of the 42 facilities inspected by the IG, less than half were following the correct procedures. I recognize that the failing rates of compliance with these two factors does not necessarily mean that the equipment was not cleaned properly. It does not necessarily mean that the staff do not know how to use the equipment.

But I think what it does mean is that something is wrong in terms of the management of VA, since these lapses occurred after the instance of contamination at other VA facilities. They occurred after the VA sent out several directives concerning these issues and after a lot of media attention.

I must admit, I do not understand how VA medical facilities were not 100 percent alert after all of this. I am sure that by now you are familiar with the IG report I am describing—probably very familiar—but I just want to quote one part. "The failure of medical facilities to comply on such a large scale with repeated alerts and directives suggest fundamental defects in organizational structure."

I could not agree more. After the report was released I did write a letter to the Secretary outlining my personal concerns. I believe we are fortunate to have representatives of non-VA institutions who have the best and most timely information about the specific challenges facing our veterans who give us their thoughts. Perhaps they have some suggestions on how to address the problem.

I am especially concerned about what I quoted; this structural issue really, really worries me. I found as a previous Cabinet Member that those are the most difficult problems to address. So, I am very anxious to hear how we fix what we are dealing with in the go-forward plan.

Thank you, Mr. Chairman.

Chairman AKAKA. Thank you very much, Senator Johanns.

Now for questions. Dr. Nolan, you made a very good point in your testimony when you said that too often we are reacting to problems instead of designing our systems to prevent them. How would you suggest we restructure our systems to reduce the chances of these kinds of errors that are occurring?

Mr. NOLAN. Well, it starts with aims. We have many, many facilities in the VA system. The question, say of the endoscope reprocessing is, are these problems limited to a few facilities or is it systemwide?

My prediction would be that even the best facilities will not be defect free. So, if this is a priority systemwide, my view is that unless we take a design approach—as opposed to each facility fixing its own problems we are never going to get to the point where all of us want to see this care for our veterans. What would that mean?

It would mean that we design systems that can be executed reliably across the board in different settings. This is not a trivial matter; it is not a matter to be left to individual facilities. In my testimony I mentioned just a small change of whether the bank card or the money comes out that can have a big effect. Well, you can imagine all of the small changes which can have an effect on this.

My recommendation would be start with quality design with a qualified group of people, including people for facilities. Make sure

we have processes that can be executed reliably then put the accountability for the quality control and quality improvement on facilities. But if we start going back to each facility we will be back in the same situation in the near future.

Chairman AKAKA. Dr. Wise, in light of some of the problems in VA's quality management as described in the IG reports, will you be changing the way in which you evaluate VA and private hospitals?

Dr. WISE. There has been. Obviously we have taken a lot of this information and brought it back to our surveyors. The way we do surveys is we have an extensive program on infection control and prevention. We tend to be driven by where the scientific evidence is, where those scarce resources should be used.

Currently people talk about the four major causes of infection—things like catheter-related, ventilator, et cetera. As we start to hear about these other types of processes we need to pull back and make decisions of how we should begin to take a look at this which is disinfection and sterilization.

Actually over the last year we have run into significant problems around the issues of steam sterilization, which is quite different. It is when instruments are then sterilized by steam and brought forward. We now know that there have been significant problems with steam sterilization. We are hearing some very concerning issues about what is going on with colonoscopies and all endoscopes. There is no question now that we are going to pull back and take a look at a much broader process, specific to what is happening with this area and that will become more of a focus now of our survey.

Chairman AKAKA. Ms. Watrous, we have heard about the problems with prostate cancer treatments in Philadelphia VA. How did the Philadelphia VA Hospital perform during your last inspection?

Ms. WATROUS. Thank you for that question. We did a CAP review there in September 2007. There were a number of issues that we identified needing improvement there including peer review, tracking patient complaint data, improving processing time for patient safety reviews called Root Cause Analyses, et cetera.

There were a total of 12 recommendations that we found there at Philadelphia, so they certainly had issues that they needed to fix.

Chairman AKAKA. Dr. Nolan, a recent news story described a problem where a doctor from the University of Pennsylvania, who was under contract with VA put radioactive implants in the wrong place in dozens of prostate cancer patients. Isn't it part of good quality management for a health care system to require proof of competency to perform a procedure before privileging a physician to do it?

Mr. NOLAN. Yes, of course, it is part of quality planning and design. I am not particularly familiar with all the details of that incident, but the question becomes, is this particular physician a special case or is the variation in that system in need of redesign?

Chairman AKAKA. Ms. Watrous, what role has the Veteran Integrated Service Network played in overseeing the quality of health care in Veterans Administration and what role do you think they should play?

Ms. WATROUS. Each of the Network offices has a dedicated staff person for quality management—a quality management officer. They are expected to do oversight of their facilities'—the facilities within that network—quality management programs. I know that is probably variable across the system. We are actually working on a task force with the VHA folks to develop an assessment tool that can be used across all of the facilities and all of the network so there is more consistency in their quality management programs.

I do think they have a role to play, an important role. Again, we focus on the systems. If the system is in place it is much more likely—an important alert or any kind of new direction coming down from headquarters—is more likely to be implemented if we have good systems in place. All similarly, if there is an adverse event—we all hope that there won't be—but when there is an adverse event, if the systems are in place it is more likely to be identified and addressed and, hopefully, a review process put together so that that particular event will not repeat itself.

Chairman AKAKA. Dr. Daigh, do you have any further comments on that?

Dr. DAIGH. Yes, sir I have a few. I would say that I've been disappointed at the VISNs ability to influence what happens with respect to the delivery of health care, the quality of health care across VISNs.

We looked at the peer review process sometime ago and there was a specific role for VISNs to try to ensure that peer review is accomplished in a meaningful way. So, if you have a hospital that has a large number of internists, they may well have a pool of physicians who can provide peer review. If you have a hospital that has some specialist for which there are not very many, you would hope that there would be a system where within the VISN one could pool a number of experts who could then provide adequate peer review.

So, from my point of view I think we see hospitals having difficulty individually. We do not see hospitals have difficulty by VISNs. So I am not confident that VISNs are appropriately affecting quality of care issues.

Chairman AKAKA. Thank you. Senator Burr.

Senator BURR. Thank you Mr. Chairman. Dr. Nolan let me ask you to look at the VA in comparison to sort of the private health care infrastructure that we have in this country. In the private health care system do they routinely not sterilize or disinfect reprocessed devices?

Mr. NOLAN. Not intentionally.

Senator BURR. And is it my understanding that a manufacturer of a reprocessed device issues with that device their recommendations about sterilization or disinfection and in addition to that there is a back up in the application approval process at FDA there is also some requirements that FDA issues as to the use of that equipment?

Mr. NOLAN. Yes.

Senator BURR. So is it safe for everybody to assume that a health care professional hired to work with this equipment would either know the manufacturer's recommendation for sterilization/disinfec-

tion or the FDA's recommendation that probably dovetails with the manufacturers' for disinfection or sterilization?

Mr. NOLAN. Well, let's assume what they may not have is and it may not be working in a process which reliably allows them to carry out their intention.

Senator BURR. So why would an institution not require a health care professional to follow the manufacturer's recommended sterilization and/or the FDA's recommendation? What benefit would there be?

Mr. NOLAN. I cannot see a benefit of requiring and not to follow it. The question is are they in systems which allow them to follow it reliably? They may be able to follow it 90, 95 percent of the time.

Senator BURR. Is there a significant cost to the sterilization/disinfection?

Mr. NOLAN. I am not an expert in disinfections.

Senator BURR. Dr. Wise can you help me at all?

Dr. WISE. The types of devices you are talking about are quite complicated. Actually some of these colonoscopies will be 20, 25 different steps and the problem is if there are so many changes going on in the actual devices that a device that you are using today may end up having changes that you are not using——

Senator BURR. And in fact, the safety alerts that were put out by the VA actually were put out because of changes in certain devices if I understand the chronology of those alerts.

Dr. WISE. That I am not sure, but I do know that one of the things that we are talking about—systems—is that when you are dealing with 20–25 steps, you probably need to have something on the wall that says, "here you do this, this, this." It is pretty much like a checklist. If you are trying to commit those steps to memory, the chance that you are going to miss one or after a while start doing the same thing consistently, becomes much higher.

So, that's really one of the changes that needs to be made—when you walk into one of these types of departments you would see that.

Senator BURR. Well, I will turn to the AIG. I take for granted that there was not a step-by-step process clearly visible for individuals to follow.

Dr. DAIGH. The directive from VHA was that there would be on the wall, basically where these reprocessing occurs, the instructions for the different kinds of scopes that that facility had.

Senator BURR. And you found that——

Dr. DAIGH. And we found that about 20 percent of the time that instruction was not there. So you would think that there was noncompliance about 20 percent of the time for that feature. The second feature was that we would expect that the training records of the individuals who actually cleaned the scopes would reflect that they had knowledge and expertise to clean the different variety of scopes that the facility had and that was not present a significant percent of the time. So, only 43 percent of the facilities that we visited met both criteria.

Senator BURR. According to your report in 1998, a VA panel recommended the creation of the National Center for Patient Safety Office and a director was hired shortly thereafter reporting directly to the Under Secretary for Health, VA. Your report further states

that since 2007 the National Center for Patient Safety director has been reporting to the Associate Deputy Under Secretary for Health and Quality and Safety.

You get any understanding in your investigation as to why the change?

Dr. DAIGH. We did not explore that administrative change. I have no comment on that.

Senator BURR. OK. I will take it up with the VA, but clearly quality and safety seems to have diminished from a standpoint of importance given that your recommendation and quick action in 1998 put it directly under the Under Secretary of Health and now we know how—when you sort of knock down the food chain—all of a sudden the focus begins to change.

In your opinion would an organization committed to patient safety lower it's Safety Office status?

Dr. DAIGH. I have not discussed with the Under Secretary of Health why they made or did not make that change, nor have I discussed with the principals who you are talking about, who either manage patient safety or who the Patient Safety Director reports to. I take all of those individuals to be serious individuals committed to patient safety; and how VHA determines the structure within the organization, I have not been asked to look at and have not looked at that.

Senator BURR. I appreciate that. Mr. Chairman, I will have to have a second round with this panel. Let me just say to Dr. Cross and his colleagues, I deeply respect the work that they do. Now is when I separate the high regard that I hold them in and the functions of the institution, of the agency. This is a very, very serious issue. If we were here with one veteran who had been infected because we had not sterilized or disinfected correctly, I would think that is important. If it were one, we would be here looking at the procedure, and I am not here to highlight the warts at VA. I am here after 11 alerts to say enough's enough.

I thank the Chair.

Chairman AKAKA. Thank you very much, Senator Burr.

Senator Tester.

Senator TESTER. Thank you, Mr. Chairman. Dr. Daigh, to just kind of follow up on some things that you said to some previous questions. You said that 20 percent of the hospitals had no instructions on how to use the equipment, 80 percent did; and then you said, if I heard you right, 43 percent of the hospitals only had instructions and what I interpret as kind of a job logbook. Is that what you meant?

Dr. DAIGH. When we were asked to look at the endoscopic issue at a national level, having looked at three sites in the report it became clear to me that the reprocessing of endoscopes was a high risk area. So we then had to come up with a way to try and address it as a national problem. I do not have individuals on my team with the knowledge to actually reprocess an endoscope. So we read the directives very carefully as to what VHA asks the facilities to do and then we checked to see whether they had done two of those things.

Senator TESTER. Procedures.

Dr. DAIGH. That is correct. So what I am saying is that essentially 80 percent of the time they had the directions on what to do and a much lower percent of the time they had the training records to demonstrate that the people, or that one person who cleans the scopes was adequately trained.

Senator TESTER. OK. Thanks. Earlier you talked about the fact that the VISNs did not have the ability to influence individual hospital quality of care, from your perspective.

Dr. DAIGH. From my perspective, what I see is difficulty in individual hospitals. The VISNs, in my view, have not stepped in to ensure consistent high quality of care across their facilities.

Senator TESTER. Is there any recommendation that you would have so that those individual hospitals could be influenced in a way to follow the procedures?

Dr. DAIGH. I believe that it would be appropriate to look at the organization within hospitals which are now organized very differently—VISNs which are organized very differently—to look at the organizational structure and determine if that is best for the current needs for VHA. I think at the same time one needs to look at the data that you need to capture to manage and look at the flow of data through the organization.

Senator TESTER. Were you able to capture, in fact, whether the VHA directives actually got to the hospitals? And if you want to defer that you can.

Dr. DAIGH. I would have to get back to you on that, but I do not believe there is any doubt that they got there. I can get back to you on that. I will check and if I am in error I will say, but I do not believe there was any doubt about that.

Senator TESTER. Dr. Wise, can you briefly explain how the Joint Commission conducts the accreditation surveys?

Dr. WISE. There are several parts. One is that we are constantly collecting information about organizations throughout the cycle. We talked about patient complaints and other information that allow us to understand what the potential strengths and weaknesses of an organization are. When you go into a hospital it is a big place. There are a lot of places to look at in a reasonably short period of time. So that information allows us to target in on patients who in some way are affected by it.

Senator TESTER. So your standard is zero tolerance?

Dr. WISE. For an organization to remain accredited it must adhere to all standards a hundred percent of the time.

Senator TESTER. OK. And is that the same as with the private sector?

Dr. WISE. Yes. They are exactly the same standards.

Senator TESTER. Exactly the same standards. Have you done any evaluations in the private sector?

Dr. WISE. We look at about over 4,000 hospitals.

Senator TESTER. Do you see that the VA is—and by the way I agree with what Senator Burr said, one case is bad—but I want to know where the VA ranks in relationship to the private sector as far as occurrences of screw ups in this particular area.

Dr. WISE. That question was actually asked, to see if we could pull the data. We have lots and lots of data. That particular analysis has not been completed; so it is something that we have the

data for, but not the effort required to do it. So, we do not know. But we do know the kinds of infrastructure that exist within the VA that does not exist within other parts of the private sector, which I had talked about in my testimony, which in fact, gives it a leg up in being able to do a whole lot better than many parts of the private sector.

Senator TESTER. OK, I am out of time. I will pass it on. Thank you, Mr. Chairman, and I thank the panelists.

Chairman AKAKA. Thank you very much, Senator Tester. Now we can move on to questions from Senator Isakson.

Senator ISAKSON. Thank you, Mr. Chairman. Following up on that question, so there is no relevant data on private sector occurrence of these infections in terms of if it happens at all or how frequent it happens?

Dr. WISE. We do not have that data at our fingertips through the accreditation process, no.

Senator ISAKSON. Do you have any idea, Dr. Nolan?

Mr. NOLAN. I do not have the data, no.

Senator ISAKSON. Ms. Watrous, in terms of the VA in previous history, has this type of occurrence happened before?

Ms. WATROUS. I am sorry, I do not have data for that.

Dr. DAIGH. What do you mean exactly, sir? Do you mean——

Senator ISAKSON. Infection from a procedure—either colonoscopy or endoscopy.

Dr. DAIGH. There have been a number of instances where instruments have not been cleaned or sterilized correctly, leading to issues with patients. So, in the prostate biopsy issue, which was cited earlier, and certainly with respect to the insertion of cranial implants some years ago, there were some issues around that. So I am aware of isolated cases where this has occurred, yes, sir.

Senator ISAKSON. Ms. Watrous, seeing these occurrences at the three VA hospitals, you have in place a procedure called CAP—Combined Assessment Program?

Ms. WATROUS. Yes.

Senator ISAKSON. And those are every 3 years in each facility. Is that correct?

Ms. WATROUS. Yes.

Senator ISAKSON. Are you now making a specific inspection of the disinfecting process of this equipment as a part of that?

Ms. WATROUS. I believe we will be adding that to our cadre of topics, yes.

Senator ISAKSON. Ms. Coates, I know you are in Georgia. It is good to have a hometown person here. Are you in Clermont or are you in the regional office in Atlanta?

Ms. COATES. I am at the regional office on Clermont, yes.

Senator ISAKSON. Is Augusta VA, the Charlie Norwood Hospital, is that in your region?

Ms. COATES. Yes, sir, it is.

Senator ISAKSON. Since the incident or instances that took place there, has there been a change in procedures or have you implemented a program to prevent the possibility of infection being transferred with this type of equipment?

Ms. COATES. My office has done that. I am working with Ms. Watrous to develop and design that for the CAP reviews.

Senator ISAKSON. Would your office be the appropriate office to put in new procedures or direct new procedures?

Ms. COATES. We would identify issues during our CAP reviews and make recommendations to VHA to make improvements.

Senator ISAKSON. So you are in the process of determining, in terms of the CAP inspections, what procedures you are going to create to ensure redundant inspections of this type of disinfectant?

Ms. COATES. Yes.

Senator ISAKSON. For all VA facilities?

Ms. COATES. Yes.

Senator ISAKSON. You have a complaint process, is that correct?

Dr. DAIGH. Yes, sir, we do. We have a hotline process that is very active.

Senator ISAKSON. You mean you get a lot of calls?

Dr. DAIGH. Yes, sir.

Senator ISAKSON. Do you have the personnel necessary to follow up on those calls?

Dr. DAIGH. I am not sure. We have the capability and publish about 50 hotline reports a year. We get several thousand calls either by email or telephone a year. Many of those, we refer back to VHA's management one level above the level of the complaint. The most serious ones, we address in writing and publish on our Web site.

Senator ISAKSON. To your knowledge, were all of the instances of infection in these three facilities self-reported by the facilities or did they come to you by virtue of the hotline?

Dr. DAIGH. In this case, all three were self-reported through VHA systems, not primarily through us.

Senator ISAKSON. Well, I think that is an important quality fact. We do not want any mistakes to take place, but we do want to have a culture that when a mistake does take place, we take immediate action from a standpoint of the specific case, and also—it would seem like in this CAP program—that I would be working as fast as I could to have procedures in place so every future inspection would address the disinfecting program on this type of equipment in the hospital.

Dr. DAIGH. Could I comment, sir?

Senator ISAKSON. Yes, you can.

Dr. DAIGH. We have been asked, and will in 90 days, do a follow-up inspection on this topic. And it has been our general observation that when things are really on the front burner and everybody is aware of it that VHA then will pay attention to it, and I think it is often important to follow up—down the road when the light has moved off that a little bit—to look closely at not only the reprocessing of endoscopes but reprocessing of reusable medical equipment. So, we will look at it and take a serious long-term look at this.

Senator ISAKSON. Thank you very much, Mr. Chairman.

And, Mr. Chairman, if I can, I want to apologize to Rebecca Wiley on the second panel, that I may not be back. I do not want her to consider that local hometown boy not coming back, but I am on the Health Care Committee markup and I have to get back there this afternoon. Thank you, Mr. Chairman.

Chairman AKAKA. Thank you very much for being here, Senator Isakson.

Now we will hear from Senator Johanns.

Senator JOHANNS. Thank you very much, Mr. Chairman.

Let me, if I could, start out with the Inspector General here. The first thing I would like to say is how much I appreciate your work.

As you know, I was the Secretary of Agriculture, where I worked with an Inspector General, and I always found that her work was very, very professional. I will tell you that some of the gray hair I have came from the various reports, but I do appreciate the work.

I quoted from your report here where it said the failure of medical facilities to comply on such a large scale with repeated alerts and directives suggests defects in organizational structure. What drew my attention to that was, unfortunately, there can be cases where an employee is not paying attention for whatever reason. Maybe they have had a bad day or a bad night or whatever, and something goes wrong, and that is deeply as tragic. But it does not imply what you are implying here.

Talk to me a little bit about that conclusion; why you think that in fact is the case; and then I would like you to just give me two or three or four, whatever, bullets on how you fix that. If it is really a structural problem here, what is your recommendation in terms of how to deal with that?

Dr. DAIGH. So, in response to your question, I do believe it is a structural problem. There are, I believe, at least several instances we have been dealing with where a directive goes out from VACO to the field on things that I think are important wherein compliance is not what one would expect. And so, I do find that to be an issue.

I think that the solution to the problem—and let me also say that the current structure of VA, I think, has produced a wonderful health care system that produces very high quality care. It also has produced a medical record, and I think an excellent culture of safety. I believe the ladies and gentleman behind me have done a wonderful job with that.

I think the problem, though, now is to stamp out variation in delivery, so that every time you deliver care it is excellent care.

And there are parts of health care that require intellect and thought and planning, and I think those need to be very carefully preserved. But there are parts of health care that are a process, almost an industrial process. You order an x-ray of the chest that needs to be done correctly, timely, and reported correctly.

And I think that it is time to take a look at whether the current variety of organization within hospitals—some hospitals have a Department of Surgery, a Department of Anesthesia; some hospitals have a Surgical Care Line. So, I think the people need to sit down and think about what organization would best allow us to drive out the variation, and I think that is the troubling part.

You have wonderful population metrics and variation that troubles us. The variation can never be driven out, but I think there are some significant steps to do that.

I also think the talent exists within VHA to do that. I think that the people behind me understand that, recognize that. I just would encourage that we move out on that topic.

Senator JOHANNS. I think the report is very thorough. We can read that. We can understand, man, something really went wrong here.

If there is anything I would ask as your office is working to try to assist a structural change here that does what you are suggesting—and I agree these things have to be done routinely and well each time—is to let us know if this is not being overcome, because if it is not being overcome then you do have a serious problem. You have got a serious management issue. You have got a serious issue in terms of how management is driving this message down to the actual care level, and that is what we need to know.

Like I said, everybody understands a variation. We do not want to see it ever, but we can understand it. But if what is happening here is variations are occurring because the message is not getting down to the care level in terms of what to do, how to do it, and when to do it, then that is a very significant issue because this problem will not go away. It will just continue to repeat itself over and over.

Then the final thing I wanted to say, Mr. Chairman, is this: what worries me about the structural issue in your finding here is what else is happening. You know what I am saying?

If there is a structural issue in the organization, I doubt that you just happen to stumble onto the problem that it was causing. I worry that there are other issues out there that you have not been asked to look at or you have not looked at or audited or whatever, that are going to be the subject of another hearing and another hearing. So I am hoping you will somehow keep us apprised of what we are dealing with and whether you are seeing the change that needs to occur to solve the problem.

Senator BURR [presiding]. Thank you, Senator Johanns.

I am going to recognize myself. You have not voted, have you?

Senator JOHANNS. I think we have. Have we been called to a vote?

Senator BURR. We have been called to a vote. You need to leave.

Senator JOHANNS. I need to get out of here and vote.

[Laughter.]

Senator BURR. I will try to fill in until the troops, the cavalry come back.

To those of you from the Inspector General's Office, in your report, you detailed how in the wake of the January 2006 event with reprocessing of prostate biopsy devices VHA had conducted a national review to assess compliance with reprocessing standards. You mentioned that all VHA facilities conducted self-assessments, and the aggregated results were published in 2007. Tell us what was found to be the main conclusions from those assessments.

Dr. DAIGH. I did not review the conclusion. I do not know the answer to that.

Senator BURR. In the course of the investigation, did you find that the VA had used the results in a constructive manner?

Dr. DAIGH. I think that the litany of notification to facilities that this is a high-risk area and the fact that there had been self-reporting of lack of following the directions at quite a number of facilities led us to the conclusion that we needed to take a hard look at what was going out universally. So we then had the unannounced in-

spection to try to determine whether compliance was systemwide or not.

Senator BURR. You know what I am asking here. It is sort of impossible to assess what and if VA took a constructive step in the right direction if in fact the IG did not even look at what the reviews were that came back from this internal process.

I am trying to give the VA a fair opportunity to detect what was wrong and begin to try to fix it. Whether that was a structural change, I think is in question. But is there any reason for me to believe that from the information they gleaned in the 2007 self-assessment, that they learned something and acted on it?

Dr. DAIGH. I would say that the fact that there were the incidents we described in the report—that would be Miami, Murfreesboro, and Augusta—the repeated notifications of failure to properly reprocess ENT scopes at several other sites, the 16 or so sites who indicated that they were not following all of the directions with respect to reprocessing led us to the conclusion that whatever had happened before was not effective at the current time. And so, I think that the facilities did not recognize this to be the high-risk area that it was or, as we go through the recent events, there should have been a facility or two that had a problem, but there were quite a number of facilities that had reprocessing problems.

Senator BURR. So, in other words, the medical alerts that went out were ignored or devalued from a standpoint of importance?

Dr. DAIGH. I think that it was not appreciated that multiple alerts about the same problem or series of problems—not exactly the same issue—set up a situation where reprocessing of these instruments was a high-risk area that needed more than just casual oversight because of the risk involved in them. Otherwise, there would not be so many recurring alerts about these topics.

Senator BURR. Last week, you released a report evaluating VHA's National Patient Safety Program. I am sort of curious. When conducting analysis with a national safety program, you made no mention of the multiple alerts that were ignored with respect to endoscopy. Can you share with me why?

Dr. DAIGH. The issue that we were looking at there was whether we thought the effectiveness of that organization could be improved or not, and we did not specifically look at the endoscopy alerts at the time that we did that report.

I should say that about 2 years ago we conducted an unannounced review of VHA to see whether or not the facilities had complied with the National Patient Safety Alert which dealt with the recall of cadaver material to be used in surgery. So an alert went out. We then, after a period of time that we thought appropriate for VHA to respond, had a similar unannounced inspection. We published that report, and VHA did extraordinarily well. We thought they had complied very well with that patient safety alert.

So, from my point of view, I thought the alerts were, in fact, being addressed reasonably and that people were responding to them. So these unannounced inspection results are a surprise to me, that we found the answer that we did.

Senator BURR. I guess I am having a little disconnect because in the previous question you suggested they were ignored. Yet, in this

process, the alerts were not important to come to a determination about. Is that what I understand?

Dr. DAIGH. I am suggesting that. Yes.

Senator BURR. Have there been any personnel actions that have been taken throughout VHA in response to any of these mistakes, to your knowledge?

Dr. DAIGH. I am aware of a variety of administrative board actions. I am unaware of the outcome of that human resources effort. So, I think the second panel could much better speak to what actions have been taken or not been taken, but I am aware that there have been efforts along that pathway.

Senator BURR. Now the VA has maintained that it is very transparent when it comes to its disclosure of adverse events, even more so than the private sector. But in your June 18 report, you detailed that during your 2007 VA facility reviews, "We assessed adverse event disclosure and reported weaknesses. We reported that only 54 percent—21 of 39 facilities—had completed full disclosure."

Given these facts, what is the IG's opinion of the VA's level of transparency both with respect to this specific situation as well as the overall VA health care system?

Dr. DAIGH. Let me say that the disclosure policy the VA has, I think, leads the country in terms of the requirement to disclose to patients when events occur that are not life-threatening, when events occur that are life-threatening, and, as a third category, when events occur that require the disclosure to a large number of people.

And I believe that when you go back and look at the disclosures that have been made—and in this case VHA identified the problem and then disclosed to the affected patients that there was a risk—I think VHA has been very forthright in their disclosure, both with respect to the prostate issue and with respect to this current problem.

Senator BURR. Dr. Nolan, relative to proper sterilization or disinfection of reusable devices, how many lives need to be at risk before this is a medical problem?

Mr. NOLAN. Well, any one death or injury is one too many. In the Quality Chasm report, Joseph Juran pointed that out.

Senator BURR. How about from a standpoint of infection? How many Hepatitis B or HIV before this is a medical problem?

Mr. NOLAN. The goal is zero, clearly.

Senator BURR. That is sort of the way I look at it.

In conducting the random site visits during the course of your investigation, you visited 42 hospitals specifically to evaluate their procedures, if I am correct. You excluded Miami, Murfreesboro, and Augusta from the review because you said separate detailed onsite inspections were taking place there. I take for granted you meant by the IG's office?

Dr. DAIGH. Yes. Victoria Coates went to all three of those sites.

Senator BURR. Could I ask you or her to give more details about what the IG is doing to ensure the safety of our veterans at those facilities?

Dr. DAIGH. I think that what we have done is identify clearly to the management of those facilities the defects that we found, and

have strongly encouraged that they comply with the standards that are written which should be followed.

We will also have a follow-up inspection, within 90 days, of VHA's facilities to assess the system's response to this directive.

We will also incorporate into our CAP process a look at aspects of reusable medical supplies so that this does not go away in 2 or 3 months; that we continue to track this until we are comfortable that everyone has the message and that that is being done well.

I do not have the power to tell people exactly how to change their process or to make personnel changes. We point out to management what we find as problems and ask management to respond.

Senator BURR. Mr. Chairman, I am nearly done, but I just want to follow this up.

Chairman AKAKA [presiding]. Sure.

Senator BURR. At what point—and I am talking about these three facilities and the continuing inspections—at what point would you determine it is appropriate for the IG to release something versus for this to be internal between the IG and the VA in hopes that this might be remediated; or are the results of your initial findings made public?

Dr. DAIGH. I would consider this a hotline in our records. So, from my point of view, Congress and the Secretary asked us to look at this issue, and so on my books this is a hotline.

Every hotline that I accept I either publish on our Web site—and I would say that that is fully 80 percent of all the hotlines we accept—and then there are a few, say maybe 10 percent or 20 percent, where the allegations are completely unsubstantiated, and to publish a series of allegations that are serious and unsubstantiated I think is not in the public interest.

Senator BURR. I would agree.

Dr. DAIGH. And I close those administratively.

We have occasionally been asked by Members of Congress about those cases, those hotlines, and then we respond appropriately with respect to that. But, if my office accepts a report, we put it on the Web.

Senator BURR. I guess my direct question is having noted those deficiencies in those three facilities, at what point would it trigger you to take a more aggressive stand relative to VA's remediation of the deficiencies?

Dr. DAIGH. I think that if—yes, I think——

Senator BURR. Does it happen voluntarily on your part or does it require us to ask you?

Dr. DAIGH. No, no, no. I think what you are asking is at what point would I call the Under Secretary for Health and say, we need to do something very quickly and very seriously systemwide to address the issue.

Let me say that if what we had done in our inspection was to actually pull scopes off the wall and inspect them for whether or not they were properly cleaned and in proper condition to be used, and if I had found in that circumstance that the scopes were not appropriate, I would have called and said that patients are clearly at risk.

The review I did looked at administrative compliance. Did you have the SOP there? Did your training records reflect that folks

were trained? That is close to saying that things are not going well, but that is not the same as saying that patients are actually at risk.

There are instances where I become aware through the hotline process that patients are at risk. I routinely pick up the phone and call Dr. Cross in either his current or his prior role, and the response has always been immediately trying to take steps to make sure that that risk is immediately mitigated, and that we can then work to figure out what the facts are and how to move forward.

So, I would say over the last 5 or 6 years I have had this job I have had that discussion a couple of times a year at least with the Under Secretary, the Deputy Under Secretary, or the Chief of Staff of VHA, and it has always been a very professional: What do we need to do to try to make sure that veterans are not harmed?

Senator BURR. I thank you.

I thank the Chair.

Chairman AKAKA. Thank you very much, Senator Burr.

I want to thank this first panel very much for your testimony. It is good to hear from the Institute, the Commission and also the IG's Office on this.

We, without question, want to maintain the quality or raise the quality of what we are doing for our veterans, and the bottom line is our veterans' well being. We must take greater measures to ensure these problems do not recur.

So, I want to thank you all for what you are doing and look forward to working with you. Thank you very much.

Let me introduce the second panel. We will hear from Dr. Gerald Cross who is Acting Under Secretary of Health. He is accompanied by Dr. William Duncan, Associate Deputy Under Secretary for Health, for Quality and Safety.

Also, we have medical center directors from Murfreesboro, Tennessee, Augusta, Georgia, and Miami, Florida, to respond to questions. VA originally identified problems with the cleaning of endoscopes at these facilities.

Dr. Cross, thank you very much for being here. Your full testimony will appear in the record and we look forward to your testimony. Will you please begin, Dr. Cross?

STATEMENT OF GERALD M. CROSS, MD, FAAFP, ACTING UNDER SECRETARY FOR HEALTH, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY WILLIAM E. DUNCAN, MD, PhD, MACP, ASSOCIATE DEPUTY UNDER SECRETARY FOR HEALTH FOR QUALITY AND SAFETY; JUAN A. MORALES, RN, MSN, DIRECTOR, VA TENNESSEE VALLEY HEALTHCARE SYSTEM; REBECCA J. WILEY, DIRECTOR, CHARLIE NORWOOD VA MEDICAL CENTER; AND MARY D. BERROCAL, MBA, DIRECTOR, MIAMI VA HEALTH CARE SYSTEM

Dr. CROSS. Mr. Chairman, my comments were written in regard to the original hearing topic which was quality management. I am now including comments on quality management, but also endoscopy and brachytherapy.

Nothing that I am going to say reflects any defensiveness or satisfaction, and, if you hear any hint of pride about our overall pro-

grams, you will hear nothing but humility and determination in regard to any errors in patient care. My focus, my team's focus, our foremost and always focus is the patient's well-being.

VA health care is dedicated to caring for our most honored citizens. Today's challenge for VA health care is consistency—consistency at all sites of care. In other words, while overall quality is above average, a few of our 1,400 facilities have, on occasion, performed poorly on some aspects of care. I am referring to the VA sites that self-reported systemic problems with their endoscopy reprocessing or brachytherapy treatment.

In the vast majority of cases, VA's experiences and achievements have had an extremely positive impact on national health care and VA will continue to play a key leadership role in the success of our Nation's health care future.

There are several reasons for it. First, VA trains a large number of our Nation's health care workers—about 100,000 health care workers per year. Second, our research has provided significant proportion of our Nation's medical research advances. In the past 7 years, VA authors and co-authors have published more than 46,000 articles, contributing significantly to the world's library of medical knowledge; and that is just the beginning.

VA also is the innovator of several of the tools that our Nation will need to support health care delivery improvements. For example, VA has developed creative techniques to dramatically lower the cost of purchasing and distributing medications. Our performance management system also holds our senior clinical and administrative leaders accountable for achieving evidence-based quality targets and has led to dramatic improvement across our health care system.

At VA, we have seen time and again that quality and innovation go together. Perhaps one of the most famous innovations is our world-class electronic health record. The use of the electronic health records for all of our patients led to soaring improvements in quality of care over the last decade.

VA innovations enable us to provide superior care to veterans we treat. For example, we developed a new system of health care such as our National Polytrauma System of Care, telemedicine and teleradiology. We are looking beyond traditional hospitals to a new concept: health care centers that will meet the vast majority of patient needs without the expense of a large inpatient facility. Our NSQIP program, that stands for National Surgical Quality Improvement Program, which monitors surgical quality is so successful that it has been adopted by others including the American College of Surgeons.

Mr. Chairman, I provided you and the Members of the Committee a few slides which demonstrate the current state of VA health care quality, which I believe is unmatched in the Nation today. These slides permit a quality base comparison between VA results and others. The slides demonstrate VA's exceptional record with regard to preventive health care including screening for cholesterol, cancer and diabetes.

Patients report high levels of satisfaction with the care they receive, whether inpatient or outpatient facilities, and the medical literature documents these accomplishments. For example, after ac-

counting for the burden of chronic illness, risk-adjusted mortality for older VA patients was almost 30 percent lower than patients enrolled in Medicare Advantage. This was published by Dr. Alfredo Selim's research in the *Journal of Medical Care* in April 2006.

If you have any specific questions about these slides, I look forward to discussing them after my oral statement.

As the Nation moves to its health care future, ethics policies, such as those developed at VA, should serve as a foundation for organizational responsibility. We have a strong policy of disclosure when we do something wrong. We disclose our errors publicly because we believe it promotes the trust of our patients. We believe it is the right thing to do. It may be painful, and I can assure it is in the short term, but it is the best thing for everyone, particularly for our patients, in the long term.

This policy of disclosure has been put to the test several times. Recently, we discovered that several of our facilities were not following manufacturer instructions for the reprocessing of endoscopes. Last year, we discovered problems with the dosing and follow-up for brachytherapy patients.

When we found these problems and determined that there was a potential risk to patients, we took action. We informed Members of Congress. We put information on the internet. We met with veterans service organizations. We contacted patients to come in for special follow-up with respect to endoscopy. And, with respect to endoscopy, we engaged the Inspector General's Office.

What is more, we implemented a corrective plan that goes beyond endoscopy to address more broadly how we use all reusable equipment and how it is handled. The plan focuses on training. It focuses on standardization, and it focuses on oversight. Further, we have devoted additional funding just as of this week, about $26 million, to upgrade reprocessing equipment. We have been working on that plan for some time.

In regards to brachytherapy, reviews of the program at the Philadelphia VAMC, my external experts gave our program high marks. Yet, when we noted problems, I directed a review of all sites—not just Philadelphia—but all sites providing this therapy. We hired a highly regarded radiation oncologist to review our practices, and all of this followed an external assessment in August 2007 by the American College of Radiation Oncology in which the brachytherapy program reviewer gave the quality assurance program high marks and described one portion as the best I have seen on any site visit.

In any case of medical error, our foremost priority is to work with individual patients to acknowledge errors when they occur and to do all that we can for each patient. We are committed to holding our staff accountable for their performance. VHA must ensure compliance with SOPs and encourage those who raise concerns about the quality of care. We need to encourage them and reward them.

Our patient safety program depends on both external oversight and internal self-reports. When our staff members feel that they can bring problems forward, we are more likely to hear about those problems. That is why we foster a culture of self-reporting.

Conclusion: In conclusion, Mr. Chairman, quality and innovation are important to our Nation's health care future. VA will continue to lead the Nation in these areas. But when problems occur, ethics, disclosure, and accountability also are vital to our veterans' trust and our veterans' care.

Thank you, sir.

[The prepared statement of Dr. Cross follows:]

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

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 respon-

sibility 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 re-

[1] There are five levels of Complexity: 1a, 1b, 1c, 2 and 3, in descending order of complexity. VA determines facility complexity based upon a formula that considers the patient population, the patient risk, the level of intensive care unit and complex clinical programs, as well as education and research indices.

lated 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.[3]

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.

Chairman AKAKA. Thank you very much, Dr. Cross, for your testimony.

Dr. Cross, this morning, we received a copy of the contract for radiation oncology services at the Philadelphia VA. It looks like VA paid $133,000 for about 5 months of radiation oncology services. Yet, nationally, such physicians make an average of $165,000 for an entire year's work. My question to you is: Did VA get their money's worth here?

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[2] Seoane-Vazquez E. et al. (2007). Endoscopy-related infections and toxic reactions: an international comparison. Endoscopy 39(8): 742–78.

[3] See ibid.

[4] See Seoane-Vazquez E., Rodriguez-Monguio R. (2008). Endoscopy-related infection: relic of the past?. Curr Opin Infect Dis; 21(4): 362–6.

[5] See ibid.

[6] See nn 2, 4, ibid; also Schembre D.B. (2000) Infectious Complications Associated with Gastrointestinal Endoscopy. Gastrointestinal Endoscopy Clinics of North America; 10(2) 215–231.

Dr. CROSS. Sir, I do not know what the amount was we spent on that contract. The comparison that you give in regard to others, I think, is that they were working, I think, only part-time on some of these programs.

I do not think we got our money's worth, and I would like to reflect what some external reviewers reported to us. I have their report, sir, right here that you can request if you choose to.

They were reviewed. Those individuals you are talking about were reviewed by the American College of Radiation Oncology. I will read you just a couple of their comments. This is an external reviewer looking at the quality of the program at the exactly relevant time that you are talking about.

And they said, this process utilized to evaluate your practice consisted of in-depth appraisals of your practice, your facility, your equipment, policies, procedures, staff and clinical treatment methods, and they describe their review as extensive. They reported that the VA radiation oncology program—this is their statement, not mine—"This VA radiation oncology department is under the control of the University of Pennsylvania."

They went on to say in their report that there is a very strong quality assurance program for the doctors and technical staff, both intra and interdepartmental. There is a printed summary of a chart-check tumor board and peer review which appears fully accurate and, according to the onsite physician reviewer, it is "the best I have seen on any site visit."

He says, continuing medical education was available to the physicians and staff, and it appeared that they met or exceeded the State licensure requirements.

Here is the summary conclusion from this report: "In summary, your PVAMC practice, as noted above, is well organized; an operated radiation oncology practice that not only meets but in many aspects exceeds the ACRO standards for practice accreditation. The ACRO is pleased to inform you that the PVAMC has been awarded full 3-year accreditation."

Chairman AKAKA. Thank you, Dr. Cross, for the answer you gave me before you read that letter.

Dr. Cross, we have heard many proclamations about how VA care is the best anywhere. How can VA's care be the best anywhere in light of the problems we heard about today?

Dr. CROSS. Sir, I appreciate your asking that question.

Our best care anywhere I think is true, and it is in regard to the overall organization.

The problem I am facing, the problem I am working with and that I am challenged to change is consistency. It is not enough that we are better. I take no glory in that. I take no pride in that. That is, as long as any patient is being hurt anywhere because there is a deficiency or variation, I cannot be satisfied.

So the issue here is consistency throughout this large system. I have 1,400 plus sites of care. I have to make sure that every single one of them is performing up to standard on these very complicated procedures, and these are complicated procedures with many, many steps.

We wrote that there are directions from the manufacturer. Well, it turns out that every single scope has a direction. It turns out

that every different manufacturer has directions. It turns out that different scopes have different directions. Then they change them periodically as they upgrade their thinking about it. Furthermore, other organizations put out guidance, and they all vary one from the other.

We have said we cannot deal with that. We are a large organization. We have to have consistency. You must go by the current directions from the manufacturer. That is the only standard that we will follow. We will ignore the other ones because we have to focus on that.

And these slides that we have given you, sir, reflect the broad overview of VA quality; and even our patients fare better in terms of mortality within our system than in other systems. But that is not enough for me. That is not enough for you, I believe, sir. While there is any problem left, we have to deal with that variation.

Chairman AKAKA. Thank you very much.

Let me call on Senator Burr for his questions.

Senator BURR. Thank you, Mr. Chairman.

Dr. Cross, welcome. And to all that are here, I meant what I said earlier. I hold you in high esteem for the jobs that you do.

Oversight, I hope you understand, is a very important role of this Committee, and I think it is impossible to fully understand the depth of a problem until you have had an opportunity to air it. Our role is to take bits and pieces that are out there and try to construct a picture out of it. It is not pleasant. I would rather not spend the time on it, but I think we all agree that the patient population that is served demands that we do this.

Let me ask you, Dr. Cross, how many hospitals in the system today are compliant with the VA plan for sterilization from infection of reprocessing equipment?

Dr. CROSS. Sir, like you, I was very disappointed in the report from the IG on their documentation issue—looking at the documentation of the SOPs and the training documents had to be in place. In fact, I mandated that each of the VISN directors report to me within days that every single one of those SOPs were in place and that every single one of those training documents were in place, and that if I walked into one of those places this morning I could be absolutely assured that I would find them. They certified that to me in writing about 2 weeks ago.

Senator BURR. You read an independent review of the Pennsylvania facility on the brachy treatment. If an independent facility went and assessed all of the facilities relative to reprocessing devices, would the report be as glowing today?

Dr. CROSS. You have hit right on the issue. None of those external agencies found the problem. None of the oversight organizations, of which we have many, found any of these issues with endoscopy reprocessing or with the brachytherapy program. We reported those. We found them internally.

That is why it is so important—this is the critical point—that we have external oversight and that we have internal reporting. My staff have to believe that they should do the right thing. If they see something wrong, they have got to come report it.

And I have got to be very careful about discouraging that by saying that I am going to shoot the messenger. I do not want to do that. If anything, I would like to reward the messenger.

But then I have to balance that with the external reporting, like with the IG, that we have a very collaborative relationship with. After they told me that they made the correction, the IG sent people out to look and make sure that it was done. If they were not, then that becomes for me an accountability issue.

And we are now taking disciplinary action at multiple sites across the country, reluctantly, not so much for the people who reported the problems—not at all—but for the people that I held accountable to institute the corrections. And so, those issues largely related to supervisors. They include demotions. They include, in some cases, changes of jobs, changes of organization, and I think one person resigned.

Senator BURR. In the National Center for Patient Safety review of the situation dated 17 April and included in the IG's report, the VA stated the following: "The analog for endoscopy reliability would be commercial or military aviation maintenance."

I am going to be real direct on this one. Keeping in mind that that is your statement and not mine, if a surprise inspection was done on an airline and it was found that the airline was compliant with both procedures and documentation 43 percent of the time, would you fly on it or would you have your family fly on it?

Dr. CROSS. Well, fortunately, documentation and the actual care of the patient are not necessarily the same thing, but I feel no satisfaction in that. I was distraught by that report. I found it unacceptable, and that is why I mandated that my VISN directors immediately confirm to me that, in fact, the paperwork that the reviewers were looking for was in place.

I agree with you. I would have been very concerned.

Senator BURR. I requested and received a list of dates when endoscopy procedures were performed for those veterans who tested positive. I am not an epidemiologist, I admit that, but I would gather that if multiple veterans who tested positive had this procedure performed at the same hospital on the same day, then there is a fairly good chance that the VA caused at least one of those infections.

The data I received back from Augusta shows that five of the seven infected patients had this procedure performed on the same day as another infected veteran—on April 16, June 10, August 20, September 10; two infected patients had this ENT procedure performed on the same day.

What is the VA's opinion of these facts?

Dr. CROSS. Here is what we have done. We have asked the epidemiology team—these are scientists that deal with investigation in terms of how infection occurs, where it spreads and so forth—that they look at this and do a detailed analysis, including genetic testing of the viruses to see if there is any link at all. They are in the process of doing this at this time. However, sir, I do have a statement I can read to you at this moment.

Senator BURR. OK.

Dr. CROSS. Coming from my epidemiology team in regard to the numbers of cases, understanding that this is preliminary, that they

are still working on this, that they do not have a final report at this time and that we are not ready to draw any final conclusions at this time. This is just where they are at the moment.

It should be noted they say that the number of veterans who have been newly diagnosed with HIV, HBV or HCV as a result or in association with endoscopy look-back analysis is consistent with or less than the number of infected veterans that we would expect to find based on previously published SERO prevalence studies. Although not definitive proof, this suggests that these infections are not associated with the endoscopy procedures.

VA is in the process of conducting an epidemiological look-back study of those veterans and others who underwent endoscopy procedures at those sites to better characterize the possible risk transmission of these infections in these procedures.

That is interesting as a matter of science. But when those patients come in and we find that they are positive, I am not worried about what the cause was. I do not question them about the cause. That is not my issue. I just want to take care of them at that point—first and foremost, take care of the patient.

This evaluation that we are doing is all in the background. It is not to question them. It is not to lay any blame. It is not to redirect where the responsibility might lie. Our first priority is to take care of the patient. This is a scientific investigation that we will publish over time.

Senator BURR. I can go to your charts because you should be proud of the lack of MRSA infections within the system.

Dr. CROSS. MRSA is a scary infection.

Senator BURR. Yes, you highlight it. And there is nobody today that can tell us we have not done everything to prevent it. We sterilize equipment. We sterilize operating rooms. Yet, somehow, this bug lives somewhere.

You highlight the fact that we do a better job than everybody else. So, I listen to that last response from your epidemiologist and I ask, well, where does that get us?

I mean I think we all know that there is—I am going to use Dr. Nolan—there is a structural problem. You cannot assure me that everybody is doing it exactly like your dictates ask. I think we all agree with that. We all agree that it should be—that noncompliance is unacceptable.

I will only say this, I hope that you will publicly or privately share with us when those epidemiologists come back after they have looked at the genomic connection, so that we can know, once and for all, if there was a direct link. Clearly, when you look at it on the surface, same day, same place.

Dr. CROSS. Different scopes.

Senator BURR. Same process followed within the hospitals.

Dr. CROSS. Sir, I concur, and I have already pledged that when we produce this report it is my intention to publish it.

Senator BURR. My last question, Mr. Chairman. You have been very kind to me today. Dr. Cross, 297 veterans are currently being tested for possible exposure to Hepatitis B, C and HIV at Mountain Home, Tennessee, VA Medical Center. In my capacity as Ranking Member of the Committee and as a Senator from North Carolina who represents 7,500 veterans in a 3-county area that are serviced

by Mountain Home, I was not told, my staff was not told, that you are contacting 297 veterans about the possibility of infection.

I assume that some of them may be from North Carolina. I have sort of got two skins in the game: as Ranking Member of the Committee actively involved in this investigation through this oversight process; as a Senator from North Carolina concerned about the veterans that live there, given the fact that this occurred after the Murfreesboro and Augusta disclosures.

Why was this not treated at the same level as the other issues with public disclosure, at least congressional notification?

Dr. CROSS. Sir, let me be very clear that I apologize to you for lack of notification to your office. The notifications were done by the local facility to the congressional delegation in Tennessee. There was also a communication with the Committee. Also, we put it on the internet to some degree. We talked to the patients and did disclosure to the patients. In fact, I have a copy of the internet site here if you want it.

Fortunately, no positives, small-scale and one of the errors that they made at Mountain Home is a different character from all the others. The type of antiseptic they were using, it was not that it was too weak; it was too strong. They were not diluting it enough, and so the actual concentration of antiseptic—one of the errors that they were making—was several times too high.

Senator BURR. Well, let me end with this because my staff had posed the question and the answer that they got was that it did not involve a large enough group of veterans.

Dr. CROSS. But we did notification, and we did call the local delegation. We were in error in not notifying you as well.

Senator BURR. What is the size it has to get to before it is at a level of importance?

Dr. CROSS. Well, at the moment, we are at zero positives.

Senator BURR. No. What is the size of the potential pool before this raises to the threshold of being concerned?

I mean 297. I am going by VA's statement, and I apologize, but that is all I can do: "The decision not to include Mountain Home results on the national Web site was that it did not involve a large number of veterans. The local delegation was notified and veteran disclosure has begun."

What is the threshold? If 297 does not meet it, then what is the number?

Dr. CROSS. Sir, I will define that according to however you would like me to define it. If it is one, we will do that.

Senator BURR. I hope that the concern at the VA is one. I am not sure that an IG investigation, I am not sure that a public disclosure, and I am not sure that a Web site notification is required at that number.

But I would just say, as the Ranking Member of the Committee, I think 297 is a big number. I think that suggests that there is something extremely serious to look at, whether there is fire behind the curtain. I am glad to hear that we are finding out there is not, but I think that that number as a threshold is significant. I just have a problem with the answer that we were given, which was it did not meet the threshold of a large group of veterans.

Dr. CROSS. Sir, the only answer I have for you is I apologize, and it was an error to not inform you.

Senator BURR. I thank you.

I thank the Chair.

Chairman AKAKA. Thank you very much, Senator Burr.

Just to let Senator Tester know, we still are in the first round. Senator Tester.

Senator TESTER. Thank you, Mr. Chairman. I will try to make this as quick as I can.

Dr. Cross, sorry I missed your testimony, but I want to go back to a previous comment that Dr. Daigh made to get your opinion on it. He talked about the VISNs' lack of ability to influence individual hospitals' quality of care. He has taken a look from a different perspective than somebody inside the organization. Do you think that this is correct?

Do you think that it can be improved upon and how are you going to do it? Or, is it not their job? Does it need to come from somewhere else?

Dr. CROSS. Let me say that it is their job, and I think that has been an area where we need improvement.

Let me tell you how. Let me talk to you for a moment, sir, if I may, about how this works. I have some of the best experts in the world on my staff to help me figure how these things should be done—safety, quality, so forth—and we put out very good instructions and directives. That is fine. That is a piece of paper. And then we have meetings and so forth to discuss that.

Execution then becomes of paramount importance. A key link in the execution chain is the VISN who are the intermediate commanders, so to speak. While their focus may be on the interaction, budget, all of those kinds of administrative things, quality of care also has to be acknowledged and a part of their responsibility at all levels. Many of them do a wonderful job on this. I think that we need to enhance the work and the role that they play, particularly in quality of care.

Senator TESTER. What role does peer review play in quality of care?

Dr. CROSS. Peer review has a long and famous history. It is not highly regarded in some organizations.

I highly regard it. We track it. We classify the numbers. We look at each facility in terms of how many peer review reports, reviews that they are doing and what grade they gave those reports. If they are not doing very many or if they are grading them in a way that we think is too generous, we call them up and talk to them about it.

Senator TESTER. How do you guard against retribution from a negative peer review analysis?

Dr. CROSS. In our system, the individual always has the right to appeal, and they can ask for a further review.

Senator TESTER. All right, but I am talking about the other direction. Let's say that I see something going on as a peer that is not up to snuff. I report it, and I am dressed down for it. How do you guard against that?

Dr. CROSS. Let me ask my colleagues who might give you more.

Senator TESTER. That would be fine. If you want to defer it, you can.

Dr. CROSS. Juan or Bill?

Mr. MORALES. Sure. I am the Director at Tennessee Valley which is Nashville to Murfreesboro.

Senator TESTER. Yes.

Mr. MORALES. Part of the peer review process is that if let's say there is another provider that reports—is that your question?

Senator TESTER. No. My question is that for a peer review process to work, the person who is being the bad guy—who is doing the work that nobody wants to do, pointing out an inadequacy in the system—needs to be guarded against so that retribution does not take place. How do you stop or guard against retribution toward somebody who is giving an honest analysis on somebody who is inept?

Mr. MORALES. Well, that is where my responsibility comes in: to make sure that whatever is being reported by the person, that we are protecting that person, that we are taking the right steps.

Senator TESTER. Are they being adequately protected now?

Mr. MORALES. I can tell you from Tennessee Valley, what we have in the organization and what we follow, the VHA policy, yes.

Senator TESTER. OK. Yes, go ahead, Dr. Duncan.

Dr. DUNCAN. I think the key element is building a culture of quality and safety and building a culture that we are a learning organization.

Senator TESTER. That is right.

Dr. DUNCAN. I think you can look at peer review as a punitive mechanism. I think we try to approach it from a viewpoint that is a learning mechanism. I think that we do monitor how many of our peer reviews fall into where there are questions raised about the care, and so we do that, and we do see that people are utilizing peer review to point out errors and point out areas we can improve.

Senator TESTER. OK. I appreciate those answers. Let's go back to Dr. Cross.

Dr. Cross, you said that you valued peer review. I know oftentimes people at the top have certain goals in mind that do not filter through the system. Maybe VISN is part of it. Maybe there are other parts. I mean is it valued throughout the system to the extent you would like to see it valued?

Dr. CROSS. Probably not, but here is what I have done to correct that. I worry about the internal aspects of peer review, the people who are reporting on their colleagues and that they may not want to do that.

Senator TESTER. Yes, that is right.

Dr. CROSS. It is alluding to what you were talking about before. So I decided we should do this externally as well. So we now ordered a grant which the acquisition folks are still working on, nationwide, to give us an external arm of peer review nationwide, and so that someone completely unrelated comes in and does this same process and gives us another level of evidence.

Senator TESTER. OK. So you are doing an investigation right now.

And, excuse me, Mr. Chairman. I know my time has run over. I have this next question to ask.

You are doing an investigation right now on Hepatitis and HIV linked to the procedures of the unclean equipment. That is correct. Who is doing your peer review?

Dr. CROSS. On the epidemiology?

Senator TESTER. Yes, on your investigation?

Dr. CROSS. We are going to publish it in the peer review journal if they will accept it.

Senator TESTER. OK. If there is another round, I will wait. If not, I can keep going.

Chairman AKAKA. We will have another round.

Senator TESTER. OK.

Chairman AKAKA. Thank you. Thank you, Senator Tester.

Dr. Cross, this is a follow-up to questions that have been asked on endoscopes. Your testimony that says VA's quality of care is good and that your quality management works. How, then, do you reconcile your testimony with the IG's report that only half—half—of the VA's facilities complied with the internal policy for endoscopes even after you told them to fully comply as part of the step-up?

The question is, what is the disconnect? Are your network directors listening to you?

Dr. CROSS. I guarantee you they are going to listen, and they know how I feel about this report. We had some very heart-to-heart discussions. I was very disappointed in that report, and, further, we are holding folks accountable.

Now, again, I want to make the important distinction that folks who come forward and report things and say they are wrong, I would like to pat them on the back and say, thank you for doing a good job.

But when we have identified something is wrong, I expect it to be corrected; and we have talked about it several times. It has got to be done, and that becomes an issue of accountability at that point.

Chairman AKAKA. Well, thank you, Dr. Cross.

Last year, we had problems with privileging of physicians to perform procedures they were not qualified to do at the Marion VA. Now the person is reporting that the doctor in Philadelphia responsible for the problems with the prostate procedures was allowed to do those procedures at VA but not at the University of Pennsylvania. The bottom line, did the Philadelphia VA have proof that the physician could perform this procedure competently before they let him do it?

Dr. CROSS. I have not looked into that specific allegation as of yet.

There is an important distinction here that I would like to point out to you about something that you raised earlier. You mentioned the contract and how much it cost. The contract was not with the individuals. The contract was with the university, the health care system, to provide the appropriate people to do that care, but that does not in any way minimize, escape or excuse our oversight of that process. I want to be very, very clear. If it is in our facility, it is our responsibility.

And so, sir, I will look into that allegation.

Chairman AKAKA. Well, thank you so much for pointing that out as one would assume the university would send a qualified person.

Dr. Cross, the IG's reports describe significant problems in VA's quality management and patient safety efforts, and you have shared with us what you will do to address those concerns. But a fundamental question arises. Do you have confidence that VA's Central Office has a handle on the quality of care being provided in the field?

Dr. CROSS. Senator Burr asked a question a while ago: why did we change the reporting relationship? I have been looking for an opportunity to answer that, and this relates to it very well, as you just opened up that discussion.

Quality is so fundamentally important that the previous Under Secretary for Health reorganized it. He felt that patient safety, quality and the Quality Office should not be managed independently. He found that they should interact very closely; that they should be working together. They should be within the same organization. So, he merged those into the same organization. The head of that organization does report to me, the Under Secretary of Health, directly.

I would like to have Dr. Duncan comment on that, sir, to provide further response to your question.

Chairman AKAKA. Thank you.

Dr. Duncan?

Dr. DUNCAN. Thank you for the opportunity to respond.

I cannot speak for Dr. Kussman, but in my conversations with him, what Dr. Cross said is absolutely correct. The IOM report, when it was looking at quality health care systems, defined—and Dr. Nolan gave those to you at his opening statement—the whole universe of what a health care system should be. It is that quality includes patient safety and that our patient safety organization is in Ann Arbor, Michigan.

It is true that they reported directly to the Under Secretary before. By reporting to me, I am in Washington every morning. I sit in on the Under Secretary and the senior leadership of the VA. I sit in with them, and they hear about quality and safety every day. I am in the Under Secretary's office. I can walk into his office anytime with any issue. So it was, I think, Dr. Kussman's desire to elevate the place of quality and safety, to coordinate it across our whole system.

And the second point I want to make is that quality and safety does not reside just in my office or in the National Center for Patient Safety. It is the responsibility of every program office. It is the responsibility of every facility director and every member of our VA family to ensure that we have quality and safety. And so, coordinating that is a huge job, and this is the reason they set up my office.

Chairman AKAKA. Thank you. Thank you very much.

Let me call on Senator Tester for the second round.

Senator TESTER. Yes, thank you. Thank you, Mr. Chairman.

OK, Dr. Duncan, quality and safety is your job. I do not doubt it just by the tone of your voice and your resoluteness to that.

We are dealing with a number of individuals here. Compared to the private sector, it may be lower than the standard of screw ups,

but it may be equal to or higher. For the purpose of this hearing and for the purpose of my perspective, I think I agree with Senator Burr. One is too many, so we have to go for zero tolerance.

What are you doing to make sure it gets to the ground, if you know what I mean? We can have all these visits in Senate Committees, and we can have visits in Dr. Cross's office and your office, but the fact is where it happens is in the hospital, on the ground with the patients. What is being done to get it there?

Dr. DUNCAN. I think that is a very central question, and right now my office is actually right in the center of the operations. So I have access to the people that oversee the VISNs and the operational element.

Senator TESTER. So, we will just back up for a minute. I do not mean to cut you off. So what are you doing with the VISNs since they are inadequate by several different people's perspective? What are you doing with those VISNs, just for an example, to get them fired up, get them off their duff and get them going in the right direction; do what they need to do to make sure things happen?

Dr. DUNCAN. We are trying to coordinate. We do this with many mechanisms where we bring together the various elements in VHA that are responsible and have quality and safety programs. We coordinate those at the Under Secretary's Coordinating Committee for Quality and Safety.

A big player in this is the Operations. The Operations has the responsibility for doing quality improvement. My office is doing the coordination. We do the measurement and analysis, and then we work with them to execute the quality improvement.

They have developed a very robust systems redesign. You heard Dr. Nolan talking about designing a system. Well, in Dr. Cross's testimony, you can see the many systems that have been put in place to do the quality improvement. So this is a journey that we are on.

Dr. CROSS. Can I add just a word to that?

Senator TESTER. Yes, you can.

Dr. CROSS. A concrete example, in this last go-round when you heard me say I made them certify that those SOPs and training documents were in place, I did something else too. By the 14th of July, their staff are to have visited every single facility unannounced—unannounced by the 14th of July.

Senator TESTER. What are they looking for?

Dr. CROSS. The reprocessing, training, and documentation issues.

Senator TESTER. Do you have the results of those visits?

Dr. CROSS. By the 14th of July.

Senator TESTER. Oh, July, OK. I am a month ahead of myself. OK. I would love to see what the results of those visits are. If that is public information, I would love to get it from you.

And the reason is this: I am a farmer, which is fairly well-known around here. You can grease the tractor until the cows come home, but if you don't get on it and get some work done, nothing ever happens.

And so, we need to make sure that the information that I believe is in your guys' heads—I really believe it. I believe that you are sincere about it, and I believe that you want to see it happen.

Something is happening—a disconnect here. It is not getting to the ground where the work is being done.

I do not know how to do it. I have my own ideas, but you guys are in the business, and I am sure there are better ideas than I have.

Just a couple more things, Dr. Cross. Has there been any evaluation or follow-up as far as the prostate issue and how many were affected; if any have died?

Dr. CROSS. When we found the issue in Philadelphia, which we found, I decided and the Under Secretary at the time decided that we should do this the way we normally do things. We should not just assume that the issue was limited to one facility. So I mandated a review of all the facilities that do those procedures.

We did find some deficiencies. I have curtailed some programs.

Senator TESTER. What about its impacts on vets?

Dr. CROSS. I am not aware of adverse impact. I know about the case that was reported in the newspaper. But, in terms of, you said, mortality?

Senator TESTER. Yes.

Dr. CROSS. I am not aware of any such issue.

Senator TESTER. I just want to close real quick, if I might, Mr. Chairman.

I spend more time on this Committee than any other committee I have, and I have some really important committees. I go around the State of Montana. I visit with vets all over the place. I have 110,000 of them in the State of Montana. They all, for the most part, speak very, very highly of the VA. Because of that, I speak very, very highly of the VA because the service they offer is really the proof in the pudding.

Where I am getting at on this is that I know that there are allowances made for things not happening and certain people getting sick because of screw ups. I am very proud of the VA. I think they do a great job. I am not proud of them on this one, and I think that it needs to be fixed.

And, if the results come back that the private sector is worse than the VA, do not even look at that. That is too low of a bar. That is like me comparing things here to the private sector. We do not want to do that. We want to set our bar at a standard because, quite frankly, this is a good outfit, and I do not like to see it get black eyes. And I will do everything I can do to help you fix it, but in the end it has to be fixed.

I was just given a timeline of how things have happened here. I know hindsight is 20–20, but if you look at that timeline it is totally ridiculous that it came to this point. This should have been fixed a long time ago. I do not think it slipped through the cracks. And I know you are not Superman, but we expect you to be.

Thank you very much.

Chairman AKAKA. Thank you very much, Senator Tester.

I have a question for the medical center directors from Murfreesboro, Miami, and Augusta, and really it comes down to two questions. One is, because we have been talking about this, how do you go about creating an environment in which employees feel comfortable bringing problems to the attention of leadership? That is one.

And the other is, can you describe for us the extent to which networks and Central Office provide you with oversight on your quality management work?

So let me, in that order, call on Mr. Morales first, then Ms. Berrocal and Ms. Wiley. Mr. Morales?

Mr. MORALES. Thank you for the question, Senator Akaka.

The environment or the culture of safety—in that employees can come forward and report things—it starts in my office setting the example that when things are reported we listen to the employees, we follow through, and we fix it. If the employee feels that they are going to come forward and nothing is done by the leader of the organization, then they know that they are wasting their time.

So it starts within my office, making sure that when things are reported we look into it. We report it immediately to the people that need to hear it, and we take care. The first question that we ask is was there any harm to our patients? That is how the culture in the organization starts.

I think the other thing is how important it is to have our patient safety officers being part of any discussion that has to do with patient activity because they bring a very different perspective. They look at things and can help with making sure that the environments are safer for our patients. So that is number 1.

Number 2, the support that we get. I can say from my perspective, that since I have been a director at Tennessee Valley—I came in at VISN 9—I have gotten tremendous support in looking at our quality management issues and how we are structured. We had our CAP review about a year ago, and they identified some areas that we needed to improve in our program. We took action. We work very closely with our network office, and also we follow through when there are things that come from either the VISN or from Central Office and things that we need to look at and that we need to pay attention to.

Chairman AKAKA. Thank you very much.

And, Ms. Berrocal?

Ms. BERROCAL. Thank you, Senator Akaka.

At our medical center, we believe that the patient safety issue is the responsibility of everyone in the medical center, and we encourage a culture that would allow people to come forward.

Similar to Mr. Morales, what we do is we ensure that when people bring issues to our attention—whether that be a Congressman's office or an employee, a patient, whomever—we are listening and we take steps to ensure that they know we are taking some kind of an action on it. In that same manner, we assign administrative investigation boards where we think there might be issues that require more in-depth analysis, and we take appropriate action if there is something that is not a system issue, but negligence on someone's part or a misconduct issue.

I work very carefully with the whole leadership team to ensure that our decisions are patient-centered, so that if we are always focused on the patient, what is proper and correct for the patient, that that is how we should make our decisions, and that is how we should always question things.

I also indicate to them that we need to create a culture where it is not just business as usual, but every single thing we do is important and critical because we take care of patients' lives.

I have the patient safety officer reporting directly to me. And what we are doing now with patient alerts and that kind of thing is: we have them come every Monday. She comes to us and reports to the whole leadership team in terms of any patient alerts and who they went to for response, how we are validating those responses. We ensure that she then keeps the evidence of how we validated that, so that I can make sure we are continuing to create a culture of consciousness about patient safety.

At the network level, we receive a lot of support. We have a Joint Commission Readiness Program at the network level. There is a Patient Safety Program. There is the Quality Management Office that provides support for us. We have the VISN Performance Improvement Teams that come by the medical centers and check to see whether we are doing things properly or not. We, obviously, have the other external reviews that we have to respond to in terms of our accountability to the network and Central Office in terms of the IG CAP and the SOARS visits, and those kinds of things.

Chairman AKAKA. Thank you. Thank you very much.

Now we will hear from Ms. Wiley.

Ms. WILEY. Thank you, sir.

In Augusta, we believe that safety has to be embedded in everything that we do. It is the underpinning of quality, and we incorporate that. I walk around, as does my leadership team, and as we are making rounds on our units, talking to our providers, we talk about safety.

We also incorporate safety as a part of agenda items for all of our committees, even at the basic levels of the organization. We include staff in a lot of our safety reviews, our RCAs—which are our Root Cause Analysis—of systems issues. We have staff that are involved in that. I sit in on all those reviews as they are summarized, so that we can look at safety and other systems issues that might need improvement.

How the VISN supports us in Georgia: monthly, our VISN director and other members of his staff, including the quality management officer, come to our medical center where we walk around and look. We talk. We meet with staff about all the pertinent issues that may be involved in our performance improvement activities.

We have a quarterly meeting that encompasses all of the quality management and performance improvement activities for all of the eight medical centers in our VISN, so that we are not only talking about quality at one site. We are looking at it systematically in our VISN.

Chairman AKAKA. Well, thank you very much for your responses. We really appreciate your being here.

In closing, we have heard of problems today in VA health care that are very disturbing. It is not enough that VA outperforms private hospitals in many ways. The Nation's veterans deserve more, and the Committee will continue to insist that VA provide the best care anywhere.

I look forward to working with the new administration, and in a way it is good to say, "the new administration" because it is like a commencement for a new system and a better system with better quality. We know some of the problems and look forward to working with you to correct that in the case where it needs to be corrected and to improve our system. But the sense here is that you all are poised to move ahead here with this administration and try to improve the system to deal with and service our veterans, which is what this is all about.

So thank you very much. I am looking forward again to working with you and the new administration to find solutions to the overarching problem of who is managing VA quality. I think we need to consistently look at this and continue to try to improve the system and maybe work up a new design, but we need to change it.

As I like to say to our old-timers, we cannot continue with a World War II system. We have to change that system and move it to these current times. This is what we are all about, and, together, we can bring these changes about.

So thank you very much.

The hearing is adjourned.

[Whereupon, at approximately 12:27 p.m., the hearing was adjourned.]

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