

**SACRED OBLIGATION: RESTORING  
VETERAN TRUST AND PATIENT SAFETY**

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**HEARING**  
BEFORE THE  
**COMMITTEE ON VETERANS' AFFAIRS**  
**U.S. HOUSE OF REPRESENTATIVES**  
ONE HUNDRED TWELFTH CONGRESS  
FIRST SESSION

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MAY 3, 2011  
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## **SACRED OBLIGATION: RESTORING VETERAN TRUST AND PATIENT SAFETY**

**TUESDAY, MAY 3, 2011**

U.S. HOUSE OF REPRESENTATIVES,  
COMMITTEE ON VETERANS' AFFAIRS,  
*Washington, DC.*

The Committee met, pursuant to notice, at 10:34 a.m., in Room 334, Cannon House Office Building, Hon. Jeff Miller [Chairman of the Committee] presiding.

Present: Representatives Miller, Bilirakis, Roe, Stutzman, Johnson, Runyan, Benishek, Buerkle, Huelskamp, Filner, Reyes, McNerney, Donnelly, Walz, Barrow, and Carnahan.

Also Present: Representatives Clay, Costello, Luetkemeyer, Ros-Lehtinen, Shimkus, Turner, and Wilson.

### **OPENING STATEMENT OF CHAIRMAN MILLER**

The CHAIRMAN. This meeting will come to order.

Thank you, everybody, for attending today's hearing entitled, "Sacred Obligation: Restoring Veteran Trust and Patient Safety."

Before we begin, I would like to ask unanimous consent that all the Members whose names are in front of us be allowed to sit at the dais. That would be Lacy Clay, Jerry Costello, Blaine Luetkemeyer, Ileana Ros-Lehtinen, John Shimkus, Mike Turner, and Frederica Wilson. Without objection, they will be allowed to participate in today's hearing.

Mr. FILNER. Hold it. I do not want Ileana.

The CHAIRMAN. Okay. Ileana, you have to leave.

Hearing no objection, thank you all for joining us for this important hearing.

We, as a Nation, put our trust in the men and women who serve in our Armed Forces to protect us and our freedom. And in return, our servicemembers put their trust in us to provide them with the highest quality healthcare.

However, incident after incident of serious patient safety violations in U.S. Department of Veterans Affairs (VA) medical facilities across the Nation in locations such as Dayton, St. Louis, and Miami resulting in thousands of veterans across the country receiving notification of their potential risk for infectious diseases like the human immunodeficiency virus (HIV) and hepatitis shatters that very trust that veterans should have in each of us.

After each of these incidents, the VA assured Congress and the country that it was aggressively addressing patient safety issues and never again would a veteran's trust be compromised by lapses in quality care at a VA medical facility and, yet, each patient safety

incident has seemingly led the way for the next lessons learned and the unacceptable and inexcusable revelation that the patient safety culture in VA is fractured and accountability and leadership at the helm are lacking.

The time for talk is over. VA has to confront these issues head on, deepen the obligation to care for the veterans affected by these incidents, and make the necessary changes within the VA health-care system to prevent any future incidents that would put veteran patients at risk.

To that end, at this hearing today, we will address in depth the efficacy of VA's patient safety policies and VA leadership's ability to provide adequate oversight of its medical facilities.

Further, we are going to explore the development of proactive strategies for addressing the issues that underlie the lapses we have seen in patient safety including the need for improvements in reprocessing of reusable medical equipment, systematic ways for VA to limit the activities of suspect practitioners, and better and more consistent risk management and notification processes for veteran patients when incidents do occur.

It is unconscionable that any one of our veterans should ever be exposed to infectious diseases because of the care they receive at a VA medical facility.

I want to assure all of you that this Committee will be tireless in its oversight to ensure that VA lives up to its creed to provide only the very best and the very safest care anywhere.

I thank you all for joining us for this ongoing and most important discussion.

Before I yield to the Ranking Member, I would like to remind the witnesses that testimony is due no later than 48 hours in advance of a Committee or a Subcommittee hearing. I am told that the Disability Assistance and Memorial Affairs (DAMA) Subcommittee did not receive VA testimony until late yesterday in preparation for today's 8:00 a.m. hearing. To me, that is inexcusable.

And in addition, I and other Committee Members submitted a series of questions 7 weeks ago in relation to VA's 2012 budget request, yet no responses have been received.

I would ask those here representing VA to please convey my disappointment about this performance and my expectation that things will improve in the very near future.

And with that, I yield to the Ranking Member, Mr. Filner, for an opening statement.

[The prepared statement of Chairman Miller appears on p. 49.]

#### **OPENING STATEMENT OF HON. BOB FILNER**

Mr. FILNER. Thank you, Mr. Chairman, and thank you for holding this hearing.

Obviously we want to gauge VA's response to several recent incidents that profoundly affect veterans, as you pointed out, due to the failure of some to follow policies, procedures, and protocols that have been put in place to prevent such occurrences.

We are going to look at what measures have actually been implemented to ensure that these types of lapses never happen again.

I have to say, and I think you would certainly agree, Mr. Chairman, that we have been here before. You have acknowledged some of the events, but let me just point out the most recent things.

In December 2008, we were notified of improper reprocessing of endoscopes, which put thousands of veterans in Murfreesboro and Mountain Home, Tennessee and Miami, Florida, at possible risk of hepatitis and HIV.

In February of 2009, another thousand veterans in Augusta, Georgia, received notifications that they were at risk for hepatitis and HIV because of improper processing of ear, nose, and throat endoscopes.

In July 2010, this Committee held a field hearing in St. Louis, Missouri, which you attended, Mr. Chairman, along with many of our colleagues here today after we had learned of lapses in protocol with the cleaning of dental equipment, which put at risk 1,800 veterans.

The most recent notification, the egregious incidents in Dayton, Ohio, affected over 500 veterans and involved a whole host of problems.

The findings beg the questions of proper accountability, effective oversight, and enforcement of clear policies and procedures.

Policies and procedures that are sometimes not followed or, worse, get completely ignored are the issue. I would like to know where is the strong leadership and effective communication that is critical when you are entrusted with the care and well-being of our Nation's veterans.

Let me point to another big concern as a result of these incidents and that is the absolute need for effective communication within management ranks and below and also between management and the Congress.

I am sure that the Secretary of Veterans Affairs agrees with me on this.

Clearly, VA has had issues with ensuring the sterility of reusable medical equipment in the past and now other patient safety issues have come to light as evidenced in the continuing problem of veterans being vulnerable to infectious diseases due to the problematic yet prevalent issue of lack of following sound agency guidelines and policies concerning patient safety.

In addition to what has been looked at over the past 3 years, I am strongly dedicated to the need for ensuring that we do everything possible so we do not trouble our veterans again.

As we are all well aware, VA has a higher commitment and a moral compact to provide the utmost level of care possible. It is this Committee's responsibility to ensure that VA has the proper resources to fulfill that mission.

Of course, we want to acknowledge and recognize the VA's excellent healthcare services overall and the dedication of the vast majority of its staff. The work that you have done so far to try to mitigate the issues that we will be discussing today is to be commended.

I would like to pretend that I am looking forward to today's hearing, but I am not. These are not easy questions. And, frankly, Mr. Chairman, the issues go beyond just the incidents themselves.

They go to the communication within the VA. It took a long time for the right people to know what was going on in each of these incidents. It goes to the communication with our VA patients. Sending a letter that basically says you may have HIV is not the way to deal with these issues.

There is no case management. There is no way for the veteran to really talk about what is happening, what the probability of infection is, how to get immediate help, blood tests and everything else. A phone call going out or a letter going out to 1,500 people or 1,800 people without further explanation, without a 24-hour hotline to call?

As far as I know, on some of these incidents, neither the Secretary, nor this Committee, was ever notified for days or weeks of the incident. We people at the VA trying to figure out how to cover it up or try to stifle the whole thing rather than allowing the most information possible? It seems to me that the culture of secrecy, the culture of covering up is too prevalent here.

Mistakes are made in every institution and they will be made in the VA. But we have to acknowledge and deal with them, get the information out as quickly as possible and honestly figure out what happened.

As far as I know, and maybe the panel can correct me, with all these incidents, we have never been told, Mr. Chairman, of any personnel changes as a result. The only way to send a message to an organization that we take these things seriously is by firing or whatever.

I know you have all kinds of guidelines for this to protect employee rights and information, but there has to be a way, even with the issues of the employee rights, to understand there is accountability here.

I do not know of anybody who has ever been fired. I do not know of anybody who has ever been let go. I do not know of anybody who has been specifically reprimanded, punished, or dealt with when they put the safety of these veterans in jeopardy.

I think there probably have been, but we have never been told that. You tell us that personnel changes have been made. That is not enough. That is not enough. That is not enough to assure us and then that is not enough to assure the public. That is not enough to make sure that the good employees at the VA know that if someone makes a mistake, they are going to be dealt with.

I think we have to find a new way to handle this, Mr. Chairman. Not just the procedures and sterilizations, but how are you going to deal with accountability in a public institution when employees do have rights, but the public accountability is paramount?

We have to understand that and deal with it in a new way.

I thank the Chairman.

[The prepared statement of Congressman Filner appears on p. 50.]

The CHAIRMAN. I thank the Ranking Member for his opening statement.

And as usual with this Committee, we ask that all Members hold their statements so that we can get to the witnesses, but each Member will be allowed to enter their statement into the record without objection for printing purposes.

And I would like to welcome the first panel to the table this morning, Dr. Robert Petzel, who is VA's Under Secretary for Health; Dr. John Daigh, Assistant Inspector General for Healthcare Inspections at the VA Office of Inspector General (OIG); and Mr. Randall Williamson, Director of the Healthcare team at the U.S. Government Accountability Office (GAO).

Gentlemen, thank you very much for joining us here this morning.

And, Dr. Petzel, you may proceed.

**STATEMENTS OF HON. ROBERT A. PETZEL, M.D., UNDER SECRETARY FOR HEALTH, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; JOHN D. DAIGH, JR., M.D., ASSISTANT INSPECTOR GENERAL FOR HEALTHCARE INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS; AND RANDALL B. WILLIAMSON, DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE**

**STATEMENT OF HON. ROBERT A. PETZEL, M.D.**

Dr. PETZEL. Chairman Miller, Ranking Member Filner, and other Members of the Committee, thank you for the opportunity to discuss the Department of Veterans Affairs' patient safety policies and strategies to build trust and ensure the safe and compassionate care of this Nation's veterans.

I am accompanied today in the first row by Dr. Robert Jesse, the Principal Deputy Under Secretary for Health; Mr. William Schoenhard, Deputy Under Secretary for Health, Operations, and Management; Dr. George Arana, Acting Assistant Deputy Under Secretary for Health for Clinical Operations; and Dr. Andrea Buck, Acting Chief Medical Officer.

I have submitted the written testimony and ask that it be entered into the record.

First and foremost, I want to apologize on behalf of the Department of Veterans Affairs to those veterans who have been affected by these lapses in patient safety practices at any of our facilities.

The primary commitment of every VA employee is the well-being of our veteran patients. When a lapse in patient safety practices occurs, we believe that we must be open and transparent with regard to our mistakes and any necessary actions that need to be taken.

We carefully consider the effects of any disclosure, but our practice is to provide more information to our veterans in an abundance of caution even if the risk is very, very low.

We believe we provide excellent healthcare overall. Despite caring for patients that are on average sicker, older, less affluent than the general population, VA's performance exceeds the best U.S. healthcare systems.

We are very open with our information. We report more quality data about our programs online than any other healthcare system in this country.

Our written statement provides an overview of our quality and safety programs, our practices for standardization, of reprocessing, and our credentialing and privileging practices and finally our risk management and notification for patients' procedures.

Right now I would like to make three points. First, we are focused on continuous improvement to all of our programs. We publish an annual report on each facility's quality and safety performance online and we are providing data to the U.S. Department of Health and Human Services' (HHS) Web site so that veterans can compare the care that is delivered in their facilities with the care that is delivered in the private practice.

We conduct detailed investigations of not only adverse events but of close calls because even if a veteran was not harmed in a particular situation, we never want to put that patient at risk for that particular problem again.

We subject our facilities to dozens, dozens of reviews annually. Our facilities are subjected to inspections by the Joint Commission, the Commission on Accreditation of Rehabilitation Facilities, the Inspector General, the Medical Inspector, the GAO, and a number of other external and internal quality and safety reviews.

We not only appreciate this oversight, we welcome it. It is through these internal and external assessments that we can detect problems, identify best practices, and change the way we do our business. No matter what the outcomes, these reviews do improve the care that we deliver to our veteran patients.

Secondly, we have made significant progress in standardizing, sterilizing, and processing reusable medical equipment across the country. Several of the incidents that are being discussed today were the result of improper reprocessing of reusable medical equipment. This is one area we are looking at for even further enhancements.

We standardized the purchase of reusable medical equipment and we are using leases to ensure that the latest and best equipment is available so that we go from 40 different brands of colonoscope at a medical center to less than 10 brands of colonoscope at that medical center to simplify the process of re-sterilizing that equipment.

We have created an Office of Clinical Consultation and Compliance that is implementing better tracking and documentation control measures over our reusable medical equipment.

And we are subjecting our programs to the requirements of a program called ISO-9001. This is an industrialized, standardized process for quality control. And we are collaborating with the leaders in this field to improve our training, accountability, and practices in our Supply, Processing and Distributions (SPDs).

We are looking to work with the private sector to automate our practices to reduce the potential for human error, and four levels of review of our SPD programs are conducted. The facility does reviews. The network or Veterans Integrated Services Networks (VISN) does reviews. There are national reviews and we have external entities that review our SPD processes on an annual basis.

Finally, we have a careful assessment process to determine when we should disclose an event to veterans. We convene a fact-finding board to discuss the event and a clinical review board to determine if disclosure should occur. This rigorous process has been recognized by *The New England Journal of Medicine* as a best practice and a model for the rest of the country.

These boards are comprised of subject matter experts from a range of disciplines to determine who should be notified and how we best should do that.

In conclusion, our mission is to serve the Nation's veterans by providing them the best healthcare anywhere. We take this responsibility very seriously. And we appreciate the opportunity to discuss these programs that we have in place to deliver on this promise.

Thank you for inviting us to testify here, and my colleagues and I look forward to your questions.

[The prepared statement of Dr. Petzel appears on p. 52.]

The CHAIRMAN. Thank you, Dr. Petzel.

Dr. Daigh.

#### **STATEMENT OF JOHN D. DAIGH, JR., M.D.**

Dr. DAIGH. Good morning, Mr. Chairman, Ranking Member, Members of the Committee. It is a privilege to discuss the published work of the Office of Inspector General as it relates to the patient safety issues under discussion today.

I believe that based on the body of work that we have done over the last several years, the VA does, in fact, provide high-quality medical care to veterans. Nevertheless we are here today to discuss failures by VA to provide properly reprocessed, reusable medical equipment at the point of care, delivery thus resulting in the notification to thousands of veterans that they are at risk of becoming infected with blood-borne pathogens.

My conclusion is that these instances result from two problems. One is the inability of selected facilities to follow established guidelines and directives with a zero defects culture, that is to do their job correctly every day and every time.

The second problem that I see from these issues is instances of leadership failure where compromises were made to acceptable infection control standards that placed veterans at risk.

I recommend the VA consider changes to their current policies and procedures and offer a few suggestions.

One, the hospital leaders must have unfettered input from their employees, particularly those employees who I would call technicians. They run the lab. They operate the ultrasound machines. They provide and support a great deal of the care that is provided throughout the hospital.

The nurses have a direct line of flow of data to the hospital leadership. The providers have a direct line of flow of unfettered data. I think it is imperative that the hospital director reach out and speak directly with the technicians to ensure that the data is congruent, that they are hearing about what is going on in their hospital.

The second, I think VA should consider position rotations or forced vacations as a management tool in selected circumstances. Where senior hospital leadership is viewed as unresponsive to employee concerns, the quality of medical care may be placed at risk.

The third, I believe VA has, in fact, an excellent adverse event disclosure policy that is, in fact, the national standard. However, I think in light of recent events, I think it is time to have a broader

discussion of the risk management policies and the communication policies that entail this adverse event disclosure issue.

And, fourth, I think senior hospital officials must very carefully examine those instances in which a provider has privileges at the hospital that are less than expected for that provider's position or recent history. A limitation of procedures alone may not provide the margin of safety anticipated by the credentialing and privileging Committees.

I thank you for this opportunity to testify today and will do my best to answer your questions.

[The prepared statement of Dr. Daigh appears on p. 58.]

The CHAIRMAN. Thank you, Dr. Daigh.

Mr. Williamson.

#### STATEMENT OF RANDALL B. WILLIAMSON

Mr. WILLIAMSON. Good morning, Members of the Committee.

The CHAIRMAN. You might check your microphone really quickly.

Mr. WILLIAMSON. I am sorry. I am pleased to be here today to discuss our report issued this morning that addresses VA policies and oversight governing the cleaning and disinfecting of reusable medical equipment, which I will refer to as RME.

Lapses by some medical centers in cleaning such equipment, which includes dental instruments, endoscopes, and surgical instruments have recently come to light. Such lapses have put thousands of veterans receiving care at these medical centers at risk to exposure of HIV, hepatitis, and other infectious diseases.

In my testimony today, I will describe our findings in two areas. First, I will address deficiencies in VA policy requirements for training its medical center staff to properly clean and disinfect RME. And, second, I will discuss needed improvements in VA's oversight of medical center staff to ensure that they comply with these policy requirements.

Regarding the first area, we visited a cross-section of six VA medical centers across the Nation and found some disturbing deficiencies with respect to VA requirements for devicespecific training for cleaning and disinfecting RME. These deficiencies indicate systemic problems that need to be corrected at the national level.

Two issues came to light here. For one, almost all medical center officials we talked with said that VA guidance was unclear as to which types of RME required devicespecific training to ensure proper cleaning techniques. This resulted in devicespecific training not being developed at all six medical centers we visited for some critical RME such as surgical instruments.

At one medical center, for example, officials told us they had developed devicespecific training for non-critical RME such as wheelchairs, but they have not completed training for more critical RME.

Another training issue involved conflicting guidance that was provided to medical care staff about developing training on how to clean RME.

Officials in three medical centers, for example, told us that certain headquarters' or VISN officials had told them to develop devicespecific training for RME that closely matched manufacturer guidelines.

Later other headquarters' and VISN officials told them to write reprocessing instructions in a way that could be readily understandable rather than strictly following the manufacturer guidelines.

This led to multiple rewrites of training instructions by medical center staff, which are both time consuming and a waste of resources and could lead to preparation of insufficient training instructions for cleaning RME at some medical centers.

Headquarters' officials told us they are aware of these deficiencies and have begun efforts to remedy them. For example, VA officials said they have recently gained access to a commercial database of standardized devicespecific training developed by manufacturers for over a thousand pieces of RME and have made this database available to medical centers.

For RME where manufacturers have not developed devicespecific training, VA officials said they plan to develop this training and provide standardized instructions to its medical centers. But at the time of our review, VA had not yet done this and had no firm plans or time table for completing this task.

With respect to RME oversight, VA has recently initiated efforts to improve its oversight of medical centers with respect to complying with RME reprocessing requirements. These efforts include increasing the frequency of unannounced site inspections to medical centers, requiring VISNs to use standardized assessment tools, and requiring the results of RME inspections at medical centers to be reported to headquarters.

Despite these changes, improvements in VA oversight are still needed. Most notably, while VA now requires that all RME inspection results from its medical centers and VISNs be submitted to headquarters, VA does not systematically analyze this information across its medical centers. Such analysis are important to assess the extent and risk of noncompliance with RME reprocessing requirements across its medical centers and to determine whether identified noncompliance cases have been addressed.

VA headquarters' officials said they planned to address oversight weaknesses we identified including analyzing information to identify noncompliance with RME requirements across its medical centers. However, completing these changes is contingent on implementation of the VA organizational realignment in this area which was still ongoing earlier this month.

In summary, while VA has taken some steps to strengthen both its methods for reprocessing RME and its oversight over this process, much remains to be done. Until VA's improvement efforts in this area are completed, veterans may continue to be at risk to RME related infectious diseases.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Williamson appears on p. 62.]

The CHAIRMAN. Thank you for your testimony.

And we will start a round of questioning. As our usual course, Committee Members will go first and then we will have a round for the non-Committee Members as well.

But on my time, and I will adhere to the 5-minute clock as well, Dr. Petzel, would you like to respond to Mr. Williamson and his presentation regarding their report?

Dr. PETZEL. Thank you, Mr. Chairman. I would.

We appreciate both the GAO and the OIG inspecting our reusable medical equipment processes as well as the other things they do because, as I said in my oral testimony earlier, we do learn. And we have concurred in the recommendations that the GAO specifically made.

I want to point out a couple of things. Number one is that we do now have a standardized database that covers the majority, the vast majority, in fact, of the processes, the standard operating procedures for processing reusable medical equipment. And that means we do have across the country standardized operating procedures for cleaning. In those areas where the commercial database does not cover, we have developed those ourselves.

And contrary to what Mr. Williamson said, we do not tolerate people writing their own procedures. We have a standard for cleaning whatever that piece of equipment is across the country. It may not have been completely in place at the time they did their inspection, but it is now and it is our practice around the country.

The CHAIRMAN [continuing]. If I could—

Dr. PETZEL. Two—

The CHAIRMAN. If I could, on number one, you said in place for most of, but the implication is not all?

Dr. PETZEL. Well, what I said was that the commercial database that we bought does not cover absolutely everything. And we have developed or we have in place processes for those things not covered, which are relatively few, not covered by this database that we—

The CHAIRMAN. Give me an example of what would not be covered.

Dr. PETZEL. There might be some small surgical instruments.

The CHAIRMAN. Does that mean you wrote them or—

Dr. PETZEL. That means the manufacturer has them, they are not in the database, and we use the manufacturer's information.

The CHAIRMAN. So you do have everything covered, but some is not in that database that you purchased?

Dr. PETZEL. That is correct.

The CHAIRMAN. Okay. And number two?

Dr. PETZEL. And number two is that the training that was described in the GAO report is, in fact, in place and has been done in the vast majority of our places. We have begun a process of certification for all of our technicians. We have developed an institute or an academy of SPD where we bring people specifically down to go through the training process.

We require that every SPD document the fact that their people, their technicians have been trained on the instruments that they are responsible for reprocessing.

And I believe that the last look that the OIG made at how well we have done with that training indicated that we were close to but not yet perfect in terms of the number of people that were trained. In other words, there were some instances where they found no evidence of the training, not that the training had not been done, but no evidence.

So that is number two is that we have indeed set up a process for ensuring that our people are properly trained.

And then the last item that I wanted to discuss in the GAO report is the Central Office oversight, again a point that we agreed with, that we need to have in place the mechanisms that allow us to be assured and are able to assure our patients and you all that we are periodically looking at the SPD and how it is functioning and assuring ourselves, you all, and the public that indeed those things that we say need to be done are being done, the training, the following standard operating procedures, et cetera.

As I mentioned in my oral testimony, there are four levels of oversight that occur in the SPD. There is a local requirement for oversight. We changed the reporting structure in SPD to a clinical person, the nurse executive in the executive quadrant.

We require that the networks periodically, three times a year, inspect the SPD using a standardized assessment tool which I think most people would agree is probably a benchmark standard within the industry. Then we from Central Office do our regular periodic inspections of the SPD for both infection control processes and re-processing.

And then finally, as mentioned, there are a number of outside organizations that periodically look. The OIG does their combined assessment programs that include looking at the SPD and that is done every 3 years. The Joint Commission looks at SPD. The medical inspector periodically looks at SPD. We have an internal Systematic Ongoing Assessment and Review Strategy (SOARS) process that looks at SPD.

So there are at least nine levels of oversight of SPD right now.

The CHAIRMAN. I think in your opening statement you talked about four levels of oversight.

I think the GAO talked about inability to follow guidelines and need for unfettered input from employees. They found disturbing deficiency and systematic problems. You said you have begun a process of certification.

If you do all of those things and your managers do not follow the rules, what do you do?

Dr. PETZEL. We would discipline them.

The CHAIRMAN. Have you?

Dr. PETZEL. We have.

The CHAIRMAN. Have you fired anybody?

Dr. PETZEL. We have proposed removal in a number of instances and almost invariably the individual has resigned or retired as a result of the proposed removal.

The CHAIRMAN. Can you give us a number of individuals that you proposed removal of?

Dr. PETZEL. There are, I believe, three physician or dental level people that that has occurred with, several chiefs of SPD where that has happened. We have also reprimanded individuals, suspensions, and letters of counseling.

The CHAIRMAN. One of the dentists was in his eighties; is that correct?

Dr. PETZEL. Close, yes.

The CHAIRMAN. Mr. Filner.

Mr. FILNER. Dr. Petzel, you are here as a representative of the VA. We have gone through this before, sir. It seems to me your job here should have been, and we have Members of Congress from all

the districts that have been affected, was to begin to restore some trust and confidence in your institution.

I hate to take a poll. If I did, if I asked how many people now have confidence that everything is fine in your VA hospital, I doubt if anybody would raise their hand. You said everything was fine. It is not true, simply not true.

You talk about transparent procedures and *New England Journals*, best practices, and, yet, every time something happens, we have a disaster.

We do not have a way of communicating. We do not have a way of dealing with the personal concerns. We do not have any knowledge that anybody has been reprimanded.

Now you tell us that you have reprimanded three employees. We have been going over this for years and now hear these results. Still, you have never told this Committee those figures before, as far as I know.

But, Dr. Petzel, we have gone through this before. We have raised concerns in our opening statement. You read your opening statement as if we never said anything. So you never addressed issues of accountability. You never addressed issues of communication, whether within your agency, the veterans or with this Committee.

I have gone through the timelines with almost every one of these Members here and their hospitals. You say panels get together to decide should we disclose, what should we disclose, who should we—it looks to many of us like they get together to decide what do we keep secret from our—you keep shaking your head no.

Why did it take 8 weeks at St. Louis where Mr. Carnahan will raise the issues for that panel to decide to tell people that almost 2,000 people were infected, possibly infected with HIV? It took 2 months before you guys decided that.

The Secretary was not notified, as far as I know, in his words to me during that whole period of time. It sounds like you are sitting there deciding “what is the minimal amount of information that we can give out so people do not get upset with us” rather than the maximum.

That first day, I would have had the Secretary have a press conference and explain the possibility of X hundred or X thousand of people being exposed. We are going to get to you right away. We want to make sure you know this is happening and put pressure on yourselves to become public because, otherwise, there is no pressure for you to do anything.

We did not know anything. The Secretary did not know anything. I do not know if you knew anything because these guys are basically meeting to determine how to keep this secret for as long as possible and maybe we do not have to disclose at all because your question was, should we disclose, not how to do it.

As I said, your whole disclosure process is as if everybody knows all your acronyms and your initials for everything and all these SPDs and RMEs as if the patients know what is going on.

They get a letter. I have seen these letters. It says basically, it is not this bad, but you may have HIV. They get a letter. It may have even gone to a wrong address.

For 1,500 people, as I said to you earlier at a hearing, you should have had 1,500 of your 250,000 employees, assigned to somebody to call them, go visit them, find out when they can come back, when they can get their blood test. Treat them as if they may have HIV, and they are scared to death that they are going to die. Instead, you send them a letter.

There is no one necessarily there to answer a phone call when they call back because you do not have people working this like case managers. One person to every five people is not enough, I think you should do one on one.

What you described as this open, transparent process does not come through. And every one of these people has constituents which I bet can confirm what I just said. Even if it is only the perception and not reality, that is just as bad. You were not very personal in your notification. You were not very clear about what it is that they might have. You did not followup in a way that was very quick. And then, we do not know anything about accountability. We know nothing from basically what you said today.

You have to develop a new system. We just killed Osama Bin Laden and they notified eight Members of Congress and the Committees were notified and, they kept that confidential. Maybe you should notify the Chair and Ranking Member of the Veterans Committees about what you are doing in terms of your personnel.

But there is no sense that you have done anything. Nobody in Dayton, nobody in St. Louis, nobody in Miami, nobody in Tennessee knows anything about that accountability. And I doubt anybody in the system knows about it, so they do not think there is any accountability.

So I wish you would address these issues. We have gone over them for several years. You and I have gone over these exact issues several times at hearings and then you do the exact same thing. You give me a prepared statement that everything is fine. You move the discussion into these arcane things about SPDs and RMEs and you neglect the basic issues of communication and accountability that are at the heart of the confidence that our people have in your system.

You may comment in any way you want.

Dr. PETZEL. Thank you, Mr. Filner.

What I want to do is first talk about our notification process. The process by which we determine who ought to be notified or who might be at risk, as I said before, is an industry standard. I will stand by that process. Under any circumstance, it takes some time, but it is transparent and it is weighted heavily in the favor of—

Mr. FILNER. Nobody knew about St. Louis for 8 weeks, 8 weeks.

Dr. PETZEL. Sir—

Mr. FILNER. If that is the industry standard, you should not—we should not be following the industry standard.

Dr. PETZEL. Sir, I am not talking about the communication. I am talking about the process that we go through. It is very thorough and it is weighted on the side of being abundantly cautious to be sure that we take into account every possible risk.

The process by which we disclose to patients involves letters, phone calls, and case managers, particularly in the instance of St. Louis. Every single individual that was affected was called. They

were offered a case manager. There was a case manager involved. In fact, in some instances, the leadership of the medical center.

I will admit that we have learned iteratively since the first episode—

Mr. FILNER. But, sir, that conflicts exactly with what you said to me at St. Louis. The Chairman was there. Mr. Carnahan was there and Mr. Clay was there. Mr. Shimkus was there. You never mentioned the word case manager. You never mentioned that they were called.

Is that right?

Dr. PETZEL. No.

Mr. FILNER. I mean, we went through this discussion with you. This is the first word I ever heard of a case manager because I said to you, why don't you have case managers. You said, yes, we will look at that.

We are both going to review your testimony in St. Louis because it is contrary to what you just said now.

Dr. PETZEL. Again, we have learned iteratively about the process of notifying people and early in this with the first episodes that we had in Miami and Augusta, I do not think we did a good job to be very candid with you.

But with the next several episodes, I think we have done a better job of sending letters, calling people, and giving a hotline number to call and making people available to them to answer their questions about what happened.

And, again, after reviewing what is done across the Nation, I would stand by the process that we have right now as being an excellent way of notifying people when there has been potential exposure.

Mr. FILNER. I hope all of our non-Committee Members who are here will speak to those issues from the way you saw them or your constituents told you. I hope so.

Thank you.

The CHAIRMAN. Dr. Roe.

Mr. ROE. Thank you, Mr. Chairman.

And not too many questions, but having served as chief of staff of a hospital and a hospital board chairman, you are responsible and you feel that responsibility for the care that is given by your institution.

And I have noticed a couple of things here that bother me a little bit for the last couple of years is that when you talk about the instruments, SPDs where the instruments are cleaned, it really gets down to one or two or three people in any hospital that are doing this. It is not a whole big system. It is people doing it.

And those people probably think they are doing the job right, but if they have not been trained to do it properly, they are going to continue to do it wrong.

I can assure you that in the private sector, had this occurred like this just did and a medical/legal case had resulted out of it, you just get your pencil out and start writing commas and zeros. I can tell you can get the checkbook out because this private system would not tolerate this.

I can tell you right now when you have this no matter if it is the SPD that does it, I know who is captain of the ship and I know

who is going to be responsible for that error that has occurred. And there have been numerous errors here.

One of the things that we have to sell in medicine is trust. Our patients need to trust us. They need to trust the VA that that is where the quality of care and transparency. Mr. Filner is absolutely 100 percent correct. I can assure you that when I had a problem go wrong in my shop when I practiced medicine, not the clerk that answered the phone made the call to the patient, I made the call to the patient. I called them up. I explained to them. I had them come in and tell them what was going on.

And I can tell you in a large institution with multiple people, I would have had the highest level people contacting someone when they think they have HIV or a potential life-threatening condition.

Now, because these instruments were cleaned in a certain way does not mean that it gave the patient that. We do not know what the incident was to start with. I mean, we do not know, in these patients, we do not know, but they do not know either.

So I think Mr. Filner is absolutely dead on right. And it is not the crime. It is the cover-up or even perceived cover-up. I mean, nobody is trying to hide. I do not think you are trying to hide anything. I know that. In my gut, I know that.

But you have a huge system and you have to put systems in place where people are trained and to where their training is evaluated so that those things do not occur. And I do not have the feeling yet that that has been done. Maybe it has been. Maybe you can make me feel better. But from what I hear from Mr. Williamson, he did not see it that way.

Comment.

Dr. PETZEL. Dr. Roe, I believe the training is in place. I do believe the policies are in place to do this.

The CHAIRMAN. Doctor, could you hit your microphone? Thank you, sir.

Dr. PETZEL. I do believe it is up to our oversight processes to assure us, assure you, and assure the veteran population that, in fact, those things are being done.

We have learned a lot from these episodes going back to 2008. And I think we are a better system because of it and I think we do have the best, if you will, in terms of reprocessing an SPD that is available in this country right now.

Mr. ROE. One of the things that we had in our medical/legal training in Tennessee was we had the airline people come to us and go over their procedures, which are absolutely textbook. Now, when you take a plane off and you will almost find out every time it is a pilot error.

And what you will find out here without oversight, it will be an individual person making an error as in the dentist example you gave. But that was not dealt with. That is the other problem is that when you see that problem, it has to be dealt with.

And I have done that. It is not fun to go in to talk to somebody who is a 30-year member of your shop and say you are not performing at the level we accept. That is not easy. I have done that. That is very hard to do.

And I do not get the feeling that that was handled very well when this problem apparently was identified for years and never

dealt with. So again, you have to have those procedures in place and then you have to follow those procedures and they have to be lock step. If you do not, you will have these errors.

And I think the other thing you are doing is it is much simpler when you have the same equipment all the time. And you have multiple kinds of equipment and doctors are terrible about that. We have our little toy we like to play with. But we can play with any toy if we learn how to do it. The fewer toys you have, the easier it is to not make those errors.

Dr. PETZEL. I absolutely agree with that last comment. We are frantically standardizing our reusable medical equipment. We just signed two lease contracts for colonoscopes and endoscopes. There are only two manufacturers. The fact that they are leases means that we will be able to turn over the latest model.

What has happened in the past is that they will buy some new endoscopes, but they will keep the old endoscopes as well. So you have maybe 7 or 8 years worth of models all of which have different instructions about how to clean, et cetera. This is going to allow us to have only the most up-to-date models and many, many fewer instruments that we have to learn the procedures for cleaning. I think that is an excellent point.

Mr. ROE. Thank you.

I yield back, Mr. Chairman.

The CHAIRMAN. Mr. Walz.

Mr. WALZ. Thank you, Mr. Chairman.

And thanks to all of our witnesses for being here.

And I, like Dr. Roe, was at that hearing a few years ago on the endoscopes. And I do appreciate some folks brought several into my office and taught me how to do it because my goal was to see exactly what the procedure here was.

And I want to be very clear. Everybody in this room, the care of our veterans is the number one concern. And I absolutely have no doubt of that. It is a zero sum game. One injured veteran is one too many.

But I want to bring up, Mr. Williamson, to you, and I was looking at a recent *New England Journal of Medicine* report, let us be very clear here that this is not a problem associated with only the VA.

How do the private hospitals report this? When I hear numbers of 98,000 deaths, 1.5 million injuries per year in the private sector and I was. Dr. Roe, I am going to have to get with you on that. I almost thought I heard you saying that the threat of the legal action kept people doing better things, but I will clarify that with you.

But the idea on this is how much, how prevalent, can you make any comparison to—is this systemic with the leadership in the VA or how things are done or is this is a broader problem, which I would argue representing places like the Mayo Clinic and VA facilities that it is systemic across the board in medical delivery.

Mr. WILLIAMSON. Well, Mr. Walz, you may be right about the breadth of it, but we basically concentrated on VA. We did not examine any private-sector data in this regard.

Mr. WALZ. So we do not have the ability then to—we were using best practices there, but the argument I would make is are we ab-

solutely certain, and do not get me wrong, one is too many, but are we absolutely certain the practices being applied in the VA are worse than the private sector even though our goal is to have the best care?

Dr. Petzel, can you—

Dr. PETZEL. Congressman Walz, thank you. I can make just a couple of comments.

*The New England Journal of Medicine* article that I was describing before that cites us as being the best, the best example of how to assess risk and how to contact patients also cites 18 other examples of potential exposure across the country ranging from 40,000 people in one instance to just a couple in another. It is a prevalent problem across the country.

I believe, and we have had some confirmation of this from other people, that we are doing an excellent job of trying to achieve the Six Sigma performance in our SPD.

The ISO-9001 that I spoke about before is an industrialization of the whole process. Very few other people are doing that in their SPDs. The inspections that we go through are not done in many other parts of the country.

So I think that, I mean, I do not want to compare us to the private sector completely, but I think we are doing a good job, not a perfect job. As has been pointed out by a number of people, we have to do better and we will continuously improve this. But I think we are on the right path.

Mr. WALZ. So the Six Sigma process is translating. Are we focusing on the one/one-thousandths in here because I said even if that is what it is, we are going to focus on that, the care for our veterans? Is that what is happening?

Dr. PETZEL. That is the kind of performance that we are trying to emulate, correct.

Mr. WALZ. That is right.

Mr. WILLIAMSON. I would add, too, though, that we looked at VA policies and what VA requires and the standard of excellence that they require of their people you can compare VA to the private sector, and I really do not know what is going on there, but you really need to compare it against the standard of excellence that VA set for itself. And it was not doing the job.

Mr. WALZ. Yeah. Good point.

And I think that, Dr. Petzel, you agree with that, too, because I think the question and the frustration coming from my colleagues is that whether it be communication or very disturbing to me with the dental incident of someone actually passing on information of poor practices, less than best practices and, yet, the appearance was not anything done about it.

I think that frustration that the Chairman experienced asking, well, did you remove these people because there are barriers to doing that? I want to be very clear on that. Are our managers given the freedom to be able to make changes in due process with basic principles, but are they able to do that?

Dr. PETZEL. They are. The Civil Service rules are complex and complicated, but if you follow the right processes and procedures, it is possible to do that.

I want to just make a comment about Dayton and the dental that has come up a couple of different times. And I want to be perfectly clear. That was a failure of leadership. That was a failure of leadership within the dental clinic.

The people that worked with this individual knew that this was not appropriate. The technicians knew that it was not appropriate. The chief of dentistry knew that that was not appropriate. And for a long period of time, none of these people took the kind of action that they needed to take. And unquestionably that is a failure of leadership.

Mr. WALZ. I appreciate that. I appreciate all your work. And as I said, I am, of course, your biggest supporter, but I will also be your harshest critic until we get this down to the best anywhere. So I appreciate that.

And I yield back.

The CHAIRMAN. Mr. Johnson.

Mr. JOHNSON. Thank you, Mr. Chairman.

You know, as a former Air Force officer myself and as a veteran, I am very concerned about what I am hearing here. You mentioned several things. I heard earlier in your testimony or in response to one of the questions, you indicated that none of the technicians were permitted to write their own instructions, that there are standards to follow.

I think you also expressed confidence in your oversight processes to catch these things. And just now to my colleague's questions, you talked about how everyone in Dayton knew that this was going on and that it was a failure of leadership.

Which leadership are you referring to? Where is the failure?

Dr. PETZEL. I did not refer to everyone in Dayton knew this was going on. I referred to everybody in the dental clinic—

Mr. JOHNSON. Right. Okay.

Dr. PETZEL [continuing]. Knew this was going on. And I think the primary failure there was the leadership in the dental clinic.

Mr. JOHNSON. Okay. Well, let me refer you to a GAO report that came out today. The title of it says "Weaknesses in Policies and Oversight Governing Medical Supplies and Equipment Pose Risks to Veterans Safety." Down in the oversight over reprocessing requirements, let me give you this quote.

It says although VA headquarters receives information from VISNs on any noncompliance they identify as well as VAMC's corrective action plans to address this noncompliance, VA headquarters does not analyze this information to inform its oversight.

Dr. Petzel, how can you express such confidence in an oversight process that does not even properly identify and analyze the information coming up through the system? And I submit to you that the failure in leadership is not just at the dental clinic. It is right here in Washington.

Dr. PETZEL. Well, first of all, Congressman, the issue in the dental clinic in Dayton was not one of reprocessing. This was one of infection control and the practices of a particular individual.

Mr. JOHNSON. But aren't those covered under your oversight processes?

Dr. PETZEL. In a different manner than the reusable medical equipment, but, yes, there are some oversight processes associated with that.

Mr. JOHNSON. Well, let me take just a second. Why GAO did this study, Department of Veterans Affairs' VA clinicians used expendable medical supplies, disposable items that are generally used one time, and reusable medical equipment, which is designed to be re-used for multiple patients.

And this GAO study looked at all of that. So they are looking at not only the reusables, but they are looking at the exposables and they identified serious weaknesses in the analysis and identification of the information that comes to VA headquarters.

How do you respond to that?

Dr. PETZEL. We agreed with them and we agree that that was an appropriate thing to be doing and are now instituting a process to do that, to systematically look at the information we get to look for trends, to look for possible themes that run through those things. And we are now doing that. We agreed with them that that was a wise thing to be doing.

Mr. JOHNSON. I guess I refer back to my colleague, Mr. Filner. You know, we have been talking about these things for a very, very long time. Why are we just now starting?

You know, I met with a group last week, whether it is in the oversight of expendables and reusables or whether it is in oversight of the claims process, I met with a focus group that has identified glaucoma cases where patients, veterans have been identified with glaucoma and, yet, their referral for treatment took so long to get through the system that by the time it actually came up that they got treatment, it was too late and their condition was irreversible.

And in the oversight and investigation arm of this Committee, I can assure you we are going to be looking into those as well.

So how can we say that your oversight processes are even close to being adequate and why are we still talking about these things rather than doing something about them to protect the health and welfare of our veterans?

Dr. PETZEL. Well, Congressman, we have not just started doing this. We have been doing this for—

Mr. JOHNSON. But that is what you just said. That is what you just said.

Dr. PETZEL. I said that particular—

Mr. JOHNSON. You said we are now doing it.

Dr. PETZEL [continuing]. I said that particular aspect of the oversight is something that we are beginning to do early in 2010.

Mr. JOHNSON. My—

Dr. PETZEL. But the process of looking at RME, of improving RME, of oversight, of training, et cetera, these began quite a long time ago. And they have been continuously improved since our first instance of exposure possibly in 2008.

Mr. JOHNSON [continuing]. My time is up, Dr. Petzel, and I am going to yield back, but I want to just summarize with this. And I agree with my colleague, Mr. Filner.

If there is anything that it appears that the VA is expert in, it is talking around these problems and kicking the ball down the stream in a number of areas. We do not seem to get specific solu-

tions to specific problems that greatly affect the health and welfare of our veterans. And that is a very concerning scenario to me.

Mr. Chairman, I yield back.

The CHAIRMAN. Mr. Reyes.

Mr. REYES. Thank you, Mr. Chairman.

And thank you, gentlemen, for being here this morning.

I wanted to ask if there was a way to compare what is occurring at the VA in terms of these particular issues, failings with whatever the standard might be on the civilian side or perhaps even in other systems similar to the VA even if we are considering other countries.

I understand that my colleague, Mr. Walz, asked something similar, but I have to leave for a little bit and so I apologize for doing that. But I wanted to know if there is a basis for comparison about what is occurring at the VA.

Dr. PETZEL. Well, Congressman Reyes, there is and there is not. First of all, whatever, however we compare to the civilian sector, the fact that this happens to even one of our patients is not a good thing and needs to be changed and needs to be improved.

So on the one hand, it is almost irrelevant how we compare to the private sector if we are allowing these things to happen. I think we need to address that directly in the ways that we are able to do this such as what is our disclosure policy like, how does our disclosure process work. We can compare that to what some private-sector people do. And ours compares very favorably.

In terms of the incidents of this happening, it is not possible to compare it. And, again, I think that is irrelevant. The fact that it happens once is too often in our system and we need to be working in the direction of this not being able to happen ever again.

Mr. REYES. I understand.

Dr. PETZEL. It is very hard to compare. I just have to say it is very hard to compare.

Mr. REYES. Well, first, but my point is and you are right. Even one instance is one too many, but the reality is, and that is why we have lawsuits against doctors, against hospitals, sponges have been found stitched in after operations and scissors and all those kinds of things, the reality is that those kinds of things exist and happen in medical treatment.

My point was if we are going to, are we in essence holding the Veterans Administration accountable realistically compared to other medical systems or are we in a situation where perhaps the VA needs to have an assessment, a self-assessment of the quality of healthcare that is going on because perhaps incidents are much higher than they would be in other kinds of systems?

That was the point of my question. Yes, we can criticize you for every single misstep, but, you know, we all should strive for perfection, but the reality is perfection does not exist in the medical world just like it does not exist any place else.

We are seeing the shuttle delayed by a week or so because of a mechanical problem. And that is in a system that is designed by all the checks and double checks and triple checks to be a zero defects operation. So that was the question that I had.

Dr. PETZEL. Congressman Reyes, I appreciate that. First of all, as the gentleman from the GAO said, we have to be held account-

able for following the policies and procedures that we have out there. I mean, we should, number one.

And number two is that whatever the comparison might be between the private sector, we need to again be held accountable for how we do. And I think that the goal has to be that we do not leave any surgical sponges in a patient's abdomen, that we do not fail in our reprocessing efforts with any piece of reusable medical equipment. I mean, that needs to be the standard against which we are judged, not necessarily what goes on.

So I appreciate the concern and I appreciate the angst that people feel about the failures that we have, but I do not want to excuse those by saying that we are better than the civilian sector.

We have to solve those problems internally by following or having the right policies and procedures, by following those policies and procedures, by having the kind of oversight that is necessary to assure us that is happening, and then, as you all have said repeatedly today, we need to hold people accountable if they do not follow those procedures.

Mr. WILLIAMSON. If I could add to that, I think, Chairman Miller, you hit the nail on the head initially when you said that you could have all the requirements, you know, very good requirements, but if people are not following them, therein lies a problem. And let me just give you one example.

In July of 2009, VA came out with a directive for its medical centers that said you shall have or you shall develop devicespecific training for your RME equipment.

When we went into St. Louis in the fall of last year, they had not developed that kind of training requirements for 80 percent of their RME. And that was 15 months after the directive came out and it was 6 months, we were in there 6 months after the initial incident with the dental instruments.

So I think, again, it is tough to compare the private sector with VA. I think VA in many cases had very good policy requirements and very good policies, but you have to get people to implement them.

The CHAIRMAN. Thank you.

Mr. REYES. Thank you, Mr. Chairman.

I was just going to ask perhaps the question that needs to be answered is, as we talk about accountability, how when issues like this come up, how they respond to it, not just with procedures, but accountability by the people that have been involved which, by the way, when Dr. Petzel mentioned, the Secretary has been in my district and I think Mr. Filner was there with us, his goal is to have the best available healthcare system on the planet, that has been articulated. We just have to make sure that there is accountability.

Thank you.

The CHAIRMAN. Mr. Runyan.

Mr. RUNYAN. Thank you, Mr. Chairman.

And thank you all on the panel for your testimony.

I actually just chaired the DAMA Subcommittee hearing that the Chairman spoke about earlier. And I want to go back a little bit to what I ended up saying at the end. And I know the Chairman and several other of the Subcommittee chairmen have had meetings with Secretary Shinseki and we talked about accountability.

The fact that we use the word oversight means there is a total lack of accountability. It really needs to leave our vocabulary because oversight means there was a mistake and we need to move on from that because we all agree to that fact.

But going back to the dental scenario we were talking about that everyone knew was going on, have we made any steps in developing procedures and/or whistle blowing within that management team and moving in that direction to really stop something like that from happening because I think that is another place where I know people are afraid of stepping on toes of people senior to them?

And I really think it needs to be addressed because obviously there is a situation where that did not need to be happening. I think if you had procedures and protocols in place, you could have avoided those situations.

Dr. PETZEL. Congressman Runyan, you make an excellent, excellent point. What is missing and what needs to be there and needs to be in all of our medical centers is what is developing in St. Louis and that is an atmosphere where people can come forward, as you said, to the management, to whoever they need to come forward to and say this is happening, this is wrong, somebody needs to look at it. And that did not happen at Dayton. And for a long time, that did not happen at St. Louis.

There is very good evidence that things are changing in St. Louis. And my expectation is with the management team that is now in place in Dayton we are going to create that same kind of atmosphere.

Not only do people need to be able to come forward, but the management team needs to be able to sit down and candidly discuss what is going on in the medical center to keep each other informed as well as hearing from what is coming up. And, again, just to reiterate, that was not the case at Dayton.

Mr. RUNYAN. I think we can all totally agree on that. And, you know, my experience with dealing with higher powers is, you know, a lot of times, the truth hurts. And I think to be able to have that communication, open communication in a team is desirable no matter what team you are on.

And you really have to make a push forward and just take the attitude of, you know, just the procedures that are in there, the standards that are in there, and, you know, the accountability you have personally to just get the job done and not worry about what my superiors are thinking but knowing that whether someone lower down has the backing of the Secretary who is going to blow the whistle, they need to be informed and assured that if they do blow the whistle on someone that it is not going to cost them their job and/or their career.

With that, Mr. Chairman, I yield back the remainder of my time.

The CHAIRMAN. Mr. Carnahan.

Mr. CARNAHAN. Thank you, Mr. Chairman and Ranking Member Filner.

You all have been on this issue. You both have been to St. Louis with a Missouri, Illinois bipartisan delegation and I appreciate your commitment to this issue.

Also, I want to make really just a brief personal thanks to Phylicia Woods, who is LA on my staff, who is going to be leaving to go in the Peace Corps after this hearing. And I want to thank her for all of her great work for my office and for veterans in St. Louis, also the Veterans Advisory Committee that we work with in St. Louis who are back home watching this hearing today, and the many committed medical professionals at Cochran that are committed to reforming that institution.

I spoke with Director Rema Nelson a little over a week ago. She described to me that they are working on a comprehensive turn-around plan, that they are working to incorporate many of these recommendations from the GAO and the Inspector General that can help this facility be what it needs to be for the veterans in St. Louis.

My question for Dr. Petzel is, are you aware of this plan? We were promised to get a draft copy of it. By the end of last week, we have yet to receive that.

But I think it is critical to turn that facility around, to have such a plan, to get buy-in from our veterans, our community leaders because we want them to succeed. But I think they have to have an aggressive plan to make that happen and they have not had it up to now.

Dr. PETZEL. Congressman Carnahan, I have not seen yet the plan. As soon as we finish from this hearing, I will get in contact with the director, Rema Nelson, and find out where it is. And if she has promised a copy of it to you, we will be sure that you get it.

[VA subsequently provided the following information:]

The St. Louis plan for the way forward was delivered by OCLA on Tuesday, May 10, 2011.

Mr. CARNAHAN. To me, that is critical point going forward.

And to the point of reforming the adverse event disclosure procedures, we may have the best scientific procedures there are in the world, but if it does not reflect the human impact on veterans, it is not a good system. So we have to have the human side of that system in place.

And to Mr. Filner's point, at the hearing in St. Louis, there was not a case management part of this in place. People in St. Louis, they got a cold form letter like a parking summons in the mail. That is it. And so that is when folks at the hearing said at the request from many people at that hearing that they would follow on and have the more personal followup.

So I appreciate that that happened, but that is not where this started.

Dr. PETZEL. Thank you, Congressman.

I will have to go back and review my recollection of it. I do know that we eventually ended up with case managers' phone calls in addition to the letters. And you may well be right that that occurred after the hearing. I just do not remember the sequence.

Mr. CARNAHAN. I am right and that is the way it happened.

Dr. PETZEL. Okay.

Mr. CARNAHAN. So we need to review it. That is the way it happened.

Dr. PETZEL. I will believe you.

Mr. CARNAHAN. Anyway, the other thing, in light of the incidents at Cochran and other medical centers around the country, at what point is the management evaluated at these institutions and are they held accountable?

Again, I am very pleased that the management of Cochran is developing this plan, but what we have heard from Dr. Daigh and others there have been repeated visits, citations, problems that have not been addressed starting with his work back in March of 2007, another visit and evaluation in August of 2008, May of 2009, March of 2010 and, of course, the Congressional hearing in July of last year. A lot of these problems are still lingering or not fixed yet.

And, you know, the question is, how many times do our veterans have to fall in the same pothole before we fix it? And so I want to have this system in place. I want to have a comprehensive plan in place for Cochran. I want to get the community and veterans to buy-in, but at some point, people have to be held accountable if it is not implemented.

Dr. PETZEL. I absolutely agree with you, absolutely agree.

Mr. CARNAHAN. Mr. Chairman, my time is up and thank you again. And I yield back.

The CHAIRMAN. Thank you.

Dr. BENISHEK.

Mr. BENISHEK. Thank you, Mr. Chairman, Mr. Filner, and thanks for the panel here.

I worked at the VA during the time of this colonoscopy event and I was aware that they shut the whole thing down. So it has some personal meaning to me.

And I guess what I have found here is I guess you talked about this dental clinic a little bit, but are those people you identified here in your testimony, you know, the dental supervisors, the facility chief of staff, I mean, that dentist in question, I mean, did those people—have those people been punished or have they been fired or what exactly happened to those people?

Dr. PETZEL. I have to speak generically. The principal in question has retired. And there is no way that we can prevent somebody, even though we may want—

Mr. BENISHEK. Right.

Dr. PETZEL [continuing]. To discipline them, from retiring—

Mr. BENISHEK. What about the chief of staff?

Dr. PETZEL. The chief of dentistry I believe has resigned as well. And the chief of staff of that medical center, we have not yet determined what the situation is going to be.

There are three administrative investigative boards going on right now as it relates to Dayton and we do not have the results of those yet.

Mr. BENISHEK. All right. This is the kind of thing that is frustrating when there is, you know, a serious lapse of leadership that you mentioned, and, yet, you know, a significant amount of time has gone by and you have not decided what to do with this guy or gal.

The other thing that disturbs me is Mr. Williamson's testimony about the 15 months elapsing between the, you know, the saying that you are going to be doing implementation of protocol for clean-

ing RMEs and then he reports that 80 percent of the—that has not been done in 80 percent of the places after 15 months.

I would like to know who is responsible for that. I mean, who is the guy in charge of that, implementation of that process?

Dr. PETZEL. Just a comment. There were six medical centers that they reviewed out of 152. And I do not know where those medical centers were. If the GAO is willing to identify them, we would be delighted to go in and look and see what the problems were and what happened.

Mr. FILNER. Why didn't you ask them before this?

Dr. PETZEL. I beg your pardon?

Mr. FILNER. Why didn't you ask them to identify the medical centers?

Dr. PETZEL. I just got the GAO report.

Mr. BENISHEK. Well, it is just frustrating to me to have—you know, we have two agencies of the government here that sort of conflict. And, you know, Mr. Williamson seems to identify an area of leadership, that there is something wrong, where there is 15 months and now we—I cannot—how do I understand this information. You are saying one thing. He is saying another. And we are trying to decide how to best treat our veterans.

I think we definitely need to followup on this, you know, from this Committee further and make sure that there is, you know, not only at the chief of staff level but higher up in the chain of bureaucracy, that we have effective leadership and accountability for those people at each of those higher up positions.

Mr. Williamson, did you have a comment?

Mr. WILLIAMSON. By the way, we went to Albany, Cheyenne, Detroit, Miami, Palo Alto, and St. Louis.

You know, obviously we cannot travel to 90. And what we try to do when we go to a location is we look for systemic problems that transcend one facility. So while you only may go to a small number, you are verifying that something is missing throughout the system. So that is kind of the methodology that we use.

I have to say that as most of the Members here who have been a recipient of GAO reports know, we have a very rigid and rigorous process for verifying our information. And all the things that I have told you in the report and in my opening remarks, VA has agreed with. We have an exit conference with VA. We give them 30 days to comment and so on. And we verify that pretty rigorously.

So I do not think Dr. Petzel is disagreeing with the 80 percent figure I used. I think he is probably coming from a different way. But, you know, accountability is our middle name. And so we are pretty careful, you know, about being right.

Mr. BENISHEK. Well, thank you for your answer.

I just want to try to follow up with this at a later date, so I do not lose track of this kind of information. I appreciate your comments and yield back the remainder of my time.

The CHAIRMAN. I was just looking at a copy of the GAO report where there is a letter from Mr. Gingrich, Chief of Staff, saying VA has reviewed this report and appreciates the opportunity to comment on the draft.

So VA had seen the draft, correct?

Dr. PETZEL. Just got it.

The CHAIRMAN. You saw the report. This is talking about the draft.

Dr. PETZEL. Oh, the draft. Yeah, I am sure that it was reviewed here. I cannot recollect that I saw it, but, yes.

The CHAIRMAN. You have not reviewed the draft?

Dr. PETZEL. I cannot recollect that I did. That does not mean I did not. I just do not know.

The CHAIRMAN. If there was a report entitled "Weaknesses in Policies and Oversight Governing Medical Supplies and Equipment Pose Risks to Veteran Safety," you would not remember that you saw it?

Dr. PETZEL. I might not, no.

The CHAIRMAN. I hope you did. I hope you did or somebody at VA did.

Ms. Wilson, you are next. Thank you for joining the Committee today.

Ms. WILSON. Thank you, Chairman Miller and Ranking Member Filner.

I am new to this and I inherited this from my predecessor, I am from Miami, Kendrick Meek. And so my following of this debacle was by reading the *Miami Herald*.

And then my great Congresswoman Ros-Lehtinen invited me to a tour of the VA hospital and a meeting with the people there, with the administrators there, and then a press conference.

And at the meeting, I was really shocked by the cavalier attitude of the administrator of the hospital and the way she was going about answering the questions.

First of all, I found out that there were five people who contracted HIV-AIDS (acquired immune deficiency syndrome), HIV, eight hepatitis C patients, and one hepatitis B. We are not sure whether it was from the instruments or but they have it and they were tested with the unsterilized instruments.

So my question to her was, where are these people now and what are they doing. And no one at that meeting had an answer. No one could tell us what was happening with these particular patients who were infected.

So I asked them to assign one person from the hospital to be in charge of, sort of like a case worker, to make sure that they were being treated, that they were following up with it, and to get back to us and let us know what was happening.

So we got a letter saying that they had followed up with all of them except four. And they could not find these four. And they could not find the—they could not—four were—came in for one treatment and then—I mean, two and then two they could not find at all.

So my concern was that these two people, and they did not identify which two they were, they did not identify which malady they contracted from the hospital, and I am just wondering for their safety and the safety of the public is there any way that we should include the Florida Department of Law Enforcement (FDLE) or the Federal Bureau of Investigation (FBI) or the local authorities to try to find these people, even private investigators, so that they would know that they are infected and they, in fact, should have the opportunity for treatment. That is the first question.

The second question has to do with Ms. Berrocal who is the woman that was in charge of the hospital. It is my understanding when this debacle first occurred she was reassigned and someone from Jacksonville took her place.

Before she was put back into her place at Miami Hospital, there was supposed to have been a report and some sort of evaluation that was supposed to be released before she was sent back to her position.

She was sent back to the position. There was no report done. The *Miami Herald*, through a public records request, asked for this report and to date, they still do not have it. And she is still there.

Are you aware of all of these circumstances at the Miami Veterans Hospital?

Dr. PETZEL. I am aware of them, Congresswoman. There was a report. And Ms. Berrocal is back at the Miami VA Medical Center. I do not recollect the specifics of what was in the report, but we can certainly resurrect that and see.

I would say that I think that Congressman Ros-Lehtinen and others would agree that Miami is really beginning to turn around, that the atmosphere and the practices of that hospital are really quite improved over what they were when we originally had the colonoscopy incident several years ago.

Ms. WILSON. My question has to do with finding the patients who are unaccounted for. What can we do to find them at this point?

Dr. PETZEL. That is a good question. And I honestly do not know. I know that the medical people follow up. I do not think that they use private investigators, the police, or the FBI. That is certainly something that we can look into if we still are not able to contact those last two patients. And we will look into that.

Ms. WILSON. Okay.

The CHAIRMAN. Thank you, Ms. Wilson.

I would like to use the Chairman's prerogative if I would and beg the indulgence of the Committee Members. And since we are dealing with Miami, which Ms. Wilson has been talking about, I would like to go ahead and recognize Chairman Ros-Lehtinen if she would to continue the questioning regarding Miami.

Ms. ROS-LEHTINEN. Well, thank you so much, Mr. Chairman and Mr. Filner. Thank you for your leadership on this issue that has been ongoing. It is so frustrating for so many of us. And Mr. Under Secretary, you said you are doing better, but you continue to find patients who were not notified in Miami, 12 additional names this past December. You state that excellent way of notifying industry standards, those kinds of phrases.

And while I am happy that the VA is making efforts to reform its procedures in the area of reusable medical equipment and in notifying at-risk patients, we have been down this path before. We are so frustrated. Ms. Wilson, Mr. Rivera, Mr. Diaz-Balart and I.

In 2009, the Miami VA, as you know, notified over 2,400 veterans that they may have been at risk for infectious diseases. Then a year later during a review of the VA's facility logs, a year later an additional 79 veterans were discovered to have been at risk. And now just this past December where Ms. Wilson was talking about another 12 names were discovered in an third review. Of these veterans, 17 have been tested for HIV hepatitis B or C. It

doesn't mean that it is cause and effect, but it is very alarming. So over these 3 years, the list has kept growing.

Members have previously sat in this very Committee room, were assured by VA that the Administration was taking action to correct this previously failed policy. This has not happened, those steps have not been put into place.

The VA Central Office initially left it up to the Miami VA to identify at-risk patients, and I would like to ask these questions.

Will another review, if we were to do another review, find more at-risk patients? What degree of confidence do we have that every time you have done a review you have found additional folks who have fallen through the cracks? I don't have confidence that the entire pool of at-risk patients have been identified.

Secondly, are there now oversight mechanisms in place at the VA Central Office where an independent authority will take charge and make certain that a local VA like Miami will meticulously review patient files to identify those who require notification? Or is the attitude of the Central Office things are going well, patients are being identified, and all systems go?

And number three, so here we are again, Members are being told that the VA has taken steps to eliminate the problems from the VA centers, and if additional names are found or if it is discovered that facilities continue to use improperly sterilized equipment what then? What steps will be taken?

And I share Congresswoman Wilson's frustration. We have had so many meetings about the follow up, and I remember the first meeting that we had, and that was with her predecessor, Mr. Meek, and we made this oh so brilliant suggestion that perhaps they could go door to door and knock on the veteran's home, apartment, wherever the veteran is, and they said, oh, that is a good idea. And we are just so brilliant that way. And so they said, okay. So they got back to us and they said, yes, we have knocked on the doors. And then we kept asking, okay, of those you have identified and you have knocked on their doors, have each of these veterans been informed that they can get treatment? Have they turned the treatment down?

And I understand that there are privacy concerns. We are not asking for their names and their addresses, but they cannot tell us, at least they haven't told us. They have not told us this is the pool, these have been notified, these are under care. We have no degree of confidence that they are in fact getting care. We don't have to force someone to get care, but we are talking about community health problems if these veterans don't get the care.

So it is not just that veteran, it impacts the entire community. You can't force them to get care, but you can certainly work with that veteran to have that veteran understand how serious this is, how it can impact the community, and let us know that those veterans are indeed getting care.

But I want you to understand how frustrated we are that we have these meetings once and again and again, and honestly we are saying this is water, and they will say, oh, okay this is water, and it is very patronizing to us, because we know that they must know more. I pray that they know more than they are telling us.

I pray that the veterans are getting the treatment that they are getting, but they are not telling us.

So, I would like to say, with a degree of confidence, to my constituents this problem really has been worked out after all of these years, but I don't have that confidence, but I thank Ms. Wilson for everything that she has been doing and Mr. Rivera, Mr. Diaz-Balart, we are all united, we have a very united delegation on this, and I thank the Chairman and the Ranking Member for being such fearless leaders on this.

I would like to see if you could answer those questions. Are we going to do another review in Miami? Do you have a degree of confidence that every at-risk individual has been identified, that there has been some followup care, that everything really is what it should be? And if it turns out that it isn't what then?

Thank you, Mr. Chairman.

Dr. PETZEL. Thank you Congresswoman. I can answer those questions. First let me start with the last.

We can provide you with information. Again, not specific names, but about the number of people that have been contacted, the number of people that are under care, and that is available and we will certainly get that to you.

The second thing is when they are notified part of that notification involves one of the consequences of this potential exposure and what are the remediations so that if somebody feels as if this indeed was the cause of their contracting HIV or hepatitis C they have a legal remedy, and every single person that we notify that is positive is told about that legal remedy.

In terms of the—

Ms. ROS-LEHTINEN. And let me ask you, when you say that we can get you that, that is the same thing that happens to us when we meet with them. They will say they can get it to us as if we were meeting on what to order for lunch. I mean that is the purpose of our meeting, so that is the information we want, and then after every meeting they say we will get you that info, so that is the purpose of what we want. All of those individuals without any names where are they getting care?

Dr. PETZEL. We can get that to you within a week.

The second question involved the process and how certain am I that we have identified and notified everybody. And I am as certain as I am going to be, that we have done that.

We learned a lot in the Miami process, just to reiterate. Initially that was the identification of who should be notified was the responsibility of the facility, and they made a decision to use a computerized medical record and the coding that was in there to identify the people that had colonoscopies. It was found out several months, almost a half a year, after that notification someone called up and said, I had a colonoscopy during that period of time but I wasn't notified.

So there were some errors, if you will, in the coding that occurred that went into the computerized medical record. That was the second iteration.

And then the third iteration had to do with a logbook that shouldn't have been there but was used and had in it again 11 patients that weren't on the computer list because those 11 patients

had been inappropriately coded when they went into the computer list.

But the primary lesson we have learned here is that we have a Central Office team now that does the process of identifying who should be notified.

This event is something that occurs hopefully once in the lifetime of a medical center. They have no experience in developing the material that you need to get a list, so we have now made that a Central Office function.

We send a group of people down who have experience doing this and have done this in other circumstances and they have become responsible for developing the list of people that need to be notified.

Ms. ROS-LEHTINEN. Thank you. And Mr. Chairman, just one last note. The *Miami Herald*, Fred Task, has been doing an excellent job on this and I hope that he would not need to file another Freedom of Information Act to get information about these vets. I would hope that you would share information with our community, not names and addresses, but what is new on the status. It is a big concern with them.

[The VA subsequently provided the following information:]

Of the 17 patient positives, one (1) expired from other causes. One (1) patient is currently being followed and treated at a VA Medical Center in Arkansas and was last seen on April 9, 2011. One (1) patient is currently being followed by his private physician in the Miami area. The remaining fourteen (14) patients are being followed by the Miami VAHS. Of those, eleven are actively receiving care. The remaining three patients have not responded to VA's outreach efforts. We will continue to make sure that they are aware of our services and remain available to treat them if they choose VA care.

The CHAIRMAN. Thank you, Madam Chairman. Mr. Clay.

Mr. CLAY. Thank you, Mr. Chairman, thank you for conducting this hearing.

Let me personally thank you and Mr. Filner as well as the Committee staff for giving the time and attention to the issues that have arisen over the last year or more at Cochran VA hospital in St. Louis in my district.

Let me start with Dr. Daigh or Mr. Williamson. Have the sterilization problems in the dental clinic at John Cochran hospital been resolved?

Dr. DAIGH. Yes, sir, I believe they have.

Mr. CLAY. Thank you. You think they have.

Okay, now what was the final source of the contamination in the surgical unit? What was the cause? Can either one of you speak to that? Or can you, Mr. Petzel?

Dr. PETZEL. I think I can. I don't believe, Congressman, that they have had any experience with that, and I assume that you are referring to the fact that there was some discoloration discovered on surgical instruments by one of the scrub nurses, and we then stopped surgery in St. Louis while we tried to discover what that discoloration was.

There was not a sterilization problem or an issue, those instruments were sterile, and eventually we came to the conclusion that it was a combination of events; the fluid that was used in pre-wash and the filters on the steam sterilization unit. When the solution

was changed and when the filters were changed we were able to get rid of the discoloration and that started up again.

This is something that we discovered and I think was managed quite well.

Mr. CLAY. Okay, Doctor, was that a vendor issue or was it inside the hospital?

Dr. PETZEL. Well, it was inside the hospital insofar as the instruments were being sterilized in the hospital, but again, it had to do apparently to the fluid that was being used and to the filters in the sterilization.

Mr. CLAY. Which caused the spots on the instrument.

Dr. PETZEL. Which caused spots on the instrument, correct, discolorations, but not an issue of sterilization.

Mr. CLAY. Okay. Let me ask you, why does Cochran VA Medical Center consistently receive a low patient satisfaction when compared to other VA facilities, and why does this problem persist year after year?

Dr. PETZEL. Let me take a few minutes to explain this.

Mr. CLAY. Go right ahead, I have a little time here. Go right ahead.

Dr. PETZEL. When you look across the country inside or outside the VA wherever you have customers, wherever you have patients the satisfaction of the individual patients with their care is a direct reflection of employee satisfaction. There is a very, very strong relationship. If you have a satisfied workforce that enjoys their job and is doing it, you know, with a smile, so to speak, you are going to have generally speaking a group of patients that are going to also feel good about their experience.

And I think there was a history at John Cochran, again before my time, where we had an employee group that was not particularly satisfied or happy in the workplace.

Mr. CLAY. Now wait a minute, let me stop you. That tells me as a cultural issue—

Dr. PETZEL. Absolutely.

Mr. CLAY [continuing]. In that facility.

Dr. PETZEL. Absolutely.

Mr. CLAY. Have you addressed it and how?

Dr. PETZEL. I believe that we are addressing it. Rema Nelson, the new director there has created a much more open atmosphere where people can talk to her about problems, she is approachable, she is out walking around that hospital continuously testing the waters, taking the temperatures, seeing how things are happening.

We hear now from the union and from the service organizations that the atmosphere there has changed, that this is a better place to work, a happier place to work.

My hope and expectation is that this is going to be reflected in the patient satisfaction scores.

Mr. CLAY. When will we know that?

Dr. PETZEL. Every month we do a series of inpatient and outpatient satisfaction scores, so I am hoping relatively soon. I don't know how long. I don't know how long, but I am hoping relatively soon we will see a change.

Mr. CLAY. Okay, my concern is this, Doctor. If we cannot improve conditions perhaps it is time for the St. Louis region to try perhaps

a voucher system for patients to receive medical attention from our two world-class medical facilities that are a stones throw away from the VA Cochran.

If you cannot do the job for these people that deserve it, perhaps we need to look at another system to deliver medical care to them.

Dr. PETZEL. My expectation is that we are going to see improved patient satisfaction scores at the John Cochran.

Mr. CLAY. As soon as you receive it share that with us.

Dr. PETZEL. We absolutely will.

[The VA subsequently provided the following information:]

**Patient Satisfaction at St. Louis VAMC, 2011**

*National Satisfaction Scores (SHEP)\**

<b>INPATIENT SATISFACTION</b>	<b>2011 (%)</b>
John Cochran	42.3
Jefferson Barracks	Cases too low
Overall	42.3

<b>OUTPATIENT SATISFACTION</b>	<b>2011 (%)</b>
John Cochran	54.7
Jefferson Barracks	40.3
Overall	49.1

Because of the time lag between the time of care and the survey report, the FY 11 scores reflected here only data from October through January. Until second quarter data is obtained a comparison between FY 10 and FY 11 is difficult due.

*Quick Card*

In order to provide some real time information on customer satisfaction, the Medical Center has implemented a Quick Card survey system. Here are the results of the Quick Card surveys from December 2010 through April 2011:

<b>QUICK CARD QUESTIONS (yes/no)</b>	<b>YES RESPONSES (%)</b>
Courtesy of Staff	97
Timely Service	88
Experienced Delay	25
Facility Appearance	94
Professional Appearance of Staff	97

Mr. CLAY. Thank you. Thank you, Mr. Chairman, and I yield back.

The CHAIRMAN. Ms. Buerkle.

Ms. BUERKLE. Thank you, Mr. Chairman, and thank you to you and to Ranking Member Mr. Filner for your taking the lead on this issue, very important issue, and thank you to our panelist today.

I am Chairman of the Subcommittee on Health. I am a registered nurse and I also am an attorney and I represented a major teaching hospital for many years, so this is all of very particular interest to me.

I think the first thing that concerns me is when we refer veterans to our healthcare veteran facilities that they have some sense of what Dr. Roe mentioned, trust, and that we are referring them to a system that will take care of them, and at the very least that care should be what the industry offers.

I think you are all familiar with JCO, every hospital hunkers down when The Joint Commission comes in and reviews all of the processes, every system, every process, and they hold the hospital accountable and everyone prepares for that and there is that accountability factor.

So I guess my first question, Dr. Petzel, is what in the VA system is analogous to the JCO reviews that a hospital has to undergo every few years?

Dr. PETZEL. Well, Congresswoman, first of all we do undergo the Joint Commission reviews just like everybody else, so our hospitals are all accredited by the Joint Commission.

Number two, and the process has changed recently insofar as now you don't know when they are going to come, and what happens is what we call continuous readiness. That is you have to be ready for them to drop in at any moment. They do not announce that they are coming and they show up at your doorstep on a Monday morning or a Tuesday morning and begin their survey.

It is a tremendous improvement from my perspective, because previously we all dropped everything for 6 months before the Joint Commission came and cleaned the floors and uncluttered the hallways and did all those sorts of things and now you have to do that all the time, which is the way it should be.

We also have the SOARS process, which is an internal within the Veterans Health Administration (VHA) process of inspection that occurs. The OIG does their Combined Assessment Program reviews. Every 3 years they go to every facility and are much more thorough than the Joint Commission in terms of oversight and looking at us. And those are probably our two biggest VA-related internal reviews like the Joint Commission.

Ms. BUERKLE. Well, then how do situations like these occur with that kind of oversight, with that—kind of what happens that these situations—the VA finds themselves in these situations? Any private hospital would have corrected it, it wouldn't happen again. And these instances continue to occur. And if you have this oversight in place why aren't corrections being made?

Dr. PETZEL. Well, at each one of the medical centers, Congresswoman, that are involved those corrections have occurred. We don't have a recurrence of any of these incidents at any of the medical centers that were—of these four that we have been discussing. They have cleaned up their act, they have changed their practices, and they are doing the things that they need to do to appropriately sterilize the equipment.

I think that why this has happened in our system, we are a national integrated system, everybody should be aware of what is going on, and I think again there is a failure of leadership, people

not holding other people accountable, people not checking to be sure that indeed everybody does have training in the SPD, indeed everybody does do their job. We are supposed to watch somebody do their training, and I think when these things break down it is a failure of those things to happen. It is again a failure of leadership.

Ms. BUERKLE. I would submit that if it is happening in any of the VA hospitals and it hasn't been corrected we are looking at a hospital system, and so the policies and procedures should apply to all. So if there is a problem here that correction should take place in all of the hospitals, and apparently that hasn't been done.

Dr. PETZEL. And I absolutely agree with you, Congresswoman, that is absolutely the way this system should work.

Ms. BUERKLE. Just briefly in my few seconds that I have left. When we look at medical malpractice, the question is also asked what is the deviation in the standard of care, and that is how we gauge whether or not there is malpractice.

What is the standard of care that the VA hospital, what standard of care would you be adhering to? Which one standard of care? I hear lots of different oversights, but what is the standard of care you apply?

Dr. PETZEL. I am sorry, Congresswoman, I don't quite understand the question.

Ms. BUERKLE. Well, I assume the VA hospital adheres to one set of processes and one set of procedures based on something, and whether it is JCO standards or what—it sounds to me like it is rather arbitrary.

Dr. PETZEL. First of all sort of at the top would be the Joint Commission standards. We are again accredited by the Joint Commission, every one of our 152 medical centers and 871 outpatient clinics have that accreditation, so that would be one standard.

Second, we have policies and procedures that are much more specific than what the Joint Commission would be looking at for many, many things, and we adhere to those standards.

And I think we would not get argument either from Dr. Daigh or Mr. Williamson about our policies and procedures. We have good policies and procedures that are at the top. The problem is adherence to those policies and procedures. The problem is our people following those policies and procedures.

So I am not as concerned about the standard that we are setting as I am about are we adhering to that.

Ms. BUERKLE. I am out of time. Would the Chairman just allow one more question?

The CHAIRMAN. Very short.

Ms. BUERKLE. Dr. Daigh, would you agree with what Dr. Petzel is saying?

Dr. DAIGH. Yes, ma'am. I believe VA has really quite excellent policies and procedures that are in most cases industry standard and often put together with the use of experts who spend part of their time at VA facilities and part of their time at the various universities. So much of the staff at the VA is medical school plus VA, so I think their policies are correct.

As I indicated in my statement, I think the issue is execution, that is doing what you are supposed to do every day.

Ms. BUERKLE. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman. I want to thank the Chairman and the Ranking Member for their tenacity on this issue, but I particularly want to thank the Chair.

Chairman Miller has taken a particular interest in these issues. His care for veterans has been evident throughout his work on this Committee, but in these instances where these specific infractions came to light Chairman Miller has dived in, he came to my community and has personally read all the documents that are involved, and I want you to know that if it hadn't been for Chairman Miller, I don't think my community would even have the information that it has today.

The VA has stone-walled my community, they have not been responsive. If it wasn't for this Committee beginning to force the VA to work with my community, I honestly believe that we would have even less than we have today.

Mr. Petzel, you said this is unquestionably a failure of leadership. Then when you were asked about accountability for that leadership, what happened to those people who would have been that failed leadership, you really didn't know what had happened to the people in this chain.

We have in my community a dentist who for almost 2 years violated the standard care of practice, not sterilizing equipment, taking things from people's mouths, using the same gloves the entire day while working on people, not cleaning instruments and tools that he used on numerous people, and this isn't something that was going on for a couple decades in secret, it was visibly obvious, it was in a clinic that it occurred, that was located directly above the director's office. This wasn't even in an isolated, located facility away on campus. This is something that was known.

So when you say failure of leadership I agree. The dentist in question though got to retire, the Chief of Staff got to retire, the director was promoted.

So if it is leadership, if we go up the chain of command where it goes from the patient to the dentist to the chief of staff to the director no one has been held accountable. So we have a failure of accountability.

We also have a failure of being able to complete an investigation. The OIG was unable to talk to the dentist in question because he retired, or the chief of staff, or even the complainants because the people having left the system. So we don't have accountability and we don't even have the ability to do a complete and total investigation.

The review that was undertaken by the VA was pretty much done in secret. The review board that the VA empanelled and even the testimony that was taken when it was released to the community, the names of all the individuals were redacted, and they were redacted so we wouldn't even know who it was that you were relying on to review what had occurred in advising the VA as to what patients to be notified or even what their care was supposed to be.

I contacted the Greater Dayton Hospital Association for my community, your regional peers, and I asked them to review what you did provide the community. They provided a report basically saying

one, that all of the information needs to be released. There is a number of documents that are really critical for our community to understand whether or not you are taking appropriate precautions for those that were subjected to a risk of HIV and for hepatitis.

Secondly, they disagree with your scope of the patients that are notified. They believe that many more people were subjected to exposure to HIV and hepatitis, and so they have asked for in addition to an expansion of the documents that are released for additional patients to be notified.

Now I appealed your redacting of the documents that were provided to us. I was told that you wanted to protect those who were part of the review board so they would not be subject to harassment.

You know in our court system we don't let juries stand behind a screen. We require that they be held accountable to the community for what their decisions are on things that are very, very significant judicially and to people's lives.

There is no reason why you should be empanelling review Committees that are then done in secret, that we all then have to guess as to what their motives were, their backgrounds, their experience, or their basis for their determination.

When I asked for the non-redacted version to be released, you answered that even the dentist's name in question should not be released because of the nature of the investigation and seriousness of the allegation, the dentist could be subject to harassment or worse. You actually indicated that you didn't want to release it because he could be subject to annoyance or harassment. Annoyance or harassment like being subject to the risk of HIV and hepatitis? I mean this is incredibly serious, and the VA is not being open with my community or I think even giving an ability for proper oversight from Congress.

I have three questions for you. You said this is a failure of leadership, now we are going to come to the issue of your leadership.

Are you willing to expand the number of patients that were notified, tested, and received treatment as a result of the actions that occurred at the Dayton VA? Are you willing to release the documents that were requested by our Greater Dayton Hospital Association so that they can review your investigation to these practices? And are you willing to release the non-redacted review transcript from your review board so that we can actually evaluate your approach on this issue?

Dr. PETZEL. In answer to the first question, we are and will go back and look at the process that we went through in terms of identifying the patients that needed to be identified.

At this present time I stand by the decision that the clinical review board made as to who should be notified, but we are going to look at that.

Number two is that we have made available to the Committee, to the Chairman all of the material that they request. We cannot release some of this material to the Greater Dayton Hospital Association. We cannot release—

Mr. TURNER. Sir, hold on a second. I know my time is brief, but if you would permit it, Mr. Chairman.

I have the documents of the Freedom of Information Act provisions that you are standing on, they are all discretionary, and when I was briefed by your staff in my office they admitted it was discretionary. So please don't say that you cannot release them, because of course you can. There is no patient information that is being protected here, because no patient information is included in what is being asked. It is procedures, policies, and actions.

Dr. PETZEL. I am sorry, Congressman, but I have been told by our attorneys that we cannot release to you, or to the community, those unredacted documents.

Mr. TURNER. Okay. Well then they were in my office, your attorneys by the way, if you and I meet in my office with your attorneys and your attorneys say that it is discretionary does that mean that you are willing to release them? Because you are not prohibited from releasing them.

Dr. PETZEL. If they tell me that they are releasable——

Mr. TURNER. That it is discretionary.

Dr. PETZEL. Beg your pardon?

Mr. TURNER. That it is discretionary within your discretion you will use that discretion and release them.

Dr. PETZEL. I would have to then consider doing that, but that is not what I have been told.

Mr. TURNER. You are not required to maintain the redaction and you may release those documents.

So I would expect that you would use that discretion that you have and release them based upon your testimony today.

And then my third question. You were answering on the redaction and the release of the documents. Is it combined, both on the issue of redaction and release the documents?

Dr. PETZEL. Correct.

Mr. TURNER. Okay. Thank you. Mr. Chairman, thank you for your work on this.

The CHAIRMAN. Thank you, Mr. Turner. Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, briefly. Thank you, Mr. Chairman, I appreciate it.

Question for the panel. Should a person acquire an infectious disease and it is a result of a mistake by the VA health system, what resources are available to that individual besides the legal remedies that you mentioned?

Thank you.

Dr. PETZEL. That is an excellent question, Congressman.

First of all you can never establish for sure that it was associated with the event or that it wasn't associated with the event. The assumption has to be that if they had a colonoscopy with what was felt to be an unsterilized colonoscope and developed hepatitis C that that was responsible, so we assume the responsibility for anybody that is converted.

Two things are fundamentally available. They are eligible for and will receive healthcare from us for as long as they need it for the rest of their lives if that may be the case. Two, is that they have a legal remedy insofar as they could file what we call a tort claim and recover damages if the court indeed believes that there is a relationship between our event and their disease.

So healthcare on the one hand, compensation on the other.

Mr. BILIRAKIS. Does it require filing a lawsuit to receive any sort of compensation?

Dr. PETZEL. In most instances, yes, but let me ask one of the people here with me. I think that we may be able to service-connect somebody who develops a disease because of something we did. Is that correct? They believe so. Let me get back to you specifically about that.

Mr. BILIRAKIS. Okay, please do.

Dr. PETZEL. I will.

[The VA subsequently provided the following information:]

The statutory provision at 38 U.S.C. § 1151 authorizes payment of compensation for additional disability or death that is not the result of the Veteran's willful misconduct and is caused by hospital care, medical or surgical treatment, or examination furnished to the Veteran under laws administered by VA. To meet the qualifications of 38 U.S.C. § 1151, the proximate cause of additional disability or death must be:

- Carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault on the part of VA in furnishing the hospital care, medical or surgical treatment, or examination; or
- An event not reasonably foreseeable.

VA may pay compensation under 38 U.S.C. § 1151 for disability resulting from hepatitis B and C, as well as HIV, if there is competent medical evidence of record showing that these conditions were proximately caused by either carelessness, negligence, lack of proper skill, error in judgment, or a similar instance of fault on the part of the VA in furnishing hospital care, medical or surgical treatment, or examination.

Mr. BILIRAKIS. Thank you. I yield back, Mr. Chairman. Thank you.

The CHAIRMAN. Mr. Filner.

Mr. FILNER. Let me just go back to my original statement, Dr. Petzel.

Again, you have said over and over that again that it is a failure of leadership, and yet again, I think it is more bureaucratic defensiveness and secrecy. We don't know that there has been accountability.

I think we need to work with you and your lawyers to develop a new way to give us some assurance these issues are being handled. What you have given us today gives us very little confidence that these personnel decisions are being handled with some accountability. You gave us three examples of something happening, mainly retirement, or I forget what you called them. Three employees for all these years of problems?

Whether we can sit in executive session as a Committee and talk to you about that, I don't know. I think we have to examine that, Mr. Chairman.

We need a new process here because you are standing on Civil Service protections, you are standing on secrecy, you are standing on legal matters, and yet I don't care what the private sector does, this is a public institution. We have to get trust and confidence in a different way. The same legal remedies are not available to someone with regard to a public system any way. But I think we need to have a discussion about how we do this. This is very, very unsatisfactory.

If you could tell us more and we could get more in a setting with, perhaps, just the Chair and the Ranking Member of either the whole Committee or a Subcommittee Executive Session. We need

to figure out a way to get a better handle on this stuff, because we can't tell our constituents anything because we don't know anything. Even if we knew something it would help us to have confidence, and know it has been taken care of. I can't say that to anybody right now.

So you need to find a way to give us the confidence to give our constituents, and we would be happy to work with you. We need a new way to do this and it is just not working the way it is.

Thank you, Mr. Chairman.

The CHAIRMAN. I thank you very much. Are there any other questions of the Committee?

I thank the panel for being here today. There probably will be some questions that will be sent for the record. We thank you for your testimony.

If the second panel will begin coming forward. We have two more witnesses here to be with us today. Dr. Michael Bell, he is the Deputy Director of the Division of Healthcare Quality Promotion for the Centers for Disease Control and Prevention (CDC), and Mr. Anthony Watson, Director of the Office of Device Evaluation of the Centers for Devices and Radiological Health for the Food and Drug Administration (FDA).

We thank you both for sitting through the testimony from the first panel and the questions. We thank you for being here today.

As you have witnessed, the patient safety incidents at VA medical centers are complex and have wide ranging implications. I look forward to hearing from you today on how we can take a comprehensive proactive approach to patient safety for our veteran heroes and for all Americans.

So with that, Dr. Bell, you are recognized for 5 minutes.

**STATEMENTS OF MICHAEL BELL, M.D., DEPUTY DIRECTOR, DIVISION OF HEALTHCARE QUALITY PROMOTION, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND ANTHONY D. WATSON, BS, MS, MBA, DIRECTOR, DIVISION OF ANESTHESIOLOGY, GENERAL HOSPITAL, INFECTION CONTROL, AND DENTAL DEVICES, OFFICE OF DEVICE EVALUATION, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**STATEMENT OF MICHAEL BELL, M.D.**

Dr. BELL. Good afternoon Chairman Miller, Ranking Member Filner, and other distinguished Members of the Committee. I am Dr. Michael Bell, Deputy Director of the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention.

Thank you for this opportunity to discuss the important topics of preventing healthcare associated infections and ensuring safe healthcare nationwide.

Healthcare associated infections are infections that patients get while receiving care. These infections range from those related to highly specialized intensive care procedures down to infections

caused by lapses in the most basic safe practices, for example, reusing disposable syringes.

CDC estimates that roughly 1 in 20 hospital patients have healthcare associated infection. These infections are often severe and can kill people, and in hospitals alone they result in an estimated \$26 to \$33 billion a year in excess costs. Fortunately we know how to protect patients from many of these infections, and if we can protect them then we must protect them.

Healthcare associated infections can occur in any healthcare setting. These settings include hospitals, dialysis centers, ambulatory surgical centers, and nursing homes.

Medical care that used to take place only in hospitals is now increasingly being delivered in non-hospital settings. As that shift occurs, we are seeing a growing number of outbreaks in those settings. These are settings where infection control programs and oversight are generally less rigorous compared to hospitals.

Today I will focus my remarks on healthcare associated infections that happen because of lapses in basic infection control.

Infection control refers to the established collection of rules and procedures designed to prevent the spread of infection during healthcare, including basic safe practices such as not reusing syringes or appropriately sterilizing or disinfecting equipment. Lapses in those basic safe practices are entirely unacceptable. These are never events. Unfortunately, we continue to see egregious errors that have resulted in transmission of serious infections. As a result CDC is working in a number of ways to evaluate the problem and launch prevention strategies to stop these lapses from occurring.

CDC has worked with State and local health departments across the country and identified numerous lapses in basic infection control over the past several years. Recent examples include using the same syringe for more than one patient, accessing a shared vial of medication with a used syringe, using contaminated equipment for diabetic testing, inadequately cleaning and disinfecting medical equipment, such endoscopes, and improperly reusing medical devices like biopsy needle guides. Such practices are simply unacceptable, unfortunately they are happening across the spectrum of healthcare, particularly in non-hospital settings. More must be done to ensure that correct infection control practices are maintained wherever medical care is delivered.

CDC is actively engaged in eliminating these events. Our current efforts include developing national infection control guidelines and working with Centers for Medicare & Medicaid Services (CMS) to ensure that they are followed, developing checklists for State and CMS surveyors to evaluate facilities infection control practices, responding to outbreaks and emergent patient safety threats, educating healthcare personnel and patients about basic infection control requirements, and promoting the development of safer medical devices.

Our ultimate goal is to ensure that all patients receive safe care in every healthcare setting. We use CMS oversight and payment policies to drive adherence to CDC's infection control guidelines; however, when there is a lapse in infection control patients must be protected from harm. Local and state authorities are used to

halt the unsafe medical practice. It is then necessary to identify which individuals were exposed and to promptly notify them so that they can receive appropriate care.

Sadly in the past 10 years, over 100,000 patients have had to be notified that they were exposed to infection control lapse related to the unsafe injections, even more patients have been exposed to other areas such as improper sterilization of equipment.

Ensuring appropriate infection control in all healthcare settings is a priority for CDC. Our public health system is crucial to ensuring safe care for patients, providing a unified approach to implementing infection control, monitoring safety, investigating and controlling outbreaks, providing oversight and education, and researching new ways to improve healthcare quality.

As we work toward elimination of healthcare associated infections, ongoing vigilance is needed as new healthcare settings and changing technologies create new challenges to healthcare safety. CDC continues to address those challenges working to ensure that our patients are safe in every healthcare setting. We know how to protect patients from these infections; they can and must be prevented.

Thank you for this opportunity to testify. I am happy to take any questions you might have.

[The prepared statement of Dr. Bell appears on p. 67.]

The CHAIRMAN. Thank you very much, Doctor.

Mr. Watson, you are recognized.

#### **STATEMENT OF ANTHONY D. WATSON, BS, MS, MBA**

Mr. WATSON. Mr. Chairman, Ranking Member Filner, and Members of the Committee, thank you for the opportunity to discuss reprocessing of reusable medical devices and the importance of adequate reprocessing to protect patient safety.

Today, I will discuss the challenges to ensuring the safety of reprocessed medical devices and describe actions FDA is taking to address those challenges.

Reusable medical devices are devices that are designed and labeled for use on multiple patients and are made of materials that can withstand repeated reprocessing, including manual brushing and the use of chemicals. Some examples of reusable medical devices are surgical instruments, such as clamps and forceps; endoscopes, used to visualize areas inside the body; and accessories to endoscopes, such as arthroscopic shavers; and laparoscopic surgery accessories, such as graspers and scissors.

All reusable medical devices can be grouped into one of three categories according to the degree of risk of infection associated with their use. Critical devices, such as surgical forceps, semi-critical devices, such as endoscopes, and non-critical devices, such as stethoscopes.

Adequate reprocessing of reusable medical devices is a critically important step in protecting patient safety. Reprocessing is intended to remove blood, tissue, and other debris to ensure that devices are safe for the next patient use. Reprocessing can be both labor-intensive and time-consuming, because most reusable medical devices require a specific reprocessing regimen.

In general, reprocessing reusable medical devices involves three steps: initial cleaning which is at the point of use; transfer to the reprocessing work area where the device is thoroughly cleaned; and disinfection or sterilization, depending on the intended use of the device, its risk of infection transmission, and the materials from which it is made as well. The device is then stored or routed back into use.

Many factors contribute to reprocessing difficulties, including device complexity, absence of best practices, user error, and poor instructions on how to reprocess.

Manufacturers, healthcare facilities, healthcare professionals, and FDA share responsibility for reducing the risk of healthcare-associated infections, or HAIs, from inadequately reprocessed reusable medical devices.

HAIs are infections caused by a wide variety of common and unusual bacteria, fungi, and viruses during the course of receiving medical care.

Under FDA labeling regulations, a device must have adequate directions for use. This includes instructions on how to clean and disinfect or sterilize a reusable device to ensure that it is effectively prepared for its clinical use.

FDA applies its unique position and expertise to reduce the risk of infection from reusable medical devices by evaluating devices prior to marketing, identifying device designs that facilitate proper reprocessing, assuring that manufacturer instructions are clear, and promoting collaboration among all stakeholders.

FDA also works with manufacturers to correct product problems associated with reprocessed medical devices.

FDA expects manufacturers to design their devices to minimize debris retention, provide complete and easy to understand reprocessing instructions, and validate the reprocessing protocols using clinically relevant soil.

Healthcare institutions should periodically assess infection control practices in clinical areas, ensure that those responsible for reprocessing understand the importance of the job, and are given the necessary training to perform it properly. Reprocessing staff should understand the distinct and separate steps of reprocessing, and they should follow reprocessing instructions provided by device manufacturers.

Physicians and nurses should consider that reprocessing plays a role in device performance and follow up with the appropriate chain of accountability, such as reporting adverse events that may be related to inadequate reprocessing, following guidelines established by professional societies, and communicating with manufacturers regarding labeling issues and ease of reprocessing.

While FDA believes that the risk of acquiring an HAI from a reasonable device is relatively low and that the benefits of these important devices outweigh their risks, we are taking a collaborative approach toward improving the reprocessing of reusable medical devices.

On April 29th, 2011, FDA launched the Reusable Medical Devices Improvement Initiative to reduce the risk of HAIs from inadequately reprocessed medical devices.

FDA's approach to addressing reprocessing problems focuses on collaborating with other government agencies, manufacturers, healthcare facilities, and healthcare professionals to strengthen all steps in reusable device reprocessing by fostering improved, innovative device designs to reduce debris retention, strengthening the science of cleaning and high-level disinfection or sterilization of medical devices, and ensuring that healthcare facilities properly perform cleaning, disinfecting, and sterilization.

Specifically, FDA has issued revised draft guidance that updates and clarifies the recommended content of and review procedures for medical device applications concerning the labeling instructions for reprocessing reusable medical devices.

In addition, this draft document provides more detail about FDA's recommendations for the validation of processes intended to support reprocessing.

We have also announced a public meeting to be held on June 8th and 9th to bring together key stakeholders, including industry user facilities, standards organizations, healthcare accreditation organizations, government agencies, and professional societies.

This is the first in a series of conversations between FDA and reusable device stakeholders to discuss factors effecting the reprocessing reusable medical and FDA's plans to address the identified issues.

Finally, FDA has developed a Web page that provides general outreach about reprocessing of reusable medical devices to educate consumer and healthcare professionals.

Reducing the risk of infection from reusable medical devices is critical to protecting patients and is a shared responsibility. By using its unique vantage point, FDA is helping to address current problems with reprocessed devices while facilitating improvements in innovative design in the next generation of these devices.

Mr. Chairman, this concludes my formal statement. I will be happy to address any questions you may have.

[The prepared statement of Mr. Watson appears on p. 71.]

The CHAIRMAN. Thank you very much, Mr. Watson. Is it safe for me to assume that VA has been invited to your June workshop?

Mr. WATSON. Absolutely.

The CHAIRMAN. Thank you. Do you see a need for research into technologies to develop indicators to improve the ability to monitor the quality of reprocessing of reusable medical equipment?

Mr. WATSON. One of the elements we have introduced in our initiative yesterday was a draft guidance. I apologize that was actually Friday. That draft guidance contains information or method validation and labeling for these devices.

In that guidance we talk about the science of reprocessing, we get into the steps for reprocessing, we talk about different methods of validation, and by doing that we hope that users will be able to take that information and use it to improve their processes.

So our role as we see it is to help facilitate communication to help ensure that the right information is out there for the devices, and as well to help the manufacturers produce excellent labels so that people can understand what they are actually trying to do in the reprocessing area.

Specifically we have also included information in there that includes a human factors evaluation where users actually have to use the labeling to determine whether they can reprocess the device properly.

So our role as we see it is to help facilitate that communication, that is what the workshop is about on June 8th and 9th.

The CHAIRMAN. And I would like to ask one question for both of you to answer. Mr. Watson, if you would answer it first.

What lessons are to be learned from VA's experience with large scale adverse event disclosures?

Mr. WATSON. Well, I think what we have observed from the VA is not uncommon as some other Members of the Committee have mentioned earlier.

We have learned that we need to improve the labeling of these devices to make sure that people can use them properly. And again, I will say that by doing so we can help people do a better job of actually reprocessing these devices.

The communication that we would like to have in the June 8th and 9th workshop will also allow us to get other perspectives, by the way that guidance that we put out is a draft so we are asking for comments back on that. We are hoping that we can get some more communication in that workshop from all stakeholders we have, not only the VA, we have other healthcare organizations arriving, we have accreditation organizations like JCO, for example, the Commission is going to be there, and we are also hoping that users and medical device manufacturers will be there so that they can have a dialogue on the actual ground-level problems that they are seeing. By doing so, we can help those manufacturers come up with better device designs.

Some of the device designs that are out there right now don't facilitate reprocessing. They might have narrow lumens that make it difficult to clear, they might have hinges, they might have rough surfaces on the inner lumens that collect debris.

So we are hoping that by having this dialogue we can lay the ground work for future device designs to come out that will help facilitate those folks in the hospitals to do a better job.

The CHAIRMAN. Dr. Bell.

Dr. BELL. Unfortunately I think one of the most striking things related to what we have heard about today is that it is not unique to the VA system. It is emblematic of healthcare in the United States. We are seeing lapses in basic practices across the country and in Canada as well. This is something that needs to be tackled systematically.

I think that the benefits of being able to work through something like this include having an opportunity to deliver better products to the users. We have been able to take our long-standing guidelines, and this is nothing new in terms of science, but those guidelines are now packaged in handy tools for CMS surveyors to use when they actually look at facilities. The same tools are being used by the Joint Commission.

It is striking to me that a facility that was shut down in Nevada a couple years ago was shut down 3 months after it passed with flying colors from a local inspection. The problem there is that they are inspecting many of the wrong things. They are looking at fire

extinguishers and hallway widths, all of which are fine, but they are not looking at some of the critical issues about infection safety and other safe medical practices.

Being able to translate our guidelines into useful tools to put into the hands of the surveyors is one way that we are making use of these unfortunate examples.

Being able to build the guidelines into CMS payment policies so that at a broader level we are able to enforce adoption of these guidelines with fiscal authorities, that is a second way that we are seeing some benefit here.

With regard to the notification issue we were asked for input from the VA and we provided that. Related to that we also were able to do some consumer outreach and find out what people really wanted to hear about and how they wanted to hear it. That is something that we have published on now.

And then lastly we convened an ethics group to understand all of the ramifications of notification, including when is the notification something that could be harmful and how do you get around that harm to ensure transparency?

The CHAIRMAN. Thank you. Mr. Filner.

Mr. FILNER. Thank you for your testimony today. For the record, I would like to note that Secretary Petzel and his staff are all in the room. Thank you for staying. I was always frustrated when the VA folks would testify and then walk out and never listen to the other testimony. So thank you for being here and listening to the other witnesses.

I assume you were here for the earlier testimony. My senses was, and tell me if I am right or wrong, but the issues that we are dealing with here today are not primarily those of either the science or the procedures. We have the procedures, and Dr. Petzel explained nine levels of oversight to make sure that when mistakes occur we get those new policies in place. That is not my sense of where the problem is.

My sense is still in the accountability and the way we communicate. We are a public institution, and we have to handle things in a different way than in the private sector and how we notify not only the patients, but the public at large and the stakeholders.

I don't know what your sense is that because in all these cases that we heard, and I have been to most of the hospitals, the problem was whether the employees were implementing good policies or not or whether they were covering up those incidents. Those became the problems. I think the public understands that mistakes are going to be made, they just want to have honesty about it. What is the risk, what do I do to treat it, and let us get on with it. Not that mistakes won't get made.

I don't know what your sense is, if you want to comment on that. I am harping on the accountability because I think that is where the problem is.

Dr. BELL. Well, if I may, I will say that what you are describing is an important transformation to a culture of safety. This is something that is important across the healthcare system in this country.

There was a time when infection prevention was presumed to be the job of an infection control nurse and that that individual would

take care of. In fact it is everybody's job. Anybody who has any contact with a patient is responsible to ensure that individual's safety. And having that be understood throughout a healthcare system is one of the major goals and challenges that we face right now.

When you talk about accountability hand in hand with transparency we want a system where any individual can stop a process cold and say, no, what I just saw was a mistake, we have to stop that. We have seen that work.

Shortly after the public was notified in the newspaper of syringe reuse mistakes there was a Secretary in a clinician's office who watched the physician start to reuse a syringe and say I just read that that is wrong. We have to stop doing that, and by the way we should notify the health department.

So that kind of culture of accountability and safety is something that I think needs to increase throughout our healthcare system.

Mr. WATSON. I would like to add to that if I could. So I would like to echo Dr. Bell's comments, and I would like to say that it is not only an issue of not being able to communicate properly or lack of leadership, it is also unfortunately a lack of knowledge and understanding of the process and the procedures. There is some science, the science is well known, but not to everybody.

I think there is some element of understanding the importance of what needs to be done as well. For our part, what we have been trying to do is help propagate that message of the importance of doing the right thing all the time and ensuring that the folks that are going to be responsible for cleaning these devices actually have something less complex that they can actually clean.

We heard from Dr. Petzel that they were reducing the number of devices in their hospital, that all the people would have to learn how to reprocess. That is a very important step. One of the things that we talk about is reducing the complexity of the reprocessing system.

I think it is more than just goes to leadership, it actually goes to fixing the system, making sure that we can all communicate properly and that we all take our responsibility for the links that we put in the chain to correct the system, and that is what we are trying to do right now. And I believe from what I have heard that it is also what VA and CDC have done. We have had communication about various topics, not just this issue, where we are trying to close the loop on that.

Mr. FILNER. Thank you very much. Thank you, Mr. Chairman.  
The CHAIRMAN. Mr. Bilirakis.

Mr. BILIRAKIS. I have no questions, they were already asked.

The CHAIRMAN. Ms. Buerkle.

Ms. BUERKLE. Thank you, Mr. Chairman. Thank you both for being here today. Just a question to Dr. Bell.

What guidance do you think the CDC could provide for risk management?

Dr. BELL. By risk management do you mean in terms of preventing these problems?

Ms. BUERKLE. Yes.

Dr. BELL. We have actually just produced a consolidated document that takes all of the existing guidelines, which admittedly are substantial, and condenses them down for the use of ambulatory

care settings where many of these errors are occurring. That is now up on the Web site and is a nice 12-page synopsis of the minimum expected standards for safe practices.

I think we are recognizing increasingly that having a large scientific document sitting on a Web site is not good enough and that we need to produce easy, simple, straight forward things.

We are also partnering with organizations like the Safe Injection Practices Coalition to produce useful graphic materials and tri-fold pamphlets and so on, posters, that individuals can use at the site of care as reminders for care providers.

So I think there are many ways that we can reduce risk by pushing the information. As Mr. Watson said, it is not a lack of information, it is that the people doing the practices don't always have it.

Ms. BUERKLE. And just if either one of you know the answer to this question.

What percentage of instruments that are used on an ordinary basis in a hospital are disposable versus reusable?

Mr. WATSON. I don't have that information. We have try to go back and find that out though if you would like.

[The FDA subsequently provided the following information:]

According to our database, the Food and Drug Administration (FDA or the Agency) has cleared approximately 232 devices that are intended to be reprocessed since 1980. These are various devices such as endoscopes, (e.g., bronchoscopes, duodenoscopes, and colonoscopes), endoscope accessories, forceps, arthroscopic shavers, etc. However, this number cannot be considered comprehensive because there are limitations to the information. For example, our databases have not always had the ability to track devices intended to be reprocessed. Also, this number could include devices that have been modified and provided to FDA under a new submission. Therefore, this number would include duplicates. Another challenge is that not all devices require a submission to FDA. For example, most of the reusable manual surgical instruments are Class I exempt and are reusable. They do not need a submission to FDA to go to market.

Regarding disposable devices, the percentage in use in hospitals depends on what one calls "disposable." Some devices are comprised of both reusable and disposable components, making a calculation for the percentage in use rather difficult. For example, scalpel handles are reusable, but their blades are single use, disposable. Large bore biopsy needles may be reusable but most narrow lumen needles are single use, disposable. Endoscopes used during surgery are reusable, but their connecting tubing—to deliver and drain irrigation fluid, is disposable. There are perhaps a hundred, if not more, 510(k) clearances for the reusable rigid sterilization trays and containers which hold the reprocessed manual surgical instruments. Most of the more recent submissions have multiple models of trays in different sizes and shapes, with different internal configurations to hold specialized instruments in some cases.

Ms. BUERKLE. That would be helpful.

And as a followup to that, of those that are reusable which ones pose the most significant problems, and what are the ones? Obviously not all of reusable instruments probably have the same occurrence as with complication, so if there is any way to find out which are the ones most responsible for these problems that would be helpful as well.

Mr. WATSON. Well, if I may, we are actually doing that research to get that information, because one of the things we want to do is be able to help manufacturers understand which of their devices are most at risk. But we do know some of the device design issues that play into that and I kind of mentioned some of those earlier,

narrow lumens, devices that have rough surfaces on the inside that retain debris. If that debris happens to dry out and they don't clean it properly and it happens to dry it is very difficult to get out at a later date and it might actually still be there further down the line, devices that have attachments to them they collect debris, and sometimes there are issues chemicals and material compatibility also.

So we are actually studying device designs that we know are problematic, and in fact we have partnered with the University of Michigan, and they are doing a two-phase study for us. They are actually looking at device designs that might cause problems, and there will be some interesting information coming back on that, and they are also looking at reprocessing instructions, that is the next phase at very specific devices looking at the reprocessing instructions to see if those reprocessing instructions make sense and they can actually be followed.

So we will hopefully have more information on that at a later date, but we are looking at that right now.

Ms. BUERKLE. Very good. Thank you very much. I yield back my time.

The CHAIRMAN. Thank you very much. Any other further questions? If not we thank you. We do have some followup questions that will be submitted for the record.

All Members will have 5 legislative days to revise and extend their remarks and submit questions for the record if desired.

Thank you very much for being here, we thank VA for being here today, and we have votes coming up in just a moment, so if there is no further business this Committee meeting is adjourned.

[Whereupon, at 1:04 p.m., the Committee was adjourned.]

## A P P E N D I X

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### **Prepared Statement of Hon. Jeff Miller, Chairman, Committee on Veterans' Affairs**

The Committee will come to order.

Good morning and welcome to today's Full Committee hearing "Sacred Obligation: Restoring Veteran Trust and Patient Safety."

Before we begin, I would like to ask unanimous consent for our colleagues Lacy Clay from Missouri, Jerry Costello from Illinois, Blaine Luetkemeyer from Missouri, Ros-Lehtinen from Florida, John Shimkus from Illinois, Mike Turner from Ohio, and Frederica Wilson from Florida to sit at the dais and participate in today's proceedings.

Hearing no objection, so ordered. Thank you all for joining us.

We, as a Nation, put our trust in the men and women who serve in our Armed Forces to protect us and our freedoms. And, in return, our servicemembers put their trust in us to provide them with the highest quality healthcare.

However, incident after incident of serious patient safety violations in VA medical facilities across the Nation in locations such as Dayton, St. Louis, and Miami, resulting in thousands of veterans across the country receiving notification of their potential risk for infectious diseases like HIV and hepatitis, shatters the very trust veterans should have in us.

After each of these incidents, the VA assured Congress, and the country, that it was aggressively addressing patient safety issues and never again would a veteran's trust be compromised by lapses in quality care at a VA medical facility. And yet, each patient safety incident has seemingly led the way for the next "lessons learned" and the unacceptable and inexcusable revelation that the patient safety culture in VA is fractured and accountability and leadership at the helm are lacking.

The time for talk is over. VA must confront these issues head on, deepen the obligation to care for the veterans affected by these incidents, and make the necessary changes within the VA healthcare system to prevent any future incidents that would put veteran patients at risk.

To that end, at this hearing today we will address in depth the efficacy of VA's patient safety policies and VA leadership's ability to provide adequate oversight of its medical facilities.

Further, we will explore the development of proactive strategies for addressing the issues that underlie the lapses we've seen in patient safety including the need for: (1) improvements in reprocessing of reusable medical equipment; (2) systematic ways for VA to limit the activities of suspect practitioners; and (3) better and more consistent risk management and notification processes for veteran patients when incidents do occur.

It is unconscionable that any one of our veterans should ever be exposed to infectious diseases because of the care they receive at a VA medical facility.

I want to assure all of you that this Committee will be tireless in its oversight to ensure that VA lives up to its creed to provide only the very best and the very safest care anywhere.

I thank you all for joining us for this important and ongoing discussion.

Before I yield to the Ranking Member, I'd like to remind witnesses that testimony is due no later than 48 hours in advance of a Committee or Subcommittee hearing. I am told the DAMA Subcommittee did not receive VA testimony until late yesterday in preparation for today's 8:00 a.m. hearing. That is inexcusable.

In addition, I and other Committee Members submitted a series of questions 7 weeks ago in relation to VA's FY 2012 budget request, yet no responses have been received. I would ask those here from VA today to please convey my disappointment about this performance and my expectation that things will improve in the very near future. I yield to the Ranking Member.

**Prepared Statement of Hon. Bob Filner,  
Ranking Democratic Member, Full Committee on Veterans' Affairs**

Good morning. I would like to thank everyone for attending this important hearing today.

The purpose of today's hearing is to gauge VA's response to several recent incidents that profoundly affect veterans due to the failure of some to follow policies, procedures and protocols that have been put in place to prevent such occurrences.

We are also going to look at what measures have actually been implemented to ensure that these types of lapses do not happen again.

Mr. Chairman, I have to say, and I think you would certainly agree that we have been here before! Please indulge me in my brief chronology of events.

In December 2008, we were notified of improper reprocessing of endoscopes which put thousands of veterans in Murfreesboro, Mountain Home Tennessee, and Miami, Florida, at possible risk of hepatitis and HIV.

In February 2009, another 1,000 veterans in Augusta, Georgia, received notifications that they were at risk for hepatitis and HIV because of improper processing of ear, nose, and throat endoscopes.

In July 2010, this Committee held a field hearing in St. Louis, Missouri, a hearing you attended Mr. Chairman, along with many of our colleagues today, after we had learned of lapses in protocol with the cleaning of dental equipment which put at risk 1,800 veterans.

The most recent notification, the egregious incidents at Dayton, Ohio, affected over 500 veterans and involved a whole host of problems. The findings beg the questions of proper accountability, effective oversight and enforcement of clear policies and procedures.

Policies and procedures that are sometimes not followed—or worse—get completely ignored. I would like to know, where is the strong, proper leadership and effective communication that is critical when you are entrusted with the care and well being of our Nation's veterans.

Let me point to another big concern as a result of these incidents and that is the absolute need for effective communication within the management ranks and below. I am sure the Secretary of Veterans' Affairs would agree with me on this.

Clearly, VA has had issues with ensuring the sterility of reusable medical equipment in the past and now, other patient safety issues have come to light, as evidenced in the continuing problem of veterans being vulnerable to infectious diseases due to the problematic, yet prevalent, issue of lack of following sound agency guidelines and policies concerning patient safety.

In addition to what has been looked at over the past 3 years, I am strongly dedicated to the need for ensuring that we do everything possible so that this does not happen again.

And, as we are all aware, VA has a higher commitment and a moral compact to provide the utmost level of care possible. It is this Committee's responsibility to ensure that VA has the proper resources to fulfill that mission.

I would like to acknowledge and want to recognize the VA's excellent healthcare services and the dedication of the vast majority of their staff.

I would also like to acknowledge the work they have done to mitigate the issues at hand. We know it has not been easy.

I look forward to hearing today's testimony.

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**Prepared Statement of Hon. John Barrow**

Thank you Chairman Miller and Ranking Member Filner for holding this hearing on restoring the trust our veterans have in VA's services. We can't keep those promises if veterans don't trust that VA's facilities and services are safe.

This is an issue that hits close to home for the veterans in my district. The Charlie Norwood VA Medical Center in Augusta, GA has been found out of compliance of VA's sterilization process in 2008, 2009, and 2010. They have had to warn veterans that they may have been infected with diseases because of unclean ear, nose, and throat utensils. As recently as November, the Charlie Norwood VA Medical Center had to halt all elective procedures because they were not following the proper sterilization procedure.

Just 2 weeks ago, The American Legion inspected the Charlie Norwood VA Medical Center in Augusta, GA. The Legion found what we already know: like many VA facilities throughout the Nation, the Charlie Norwood VA Medical Center has been under the supervision of an "Acting Director" for several months. Without a permanent director a VA hospital does not have the long term leadership to initiate the reforms to ensure high quality, safe, and reliable care. And until veterans can

trust that the care they receive is high quality, safe, and reliable we aren't keeping the most basic promise to them.

I look forward to the testimony of today's witnesses, and I hope we can identify specific solutions to specific problems, like having too many "Acting Supervisors" in positions that require long term accountability.

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**Prepared Statement of Michael R. Turner,  
a Representative in Congress from the State of Ohio**

Chairman Miller, Ranking Member Filner, I would like to thank you for your leadership on this issue. Your responsiveness to my request to visit the facility in Dayton and decisiveness in holding this vitally important hearing are a testament to your dedication to our Nation's veterans.

Along with the many other tragic issues addressed in today's hearing, the events that transpired at the Dayton VA Dental Clinic are extremely disconcerting because they further illustrate systemic problems in the medical system that provides care for our Nation's veterans. The dentist in question violated infection control standards for nearly two decades. During a significant period of this time he did so with the knowledge of many fellow employees and some supervisors. In failing to report these problems the clinic needlessly put thousands of veteran lives at risk. Several patients have tested positive with hepatitis, and I, along with a panel of healthcare professionals, believe that many more are at risk and should be notified and tested.

Last week, I participated in a field hearing with Senator Brown under the jurisdiction of the Senate Veterans Affairs Committee on this same issue. As I discussed there, it is important for the community to become involved in this process because they were the victims and their input will be vital in reestablishing the community's trust. In an effort to ensure the safety of all the identified victims and potentially unidentified victims, the Greater Dayton Area Hospital Association (GDAHA) has reached out to the VA to help in this process. GDAHA is empaneled by a group of local physicians and has the community interests in mind.

During the course of their investigation GDAHA recently published an interim report in which they disagreed with the VA's decision to limit the look-back period to 1992. Instead the group concluded that the VA should notify and test all patients seen by the DIQ, to include the next-of-kin of deceased patients. Their independent conclusions were made with a view towards the best interest of the patients and community and were free from the influence of VA leadership. I have submitted this information to Secretary Shinseki and requested that he adhere to their recommendations. I hope that he will choose to enact these recommendations in order to protect those that may have been exposed and help restore the community's faith in the VA.

While I appreciate the investigations that have been conducted by the VA, I would like to point out that internal constraints placed on the OIG investigative team bring the findings of their investigation into question. I am concerned that the scope of the OIG investigation was limited by an inability to interview key witnesses. As the report itself states, the OIG investigative body was unable to interview several key witnesses simply due to their retirement. These witnesses included the original SOARS complainants, a fellow dentist and the facility's Chief of Staff. Their exclusion from the evidence gathering process devalues the OIG's findings significantly and raises a very serious question.

Simply stated: *What kind of system does the VA have in place where the leadership can evade investigative processes simply by opting into retirement?* The ultimate consequence of this model is that veterans and their families carry the scars and the taxpayers carry the debt while the responsible individuals walk away into comfortable retirement without accounting for their negligence.

This system is broke and it needs to be fixed. The VA and Congress share a responsibility to provide the greatest amount of protection for all the potentially affected veterans and their families. In light of this, I concur with GDAHA's recommendations that the VA should notify and test all patients seen by the DIQ, to include the next-of-kin of deceased patients. I also take issue with the underlying rationale to limit the scope of the testing.

In moving forward, I hope that the VA will make a greater effort to work with Congress and the community to ensure that all potentially affected victims are notified and tested. Further, I would like the VA to work in concert with regional stakeholders to identify the underlying problems that allowed this tragedy to happen, and devise a solution that will prevent it from ever happening again. In order to accomplish this, the VA should conduct an open and transparent process that includes information sharing with GDAHA and the community.

After all, our country has thousands of young men and women that are making as great of a sacrifice as any generation before them. We need to make sure that they have the peace of mind to know that if they need help when they are done, there will be a fully functioning and competent VA here to give them that help when they need it. Further, we need to ensure that a system is in place that holds the leadership accountable for their actions and does not allow them to simply walk away at the first sign of trouble. This leadership from the rear mentality has no place in the Department of Veterans Affairs and is particularly shameful in an environment built to care for those veterans that kept our country safe and free.

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**Prepared Statement of Hon. Jerry F. Costello,  
a Representative in Congress from the State of Illinois**

I would like to thank Chairman Miller for holding today's hearing to examine repeated lapses in patient safety at U.S. Department of Veterans Affairs (VA) facilities. I look forward to hearing about the underlying issues causing these failures and what changes were implemented to ensure they do not happen again.

As I have said on numerous occasions, the dedicated efforts of VA employees and their strong commitment to quality care are an example of our country's sincere promise to look after the brave men and women who have protected our Nation for over two centuries. Their compassion and expertise are an asset to the VA and I encourage the employees to remain diligent about communicating discrepancies in protocols.

Many of my constituents receive medical care from John Cochran Veterans Medical Center (VAMC) in St. Louis, Missouri, which was the subject of a July 2010 field hearing to examine lapses in cleaning reusable dental equipment. This occurrence was disturbing by itself—putting the health of 1,812 veterans at risk—but to know that it is one of many instances in which the VA has failed to perform the basic duties of its daily operations is truly shocking. For example, a March 7, 2011, VA Office of Inspector General (VA OIG) report on a site visit to John Cochran VAMC noted numerous inconsistencies remained after the July hearing, ranging from the unavailability of manufacturer's instructions on how to clean reusable medical equipment (RME), insufficient staff training, and inadequate oversight.

Several other reports and investigations by the VA OIG and the General Accountability Office (GAO) have also identified continued breakdowns in management practices for VA and facility leadership. Despite the fact that both the VA OIG and GAO indicate that policies and directives are in place, we are holding another hearing regarding repeated oversight and compliance failures that put patient safety in jeopardy.

These occurrences must stop and I implore the VA to work with Congress to implement the proper training and oversight necessary to limit these occurrences in the future, as we have been promised several times would happen by VA officials.

Patient safety remains our top priority and our veterans deserve the very best care available. Congress has a sacred obligation to ensure the VA has the resources necessary to fulfill this promise.

I look forward to today's testimony.

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**Prepared Statement of Hon. Robert A. Petzel, M.D.,  
Under Secretary for Health, Veterans Health Administration,  
U.S. Department of Veterans Affairs**

Chairman Miller, Ranking Member Filner, and other Members of the Committee. Thank you for the opportunity to discuss the Department of Veterans Affairs' (VA) patient safety policies and strategies that build trust and ensure the safe and compassionate care of our veterans. I am accompanied today by Robert Jesse, M.D., Ph.D., Principal Deputy Under Secretary for Health; William Schoenhard, Deputy Under Secretary for Health Operations and Management, George Arana, M.D., Acting Assistant Deputy Under Secretary for Health for Clinical Operations, and Andrea Buck, M.D., Acting Chief Medical Officer.

First and foremost, I would like to apologize on behalf of the Department to those veterans who have been affected by a lapse in patient safety practices at any of our facilities. The greatest commitment of every VA employee is the well-being of our veterans. In the Veterans Health Administration (VHA), from the housekeeper, who ensures each patient's room is clean, to the Under Secretary for Health, we are united in a common mission to protect and provide quality healthcare for those who served to defend this Nation.

When a lapse in patient safety practices occurs, it is VA's fundamental belief that we must be open and transparent with regard to our mistakes and any necessary actions that may result. This can result in disclosing medical events even when not a common practice by others in the medical community. For example, in 2010, *The New England Journal of Medicine* published an article noting that large-scale adverse events in medical settings are not uncommon; the article described in detail VA's disclosure policies and concluded, "The VHA policy represents a valuable resource for all healthcare institutions."<sup>1</sup> We carefully consider the effects of any disclosure, but our practice is to provide more information to our veterans in an abundance of caution, even if the risk to their health is low.

We are particularly concerned about any event where veterans are put at risk because we believe we provide excellent care, and we have the data to support that belief. Despite caring for patients that are, on average, sicker, older, and less affluent than the general population, VA's performance overall exceeds the best U.S. healthcare systems. Our data collection and publication program is unprecedented in U.S. healthcare, as we report more data about our programs online than anyone else. As the *Wall Street Journal* observed in March 2011, "This usually comprehensive sort of consumer information on medical outcomes remains largely hidden from the tens of millions of Americans outside the VA system."<sup>2</sup> Professional publications and the mainstream media have recognized and lauded our accomplishments in providing the best integrated healthcare in the country. Recently, *The New England Journal of Medicine* published an article praising our programs to reduce healthcare-associated infections by methicillin-resistant *Staphylococcus aureus* (MRSA), a bacteria known to be resistant to most antibiotics.<sup>3</sup> In the words of a *New York Times* editorial about this study, "If other hospitals could replicate the effort, thousands of patients might be saved from needless infections acquired after they entered the hospital."<sup>4</sup>

These accomplishments are significant, but they are not, and never will be, enough. We owe it to our veterans and ourselves to continually strive to be better. We must be the veteran-centric, results-driven and forward-looking organization the Secretary has called us to be. This means we will continually learn how to do our jobs more effectively, more efficiently, and more compassionately.

My testimony today will provide an overview of our quality and patient safety programs. It will then describe our practices for standardized reprocessing of reusable medical equipment; our systematic approach to limiting the activities of suspect practitioners through rigorous credentialing and privileging, as well as peer review; and risk management and notification processes for veterans.

#### **VA Quality and Safety Programs**

VA is committed to providing the safest and highest quality healthcare for veterans. We have established a wide array of innovative and comprehensive programs to measure, analyze, improve and report on all aspects of healthcare quality and patient safety. We have published an annual report on each facility's quality and safety performance since 2008, and these reports are available online (<http://www1.va.gov/health/HospitalReportCard.asp>). The 2010 report includes new metrics, such as medical and surgical outcomes data, as well as a detailed analysis of VA's safety reports. We have identified six domains in line with the Institute of Medicine's recommendations for quality in healthcare: effective, equitable, safe, timely, patient-centered, and efficient. We have been an early adopter of performance measurement and improvement because we at VA have a special responsibility to maintain the trust of the veterans we serve and the public at large.

All eligible VA facilities and programs have been accredited by The Joint Commission, and over 200 programs were accredited by the Commission on Accreditation of Rehabilitation Facilities. The Joint Commission's accreditation is nationally recognized as a symbol of quality and is considered one of VA's major external quality reviews. Joint Commission accreditation confers recognition that VA healthcare organizations meet certain standards of quality and safety, as well as compliance with

<sup>1</sup>Denise M. Dudzinski, Philip C. Hébert, Mary Beth Foglia, and Thomas H. Gallagher. "The Disclosure Dilemma, Large Scale Adverse Events." *The New England Journal of Medicine*. Vol. 363, no. 10. September 2, 2010. P. 978-986, p. 984.

<sup>2</sup>Thomas M. Burton. "Data Spur Changes in VA Care." *The Wall Street Journal*. March 29, 2011. Available online: <http://online.wsj.com/article/SB10001424052748703512404576208812390820304.html>.

<sup>3</sup>Rajiv Jain, et al. "Veterans Affairs Initiative to Prevent Methicillin-Resistant *Staphylococcus aureus* Infections." *The New England Journal of Medicine*. Vol. 364, no. 15. April 14, 2011. P. 1419-1430.

<sup>4</sup>The New York Times. "Hospitals Shouldn't Make You Sicker." April 17, 2011. Available online: <http://www.nytimes.com/2011/04/18/opinion/18mon3.html>.

healthcare quality standards of payors. The Commission on Accreditation of Rehabilitation Facilities reviews VA programs designed to provide specialized treatment and quality rehabilitation to veterans with disabilities. Various specialty programs are also often reviewed and accredited by boards with expertise in those disciplines. We estimate that more than 4,100 site visits occur at VA healthcare facilities each year to support approximately 2,000 total accreditation reviews and inspections.

According to the Healthcare Effectiveness Data and Information Set (HEDIS), VA facilities provided high quality outpatient medical care and compared favorably with the top performing health plans in the Nation. When looking at disease-specific healthcare within inpatient settings, VA also compares favorably with the best hospitals in the Nation on core indicators of quality that are published on Medicare's Hospital Compare Quality of Care Web site. The rates of hospital-acquired infections at VA were generally low when compared with national averages according to the Centers for Disease Control and Prevention. Many VA facilities report rates that match or are lower than the top 10 percent of reporting hospitals in the country (lower infection rates are better). High quality outpatient care was available to veterans regardless of where they lived. Women veterans receive gender-specific care that substantially exceeds care available in non-VA healthcare systems.

There are several programs that have proven instrumental to VA's success in overseeing quality care. First, VA's Surgical Quality Improvement Program (VASQIP) monitors surgical procedures and tracks risk-adjusted surgical outcomes, including complications (morbidity) and mortality rates. VASQIP analyzes aggregate patient data from surgical outcomes of 124 VA facility surgical programs using mathematical models to predict an individual patient's expected outcome based on the patient's pre-operative characteristics and the complexity of the surgical procedure being performed. This calculated expected outcome is then compared to an observed outcome on a regular basis. Facilities with an observed adverse outcome that significantly exceeds expected outcomes undergo a quality improvement assessment to identify specific issues that require resolution to enhance patient safety. This kind of monitoring has resulted in reductions in patient morbidity and mortality across the organization. VASQIP was developed more than 15 years ago, and the American College of Surgeons now offers a similar program to private sector hospitals.

Another effort is VA's National Center for Patient Safety (NCPS), which was established more than 10 years ago to improve the quality and safety of care we provide. One key process that NCPS uses when an adverse event or a "close call" happens is a root cause analysis (RCA) to identify the basic or contributing causal factors. This is an interdisciplinary review process that focuses primarily on systems and processes, rather than individuals, to determine what actually or almost went wrong. These investigations can identify changes that should be made to either redesign or develop our practices and reduce the risk of a similar event in the future. Approximately 40 percent of RCAs are done on events that produced little or no harm to patients. This is a testament to VA's developed culture of safety, as it reflects the willingness of staff to identify close calls for review and analysis. The five most common subjects for an RCA include falls; delays in treatment, diagnosis, or inpatient surgery; "high alert" adverse drug events; unexpected deaths (other than suicide); and outpatient suicides. Both The Joint Commission and VA require an RCA to be completed within 45 days; as such, we track the timeliness of these investigations, and we have shown continued improvement over the last several years in completing these in a timely manner.

Finally, VA has recently begun publishing detailed quality and safety data online to inform veterans and the public of the care we provide. These efforts also improve our internal accountability structure. ASPIRE is a Web-based dashboard that documents quality and safety goals for all VA hospitals and reports on how individual hospitals are meeting these standards. The standards identified by ASPIRE are the gold standard and should be the target of every healthcare organization; for example, we have targeted zero MRSA infections in all of our facilities. We will not necessarily meet these objectives, but they should always be our goal. The Linking Knowledge and Systems (LinKS) dataset is another dashboard that summarizes outcomes in areas such as acute care, safety, intensive care, and other measures. LinKS reports quarterly risk adjusted as well as unadjusted data that shows how well each VA hospital is performing and areas in which each facility can improve. Much of the data in the LINKS and ASPIRE dashboards are simply not available in other healthcare systems, which limits VA's ability to compare itself against other healthcare systems.

Nevertheless, VA has been identified as a leader in the field, and we are setting the bar for other systems to meet. Perhaps most importantly, we are using these quality and safety datasets to inform the performance reviews of senior leadership.

A key element of the performance plan for every Veterans Integrated Service Network (VISN) Director and VA Medical Center (VAMC) Director is based on objective performance in healthcare quality and safety, as measured by independent sources of information pulled from our electronic health record system. VA has also contracted for an external peer review program, which selects a statistically significant random sample of cases for each facility and assesses the care we provided. This assists VA with validating our internal peer review process and helps ensure we are providing the highest quality of care to our veterans.

***Standardized Reprocessing of Reusable Medical Equipment***

VA has made significant progress in standardizing sterile processing techniques across the Department. We have worked with the International Association of Healthcare Central Service Material Management, an internationally recognized organization in sterile processing, to provide supply, processing and distribution training. We have also obtained a national contract to ensure all facilities are supplied with up-to-date manufacturers' instructions for sterile processing. New standard operating procedures for reprocessing are currently in place. Beyond standardizing processes, VA seeks to set the standard for effective and safe sterile processing techniques nationwide. We have been soliciting proposals from the private sector to automate sterile processing techniques to reduce the opportunities for human error, and VA is internally pursuing innovations to improve the safety, efficiency, and effectiveness of sterile processing.

Between January 1 and September 30, 2010, VA's Office of Inspector General (OIG) Combined Assessment Program reviewed 45 VA facilities to evaluate reusable medical equipment practices (RME) to determine if facilities complied with VA standards for RME sterilization and high level disinfection, provided documentation for annual training, and assessed and documented annual competencies for employees who perform RME reprocessing activities. OIG identified six areas where compliance with RME requirements needs to improve. We appreciate their assessment and their recommendations. We have concurred with their recommendations, and we have either already completed these improvements or we will do so within the next 6 months. Specifically, the OIG recommended that VA senior managers (at the national, network, and local levels) ensure that:

- Standard operating procedures (SOPs) are current, consistent with manufacturers' instructions, and located within the reprocessing areas;
- Employees consistently follow SOPs, supervisors monitor compliance, and annual training and competency assessments are completed and documented;
- Flash sterilization is used only in emergent situations, supervisors monitor compliance, and managers assess and document annual competencies for employees who perform flash sterilization;
- Appropriate personal protective equipment is donned before entering and is worn in decontamination areas;
- Ventilation systems are inspected and filters are changed quarterly in all reprocessing areas and that temperature and humidity are monitored and maintained within acceptable ranges in sterile storage areas; and
- Processes for consistent internal oversight of RME activities are established to ensure senior management involvement.

In response to these recommendations, VA has modified inspection processes at the network and facility level to ensure that employees consistently follow SOPs and that training and competency assessments are complete and documented. Staff from VA's Sterile Processing Departments (SPDs) will perform site visits to provide additional oversight to ensure that annual training and competency assessments are complete as well. We developed and deployed a standardized template as of February 14, 2011, that requires facilities to conduct six inspections of SPD per year, and for VISN staff to conduct three unannounced inspections each year. We will track and review the results of these inspections nationally to refine our oversight methods. VA has developed a national action plan to specifically address RME concerns throughout its entire healthcare system. When VA Central Office learns of an adverse event, we immediately activate a fact finding team of appropriate subject matter experts to assess the event for veteran risk. Depending on this team's determinations, VA may convene a Clinical Review Board (CRB) to determine if disclosure to patients should occur. We have also realigned our organization to create a national SPD office that will provide guidance and oversight for our experts in the field.

We believe veterans should be encouraged by the results of the OIG's inspection. While the report identifies areas for improvement, it also commends VA facilities for recognizing the importance of maintaining consistent RME practices to ensure

patient safety. VA's policy is to cooperate with all reviews and investigations, from the OIG and others, that have been designed to improve service and develop better practices for healthcare. Our facilities have been increasingly vigilant in monitoring, self-identifying, and investigating any inconsistencies in procedures for cleaning RME, and our facilities are conducting frequent and repeated reviews of their patient care areas to ensure that procedures are clear and followed.

The Government Accountability Office (GAO) has also reviewed selected VA facilities to assess the purchasing, tracking, and reprocessing requirements for RME. GAO specifically looked at relevant VA policies, as well as two purchasing, two tracking, and two reprocessing requirements. These requirements were instituted following patient safety incidents at the Palo Alto VAMC, the Miami VAMC, and the Augusta and Murfreesboro VAMCs, respectively. GAO did not identify any inadequacies in the purchasing requirements they selected for review in the context of patient safety. In the area of tracking requirements, GAO found VA has a limited ability to identify equipment on which there are alerts or recalls and maintaining inventory, and that it also experiences challenges developing required training in this area. For reprocessing requirements, GAO found VA did not adequately specify the types of RME that require device-specific training and that there is conflicting guidance on the development of RME reprocessing training.

We greatly appreciate the work of the GAO in helping VA ensure our programs are providing the quality of care our veterans deserve. We have already begun instituting changes to address these concerns and are ahead of the timeline we outlined for GAO. We are analyzing information on non-compliance by specific VA medical centers and are overseeing the development of corrective action plans. We are also developing a systematic approach to analyzing information to identify areas of non-compliance across the Nation, with particular focus on those that occur frequently, pose high risks to veterans' safety, or that have gone unaddressed. VA has drafted a new handbook that will replace all existing sterile processing policies; this handbook will be reviewed by experts from the field before publication to ensure its requirements are consistent with best practices and capable of implementation. To reduce the variation in equipment and accompanying processes, VA has established national product specifications and criteria for selecting standardized endoscopic equipment. Similarly, an Integrated Product Team for Endoscopes has been charged with developing recommendations for gastrointestinal (GI) endoscopic equipment. As part of our ongoing effort to standardize the reprocessing of RME, we have secured a national contract that supplies up-to-date manufacturers' instructions to all VA facilities. These efforts will enhance patient safety and quality, realize economic value, and reduce variability for set up and reprocessing this equipment.

In addition, VA is partnering with local communities to provide state-of-the-art training to those responsible for providing oversight of VA's SPD. For example, in Phoenix, Arizona, VA has entered into a first-of-its-kind agreement with a local technical college to provide VISN SPD boards with a laboratory environment for hands-on training in the reprocessing of RME. The first of these courses will begin in June. By training the trainers and those responsible for oversight within the Department, as well as providing support to community training efforts, VA is setting the standard for excellence in the reprocessing of RME nationwide.

#### ***Credentialing, Privileging, and Peer Review***

Credentialing, privileging, and peer review are essential components of our quality and safety program as they assess who is competent to perform what types of procedures and how well they perform. Credentialing refers to the systematic process of screening and evaluating qualifications and other credentials, including licensure, required education, relevant training and experience, current competence and health status. Clinical privileging is a process by which a practitioner, licensed for independent practice, is permitted by law and the facility to practice independently, to provide specified medical or other patient care services within the scope of the individual's license, based on the individual's clinical competence as determined by peer references, professional experience, health status, education, training, and licensure. Privileging is both facility- and provider-specific.

All VA healthcare providers who are permitted by law and the facility to provide patient care independently must be credentialed and privileged to do so. VetPro is VA's electronic credentialing system and must be used for credentialing of all providers who are granted clinical privileges or are credentialed for other reasons. This system helps reduce the chance for human error and improves the care we deliver at VA. All candidates must submit an application to VetPro providing information regarding malpractice, adverse actions against licensure, privileges, hospital membership, research, and other factors. We do not allow an offer of employment to be made to providers until the credentialing process is complete. This process entails

screening the candidate through the appropriate State Licensing Board, the Federation of State Medical Boards, and the National Practitioner Data Base (NPDB). The NPDB is a secondary flagging system intended to support a comprehensive review of healthcare practitioners' professional credentials by identifying any malpractice payments or adverse actions against clinical privileges. NPDB screening is required before an applicant's appointment; VA then monitors appointed practitioners through the NPDB's continuous query program for as long as they maintain an appointment at a VA medical facility. The information we receive from NPDB offers further insight into the provider's history as a clinician and is considered with other relevant data in evaluating a practitioner's credentials. VA oversees this program at the national, network and facility level to ensure compliance.

Applicants for VA positions are required to respond to questions concerning clinical privileges at VA and non-VA facilities. Privileges are valid for a period not to exceed 2 years. To approve privileges for a provider, VA requires evidence of current licensure, relevant training and experience, current competence, and information associated with the person's health status as it relates to the individual's ability to perform the requested clinical privileges. We also require information related to malpractice allegations or judgments, loss of medical staff membership, loss or reduction of clinical privileges, or challenges to licensure. At the facility level, each service chief is responsible for developing additional criteria consistent with the needs of the patient population at the facility. We continue to monitor privileges based upon quality and performance data on an ongoing basis, and we provide numerous training opportunities to ensure that those responsible for assessing and validating credentialing and privileging standards have the resources they need to help ensure quality patient care.

VA also maintains a robust peer review program to oversee quality and accountability for care. Peer review is a process carried out by an individual healthcare professional or a select committee of professionals to evaluate the performance of other providers. When conducted systematically and credibly, as is VA's process, peer review can result in both immediate and long-term improvements in patient care by revealing areas for improvement in the practice of one or more providers, which contributes to organizational improvement and better patient outcomes. Peer review is intended to be a comprehensive, confidential and non-punitive process that contributes to overall quality improvement efforts and to the improvement of care for veterans.

Peer reviews are conducted by internal and external parties. For internal reviews, it is VA policy that each VISN and healthcare facility must establish and maintain a program of peer review for quality management purposes relevant to the care provided. Our facilities must comply with the requirements of all applicable accrediting and oversight agencies that review VA healthcare facilities, including The Joint Commission. We have established criteria that indicate who can serve as a peer reviewer to ensure these individuals provide competent and accurate information to other providers. VHA Directive 2010-025 provides clear guidelines for which clinical events require a peer review for quality management purposes. As mentioned earlier, VA maintains an external peer review program to gather and validate information related to outcomes and processes for each of our medical facilities. This provides an important, independent assessment of the care we offer and provides an additional source of validation for our internal processes.

#### ***Risk Management and Notification Processes***

VA has an ethical and legal obligation to disclose to patients adverse events they experienced during the course of their care, including when the adverse event may not be obvious or severe, or where the harm may only manifest in the future. Disclosure of these events is consistent with our core values of trust, respect, excellence, commitment and compassion. Facility Directors are responsible for ensuring that healthcare providers communicate these events to patients or the patients' representative and to support staff members who are involved. It is VA policy to notify our patients of their rights under section 1151 of title 38 United States Code and the Federal Tort Claims Act, including information about procedures available to request compensation as well as where and how to obtain assistance in filing claims.

One of my chief priorities is to ensure VA is a learning organization, and I have emphasized the importance of this philosophy to all of our healthcare employees. If an error or an adverse event occurs, we must determine if this was the result of a lack of training, or some deeper problem. I believe in holding our providers accountable, but accountability can take many forms and needs to be evaluated on a case-by-case basis. Sometimes disciplinary action is warranted, and in a number of situations, we have taken these necessary steps by convening Administrative Investigation Boards (AIB) to determine the proper response which can and has included

administrative action. Recommendations from all AIBs are shared and discussed with VHA leadership for awareness and as a learning opportunity to understand how to deal with any potential future adverse event within their facilities.

In terms of notifications, any events that may require large scale patient disclosures must be documented and communicated to VA Central Office. When we learn of a potential adverse event, we convene a fact finding team of subject matter experts from a range of disciplines to assess the situation. At the conclusion of the fact finding review, a Clinical Review Board (CRB) may be convened. The CRB is made up of appropriate representatives from a range of disciplines and include experts on quality and safety, public health, ethics, operations and management, patient care, and VHA leadership. The CRB considers factors such as the population at risk, the potential severity of outcomes, the probability of those outcomes, and other factors relevant to the population at risk. VHA Directive 2008-002 provides specific guidance regarding what adverse events warrant disclosure, when disclosure should occur, and how adverse events should be communicated.

We are also keenly aware of the need to disclose in a manner that does not exacerbate problems and unduly worry our veterans or their families. We have convened a working group that is developing common guidance and templates for disclosures, and we expect to have results from this group this summer.

### **Conclusion**

Our primary mission at VA is to serve our Nation's veterans. In terms of healthcare, this means providing veteran-centered care that focuses on improving the lives and well-being of our patients. VA is more transparent and makes available to the public more information about our entire system than any other healthcare provider in the country. Our initiative in this area earned the Department the Annual Leadership Award from the American College of Medical Quality. We subject our facilities to greater scrutiny through both external commissions and accreditation organizations as well as internal reviews from the facility, network and national level, including from the Office of the Inspector General and GAO. We welcome these assessments because they provide us with learning opportunities that will produce even better healthcare systems and outcomes. And we welcome Congressional oversight, as we work together to serve our veterans.

At VA, our fundamental belief is that our healthcare system is designed to serve veterans, and that to do so, veterans must be an equal partner in their healthcare decisions. For this partnership to work, we must make sure they have access to the data they need to make an informed decision, and that they must trust us to provide them this information. We understand that disclosures can raise concerns among the public, but we believe that veterans will have greater confidence in a system that errs on the side of providing more information to them, even when their health risk is low.

Thank you for inviting me here to testify today to discuss our efforts in these vital areas. My colleagues and I look forward to any questions you may have, and we welcome this discussion.

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**Prepared Statement of John D. Daigh, Jr., M.D.,  
Assistant Inspector General for Healthcare Inspections,  
Office of Inspector General, U.S. Department of Veterans Affairs**

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

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

## REUSABLE MEDICAL EQUIPMENT

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

### **OIG Reports on RME**

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

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

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

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

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

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

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

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

This review was conducted to determine the validity of allegations regarding ongoing issues in the Supply, Processing, and Distribution (SPD) department related to

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

endoscope reprocessing and communication at the St. Louis VA Medical Center, St. Louis, Missouri.

We substantiated:

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

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

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

The VISN and Medical Center Directors agreed with the findings and recommendations. We closed this report on February 17, 2011.

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

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

The dental RME reprocessing issues at the John Cochran Division (JCD) were a long-standing problem that went unrecognized and unaddressed by VISN and VAMC managers. VHA self-identified the deficiencies and took actions to correct them; however, those actions did not always resolve the issues. Responsible managers did not verify the adequacy of RME reprocessing practices, nor did they assure that corrective actions were consistently implemented in response to VHA guidance and the Infectious Disease Program Office (IDPO) report. As a result, SOPs were not developed in a timely manner for the reprocessing of dental RME, SOPs did not always match manufacturers' instructions, and Dental Clinic staff had not received training on dental RME pre-treatment or reprocessing.

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

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

#### **Combined Assessment Program Review Results**

Despite the fact that VA leadership issued clear guidance to facilities on standards for reprocessing RME and that Congress held hearings on reprocessing failures at these sites, the OIG continues to find non-compliance with VA directives. Because of the persistence of deviations from expected performance by staff at VA facilities, a review of RME reprocessing practices was included in the OIG's Combined Assessment Program (CAP) reviews from January 1, 2010, through September 30, 2010.<sup>2</sup> Facility results were reported at the time of the inspection and rolled up to present

<sup>2</sup> *Combined Assessment Program Summary Report, Evaluation of Reusable Medical Equipment Practices in Veterans Health Administration Facilities Report*, March 14, 2011.

a representative view of the system. We found that 87 percent of the reprocessing SOPs were consistent with manufacturers' instructions and 92 percent were located within the reprocessing areas. In our observations of employees reprocessing equipment, the SOPs were followed 87 percent of the time. Documented annual training was found for 82 percent of the employees and item specific competencies were documented 87 percent of the time. Proper protective equipment was worn by employees 89 percent of the time. VA requires that RME activities (e.g. validation of staff competency, compliance with established SOPs, results of infection prevention and control monitoring, and risk management activities) be reported to the Executive Committee of the Medical Staff (ECMS). Of the 45 facilities inspected in this CAP cycle, 37 (82 percent) had documented ECMS discussion of all required elements. Compliance with these standards at the 82 percent to 92 percent level is not sufficient to ensure proper patient safety.

### **Recommendations**

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

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

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

### **LEADERSHIP ISSUES**

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

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

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

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

### **Recommendations**

Just as physicians have access to senior facility leaders via clinical department leaders and nurses have access through the Chief Nurse, VA clinical leaders should strive to receive unfiltered information from the many technicians who are critical to the daily delivery of quality medical care. Current lines of communication may

<sup>3</sup>VHA Directive 2008-002, *Disclosure of Adverse Events to Patients*, January 18, 2008.

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

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

not be adequate to get the technicians concerns to facility leaders. Ongoing discussions between the facilities leadership and the hospital's technicians may provide important data necessary to improve quality care.

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

#### CONCLUSION

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

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

**Prepared Statement of Randall B. Williamson,  
Director, Health Care, U.S. Government Accountability Office**

**VA HEALTHCARE: Weaknesses in Policies and Oversight  
Governing Medical Equipment Pose Risks to Veterans' Safety**

Chairman Miller, Ranking Member Filner, and Members of the Committee:

I am pleased to be here today as you discuss patient safety incidents at Department of Veterans Affairs (VA) medical centers and potential strategies to address the underlying causes of those incidents. VA operates one of the largest integrated healthcare delivery systems in the United States, providing care to over 5.5 million veterans annually. Organized into 21 Veterans Integrated Service Networks (VISN), VA's healthcare system includes 153 VA medical centers (VAMC) nationwide that offer a variety of outpatient, residential, and inpatient services.<sup>1</sup> In providing healthcare services to veterans, clinicians at VAMCs use reusable medical equipment (RME), which is designed to be reused for multiple patients and includes such equipment as endoscopes<sup>2</sup> and some surgical and dental instruments. Because RME is used when providing care to multiple veterans, this equipment must be reprocessed, that is, cleaned and disinfected or sterilized between uses. VA has established requirements for VAMCs to follow when reprocessing RME,<sup>3</sup> which are designed, in part, to help ensure the safety of the veterans who receive care at VAMCs.

My testimony today, based on our May 2011 report,<sup>4</sup> which is being released today, examines issues related to veterans' safety, including (1) selected reprocessing requirements established in VA policies, based on their relevance to patient safety incidents and (2) VA's oversight of VAMCs' compliance with these selected requirements.

To examine VA reprocessing requirements, we reviewed relevant VA policies and from these policies, we judgmentally selected the following two types of reprocessing requirements that we determined were relevant to patient safety incidents that were identified at certain VAMCs.<sup>5</sup>

*Training requirements.* To ensure that RME is reprocessed in accordance with manufacturers' guidelines, VA requires that each VAMC develop device-specific training for reprocessing RME. To develop this training, VA requires VAMCs to create device-specific standard operating procedures (SOP), which provide step-by-step instructions for reprocessing. VA also requires VAMCs to assess staff annually on their competence to reprocess RME in accordance with these SOPs.

<sup>1</sup>The management of VAMCs is decentralized to 21 VISNs.

<sup>2</sup>An endoscope is a device with a light attached that is used to look inside a body cavity or organ.

<sup>3</sup>VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements* (Aug. 16, 2002); VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities* (Feb. 9, 2009); and VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements* (June 26, 2009).

<sup>4</sup>See GAO, *VA Health Care: Weaknesses in Policies and Oversight Governing Medical Supplies and Equipment Pose Risks to Veterans' Safety*, GAO-11-391 (Washington, D.C.: May 2011).

<sup>5</sup>We reviewed applicable VA policies, including VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements*; VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*; and VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements*.

*Operational requirements.* To ensure that reprocessing activities are performed safely and that RME is reprocessed correctly, VA policies establish operational requirements for VAMCs, which include that VAMC staff must monitor sterilizers to ensure that they are functioning properly, use personal protective equipment when performing reprocessing activities, and segregate dirty and clean RME.

After selecting these requirements for our review, we judgmentally selected six VAMCs from the following locations to visit: Albany, New York; Cheyenne, Wyoming; Detroit, Michigan; Miami, Florida; Palo Alto, California; and St. Louis, Missouri. These VAMCs represent different surgical complexity groups,<sup>6</sup> sizes of veteran populations served, and geographic regions.<sup>7</sup> At these six VAMCs, we examined the adequacy of the selected reprocessing requirements to help the facilities ensure the safety of veterans who received care at these facilities. To do this, we examined how the selected requirements were implemented and whether or to what extent these requirements directly or indirectly created a potential risk to veterans' safety. We reviewed applicable VAMC committee meeting minutes<sup>8</sup> and other documentation on the implementation of these requirements. We also interviewed VAMC officials who were responsible for implementing the selected requirements to determine whether these requirements are adequate to help ensure veterans' safety.

To examine VA's oversight of VAMCs' compliance with the selected reprocessing requirements, we reviewed VA's oversight of these requirements and evaluated whether this oversight provides VA with adequate information to identify and address noncompliance. As part of this review, we assessed VA's oversight in the context of Federal standards for internal control for monitoring.<sup>9</sup> The internal control for monitoring refers to an agency's ability to assure that ongoing review and supervision activities are conducted, with the scope and frequency depending on the assessment of risks; deficiencies are communicated to at least one higher level of management; and actions are taken in response to findings or recommendations within established timelines. We interviewed officials responsible for overseeing VAMCs' compliance with the requirements we selected for review from VA headquarters, VA's Office of Inspector General (OIG), and six VISNs that are responsible for overseeing compliance with the requirements we selected for review at the VAMCs we visited. In addition, we obtained and reviewed relevant documents regarding VA oversight, including internal reports, VAMCs' plans to correct problems identified through oversight activities, and policy memorandums.

We conducted this performance audit from March 2010 to May 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In summary, we found that the VA reprocessing requirements we selected for review are inadequate to help ensure the safety of veterans who receive care at VAMCs. Although VA requires VAMCs to develop device-specific training for staff on how to correctly reprocess RME, it has not specified the types of RME for which this training is required. Furthermore, VA has provided conflicting guidance to VAMCs on how to develop device-specific training on reprocessing RME.<sup>10</sup> This lack of clarity may have contributed to delays in developing the required training. Without appropriate training on reprocessing, VAMC staff may not be reprocessing RME correctly, which poses potential risks to veterans' safety. VA headquarters officials told us that VA has plans to develop training for certain RME, but VA lacks a timeline for developing this training.

We also found that despite changes to improve VA's oversight of VAMCs' compliance with selected reprocessing requirements, weaknesses still exist. These weaknesses render VA unable to systematically identify and address noncompliance with the requirements, which poses potential risks to the safety of veterans. Although VA

<sup>6</sup>VA assigns each VAMC a complexity score between 1 and 3, with level 1 being the most complex, using a facility complexity model. That model uses multiple variables to measure facility complexity arrayed along four categories, namely patient population served, clinical services offered, education and research complexity, and administrative complexity.

<sup>7</sup>Each of the six VAMCs we visited is located within a different VISN.

<sup>8</sup>We reviewed minutes from the following committees: commodity standards, equipment, medical executive, infection control, and RME.

<sup>9</sup>See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999) and GAO, *Internal Control Management and Evaluation Tool*, GAO-01-1008G (Washington, D.C.: August 2001).

<sup>10</sup>According to VA headquarters officials, certain RME are difficult to reprocess because they need to be fully disassembled in order to be reprocessed correctly, so developing device-specific training for reprocessing these items is important to help ensure veterans' safety.

headquarters receives information from the VISNs on any noncompliance they identify, as well as VAMCs' corrective action plans to address this noncompliance, VA headquarters does not analyze this information to inform its oversight. According to VA headquarters officials, VA intends to develop a plan for analyzing this information to systematically identify areas of noncompliance that occur frequently, pose high risks to veterans' safety, or have not been addressed across all VAMCs.

To address the inadequacies we identified in selected VA reprocessing requirements, GAO recommends that VA develop and implement an approach for providing standardized training for reprocessing all critical and semi-critical RME to VAMCs and hold VAMCs accountable for implementing this training. To address the weaknesses in VA's oversight of VAMCs' compliance with selected requirements, GAO recommends that VA use information on noncompliance identified by the VISNs and information on VAMCs' corrective action plans to identify areas of noncompliance across all 153 VAMCs and take action to improve compliance in those areas.

### **Selected VA Reprocessing Requirements Are Inadequate to Help Ensure Veterans' Safety**

We found that the VA reprocessing requirements we selected for review are inadequate to help ensure veterans' safety.

*Lack of specificity about types of RME that require device-specific training.* The VA reprocessing requirements we reviewed do not specify the types of RME for which VAMCs must develop device-specific training. This inadequacy has caused confusion among VAMCs and contributed to inconsistent implementation of training for reprocessing. While VA headquarters officials told us that the training requirement is intended to apply to RME classified as critical, such as surgical instruments, and semi-critical, such as certain endoscopes,<sup>11</sup> officials from five of the six VAMCs we visited told us that they were unclear about the RME for which they were required to develop device-specific training.

Officials at one VAMC we visited told us that they did not develop all of the required reprocessing training for critical RME, such as surgical instruments, because they did not understand that they were required to do so. Officials at another VAMC we visited also told us that they had begun to develop device-specific training for reprocessing non-critical RME, such as wheelchairs, even though they had not yet fully completed device-specific training for more critical RME. Because these two VAMCs had not developed the appropriate device-specific training for reprocessing critical and semi-critical RME, staff at these VAMCs may not have been reprocessing all RME properly, which potentially put the safety of veterans receiving care at these facilities at risk.

*Conflicting guidance on the development of RME reprocessing training.* While VA requires VAMCs to develop device-specific training on reprocessing RME, VA headquarters officials provided VAMCs with conflicting guidance on how they should develop this training. For example, officials at three VAMCs we visited told us that certain VA headquarters or VISN officials stated that this device-specific training should very closely match manufacturer guidelines in one case verbatim, while other VA headquarters or VISN officials stated that this training should be written in a way that could be easily understood by the personnel responsible for reprocessing RME. This distinction is important, since VAMC officials told us that some of the staff responsible for reprocessing RME may have difficulty following the more technical manufacturers' guidelines.<sup>12</sup> In part because of VA's conflicting guidance, VAMC officials told us that they had difficulty developing the required device-specific training and had to rewrite the training materials multiple times for RME at their facilities. Officials at five of the six VAMCs also told us that developing the device-specific training for reprocessing RME was both time consuming and resource intensive.

<sup>11</sup>RME is generally categorized into critical, semi-critical, or non-critical items based on the degree of risk for infection involved in use of the item. Critical items, such as surgical instruments, are those that enter sterile tissue or the vascular system and require sterilization because they confer a high risk of infection. Semi-critical items, such as certain endoscopes, are those that contact mucous membranes or non-intact skin and minimally require high-level disinfection. Non-critical items, such as wheelchairs, are those that come into contact with intact skin and may be cleaned with low-level disinfectants.

<sup>12</sup>VA officials stated that manufacturer guidelines for reprocessing RME may be technically complex and may include steps that staff at VAMCs are unable to follow. For example, these officials stated that guidelines from RME manufacturers may require the use of a specific disinfectant that is not available in the United States. The Food and Drug Administration has responsibility for overseeing RME, including the guidelines written by manufacturers for reprocessing these items.

VA's lack of specificity and conflicting guidance regarding its requirement to develop device-specific training for reprocessing RME may have contributed to delays in developing this training at several of the VAMCs we visited. Officials from three of the six VAMCs told us that they had not completed the development of device-specific training for RME since VA established the training requirement in July 2009. As of October 2010, 15 months after VA issued the policy containing this requirement, officials at one of the VAMCs we visited told us that device-specific training on reprocessing had not been developed for about 80 percent of the critical and semi-critical RME in use at their facility.

VA headquarters officials told us that they are aware of the lack of specificity and conflicting guidance provided to VAMCs regarding the development of training for reprocessing RME and were also aware of inefficiencies resulting from each VAMC developing its own training for reprocessing types of RME that are used in multiple VAMCs. In response, VA headquarters officials told us that they have made available to all VAMCs a database of standardized device-specific training developed by RME manufacturers for approximately 1,000 types of RME and plan to require VAMCs to implement this training by June 2011. The officials also told us that VA headquarters is planning to develop device-specific training available to all VAMCs for certain critical and semi-critical RME for which RME manufacturers have not developed this training, such as dental instruments. However, as of February 2011, VA headquarters had not completed the development of device-specific training for these RME and has not established plans or corresponding timelines for doing so.

**Despite Changes Intended to Improve VA's Oversight of VAMCs' Compliance with Selected Reprocessing Requirements, Weaknesses Continue to Exist**

We found that VA recently made changes to its oversight of VAMCs' compliance with selected reprocessing requirements; however, this oversight continues to have weaknesses. Beginning in fiscal year 2011, VA headquarters directed VISNs to make three changes intended to improve its oversight of these reprocessing requirements at VAMCs.<sup>13</sup>

- VA headquarters recently required VISNs to increase the frequency of site visits to VAMCs, from one to three unannounced site visits per year, as a way to more quickly identify and address areas of noncompliance with selected VA reprocessing requirements.
- VA headquarters also recently required VISNs to begin using a standardized assessment tool to guide their oversight activities.<sup>14</sup> According to VA headquarters officials, requiring VISNs to use this assessment tool will enable the VISNs to collect consistent information on VAMCs' compliance with VA's reprocessing requirements. Before VA established this requirement, the six VISNs that oversee the VAMCs we visited often used different assessment tools to guide their oversight activities. As a result, they reviewed and collected different types of information on VAMCs' compliance with these requirements.
- VISNs are now required to report to VA headquarters information from their site visits. Specifically, following each unannounced site visit to a VAMC, VISNs are required to provide VA headquarters with information on the facility's non-compliance with VA's reprocessing requirements and VAMCs' corrective action plans to address areas of noncompliance. Prior to fiscal year 2011, VISNs were generally not required to report this information to VA headquarters.<sup>15</sup>

<sup>13</sup> VA headquarters generally delegates responsibility for this oversight to the VISNs. In addition to oversight conducted by the VISNs, some entities within VA headquarters conduct oversight of VAMCs' compliance with VA reprocessing requirements, including those we selected for review. Specifically, VA's OIG and Sterile Processing Department conduct site visits to investigate allegations of VAMC noncompliance with VA reprocessing requirements. In addition, since around 2005, VA's System-wide Ongoing Assessment and Review Strategy has included reviews of the selected VA reprocessing requirements as part of broader reviews of VAMC compliance with VA policies in preparation for external accreditation reviews approximately every 3 years. In 2010, VA's OIG also conducted reviews of the selected VA reprocessing requirements as part of broader ongoing reviews of VAMC compliance with VA policies.

<sup>14</sup> VA headquarters officials told us that they may refine this assessment tool over time.

<sup>15</sup> While VISNs were not generally required to report to VA headquarters information on VAMCs' noncompliance with VA's reprocessing requirements, VISNs were required to report to VA headquarters information about noncompliance that may have resulted in harm to veterans. VA headquarters officials told us that following a review of that information and collection of additional information as needed, a panel of experts would determine whether the noncompliance identified in the reviews resulted in risks to veterans' safety and, if so, whether veterans should be notified. See VHA Directive 2008-002, *Disclosure of Adverse Events to Patients* (Washington, D.C.: Jan. 18, 2008).

Despite the recent changes, VA's oversight of its reprocessing requirements, including those we selected for review, has weaknesses in the context of the Federal internal control for monitoring. Consistent with the internal control for monitoring, we would expect VA to analyze this information to assess the risk of noncompliance and ensure that noncompliance is addressed. However, VA headquarters does not analyze information to identify the extent of noncompliance across all VAMCs, including noncompliance that occurs frequently or poses high risks to veterans' safety. As a result, VA headquarters has not identified the extent of noncompliance across VAMCs with, for example, VA's operational reprocessing requirement that staff use personal protective equipment when performing reprocessing activities, which is key to ensuring that clean RME are not contaminated by coming into contact with soiled hands or clothing. Three of the six VAMCs we visited had instances of noncompliance with this requirement. Similarly, because VA headquarters does not analyze information from VAMCs' corrective action plans to address noncompliance with VA reprocessing requirements, it is unable to confirm, for example, whether VAMCs have addressed noncompliance with its operational reprocessing requirement to separate clean and dirty RME. Two of the six VAMCs we visited had not resolved noncompliance with this requirement and, as a result, are unable to ensure that clean RME does not become contaminated by coming into contact with dirty RME.

VA headquarters officials told us that VA plans to address the weaknesses we identified in its oversight of VAMCs' compliance with reprocessing requirements. Specifically, VA headquarters officials told us that they intend to develop a systematic approach to analyze oversight information to identify areas of noncompliance across all VAMCs, including those that occur frequently, pose high risks to veterans' safety, or have not been addressed in a timely manner.<sup>16</sup> While VA has established a timeline for completing these changes, certain VA headquarters officials told us that they are unsure whether this timeline is realistic due to possible delays resulting from VA's ongoing organizational realignment, which had not been completed as of April 6, 2011.<sup>17</sup>

In conclusion, weaknesses exist in VA's policies for reprocessing RME that create potential safety risks to veterans. VA's lack of specificity and conflicting guidance for developing device-specific training for reprocessing RME has led to confusion among VAMCs about which types of RME require device-specific training and how VAMCs should develop that training. This confusion has contributed to some VAMCs not developing training for their staff for some critical and semi-critical RME.

Moreover, weaknesses in oversight of VAMCs' compliance with the selected reprocessing requirements do not allow VA to identify and address areas of noncompliance across VAMCs, including those that occur frequently, pose high risks to veterans' safety, or have not been addressed by VAMCs. Correcting inadequate policies and providing effective oversight of reprocessing requirements consistent with the Federal standards for internal control is essential for VA to prevent potentially harmful incidents from occurring.

To help ensure veterans' safety through VA's reprocessing requirements, we are making two recommendations in our report. We recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to take the following actions:

- Develop and implement an approach for providing standardized training for reprocessing all critical and semi-critical RME to VAMCs. Additionally, hold VAMCs accountable for implementing device-specific training for all of these RME.
- Use the information on noncompliance identified by the VISNs and information on VAMCs' corrective action plans to identify areas of noncompliance across all 153 VAMCs, including those that occur frequently, pose high risks to veterans' safety, or have not been addressed, and take action to improve compliance in those areas.

In responding to a draft of the report from which this testimony is based, VA concurred with these recommendations.

<sup>16</sup>VA headquarters officials also told us that a temporary staff member was assigned in March 2011 to begin reviewing some information from VISNs' oversight activities. Specifically, that staff member will be responsible for reviewing whether VAMCs have developed the required device-specific training for reprocessing RME and the extent to which VAMCs are utilizing flash sterilization, a sterilization technique that should be used only in limited circumstances.

<sup>17</sup>As part of this realignment, VA headquarters is establishing a new position within the Office of the Deputy Under Secretary for Health for Operations and Management, which will be responsible for overseeing certain departments, including VA headquarters' Sterile Processing Department.

Chairman Miller, Ranking Member Filner, this concludes my prepared statement. I would be happy to respond to any questions you or other Members of the Committee may have.

#### **Contacts and Acknowledgments**

For further information about this testimony, please contact Randall B. Williamson at (202) 512-7114 or williamsonr@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Individuals who made key contributions to this testimony include Mary Ann Curran, Assistant Director; Kye Briesath; Krister Friday; Melanie Krause; Lisa Motley; and Michael Zose.

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#### **Prepared Statement of Michael Bell, M.D., Deputy Director, Division of Healthcare Quality Promotion Centers for Disease Control and Prevention, U.S. Department of Health and Human Services**

Good morning Chairman Miller, Ranking Member Filner and other distinguished Members of the Committee. I am Dr. Michael Bell, Deputy Director of the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC). I am pleased to be here to discuss the prevention of healthcare-associated infections (HAIs) and ensuring safe healthcare nationwide.

Healthcare associated infections are infections that patients acquire while receiving care. They include a variety of infections ranging from those related to specialized intensive care procedures to infections caused by lapses in basic safe practices, like re-using disposable syringes or inappropriate reprocessing of equipment. CDC estimates that approximately 1 in 20 hospital patients have HAIs. These infections are associated with increased mortality and greater cost of care; and can occur in any healthcare setting—hospitals, long-term care, dialysis clinics, ambulatory surgical centers, and even doctors' offices. As complex care is increasingly delivered in non-hospital settings, we are seeing a concomitant increase in potentially life-threatening infections related to care outside of hospitals. Infections caused by lapses in basic infection control are unacceptable. We know how to protect patients from these events; they can and must be prevented.

Based on CDC data, the four most frequent infections related to specialized care procedures accounting for approximately three quarters of HAIs are: 1) urinary tract infections; 2) surgical site infections; 3) bloodstream infections; and 4) pneumonia. These infections are caused by both common pathogens such as *Staphylococcus aureus*, including Methicillin-resistant *Staphylococcus aureus* (MRSA), and by emerging pathogens such as drug-resistant *Klebsiella pneumoniae*. In addition, we continue to see egregious failures in basic infection control and safety practices (e.g., using the same syringe to administer medication to more than one patient) that have resulted in transmission of blood borne and other pathogens (i.e., hepatitis C virus, [HCV], hepatitis B virus [HBV]). HAIs in hospitals alone result in excess healthcare costs of an estimated \$26 to \$33 billion each year. Yet, most HAIs are preventable. HHS and its public and private sector partners are working together to eliminate these costly and deadly infections. HHS recently launched the **Partnership for Patients: Better Care, Lower Costs**, a new public-private partnership that will help improve the quality, safety and affordability of healthcare for all Americans. The Partnership for Patients brings together leaders of major hospitals, employers, health plans, physicians, nurses, and patient advocates along with State and Federal Governments in a shared effort to make hospital care safer, more reliable, and less costly.

The Centers for Disease Control and Prevention, working with several other agencies in the U.S. Department of Health and Human Services, has taken a lead role in addressing the important public health challenge of preventing HAIs by identifying and implementing prevention strategies, providing guidelines for prevention, monitoring HAIs and tracking prevention progress, and detecting and responding to emerging threats.

The HHS Action Plan to Prevent HAIs sets specific targets for monitoring and preventing HAIs nationally and represents a national blueprint for promoting HAI prevention. CDC has played an integral role in the HHS led effort to develop and implement the HHS Action Plan, including chairing the Prevention and Implementation working group and co-chairing the Information Systems and Technology working group. Since the release of the initial HHS Action Plan, CDC has collaborated closely with the HHS Assistant Secretary for Health, the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs (VA), and other Federal agencies to ex-

pand and implement the HHS Action Plan to include ambulatory surgical centers and hemodialysis centers.

There has been significant progress in several areas; however more work is needed to ensure that appropriate infection control practices are adhered to in all healthcare settings. The VA has been an important partner in implementing HHS HAI prevention initiatives. However, recent infection control lapses, such as those at VA facilities in Dayton OH, St. Louis MO, and Miami FL, demonstrate the need for constant vigilance.

Today, I will focus my remarks on 3 specific areas: 1) the issue of basic infection control in healthcare, including CDC's efforts to prevent them; 2) CDC's collaborations with the VA related to HAIs; and 3) recommended strategies to halt improper practices when they are identified and to notify patients that were exposed to those practices.

#### **Healthcare-Associated Infections Related to Failure to Maintain Basic Infection Control**

CDC has worked with State and local health departments to identify numerous breaches in basic infection control practices in recent years. Infections acquired through lapses in basic infection control practices are generally through an intermediate device or material. A medical device (e.g., syringe, needle, lancet) or medication becomes contaminated with an infectious agent and the infectious agent is then passed to a previously uninfected patient through inappropriate exposure to the contaminated material. Examples of improper practices include:

- Using the same syringe to administer medication to more than one patient;
- Accessing a shared medication vial with a syringe that has already been used to administer medication to a patient; and
- Performing finger stick blood sampling with a reused lancing device or checking blood glucose levels with a blood-contaminated glucose meter.
- Improper reprocessing (i.e., cleaning and disinfection) of endoscopes
- Improper reprocessing and sterilization of medical equipment (e.g., surgical equipment)
- Improper reuse of medical devices (e.g., syringes, prostate biopsy needle guides)

These unacceptable practices put patients at risk of infectious and non-infectious adverse events and have been associated with a wide variety of procedures. Unfortunately, these practices are occurring across the healthcare spectrum and in non-acute care settings outside of hospitals, where infection control capacity is often less extensive and oversight more limited.

Healthcare should never be a conduit for transmission of infections. Basic infection control practices have long been established as part of the evidence-based and common sense precautions that are necessary to prevent transmission of pathogens.

#### **CDC's Efforts to Prevent HAIs Due to Failure To Maintain Basic Infection Control**

Leading the Nation's efforts to protect patients from transmission of pathogens due to lapses in infection control during healthcare delivery, CDC is engaged in a number of efforts to eliminate these events, including:

- development and implementation of HAI prevention guidelines,
- development of survey tools to evaluate facilities' adherence to infection control practices,
- identifying and responding to new and emerging threats to patient safety,
- educating healthcare providers and patients in basic infection control, and
- promoting development of safer medical devices.

#### *Development and Implementation of Infection Prevention Recommendations*

CDC, working with the HHS Healthcare Infection Control Practices Advisory Committee (HICPAC), develops evidence-based guidelines for HAI prevention. Key existing guidelines include: (1) the *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*, presenting evidence-based recommendations on the preferred methods for cleaning, disinfection and sterilization of medical equipment and for cleaning and disinfecting the healthcare environment, (2) the *Guidelines for Environmental Infection Control in Health-Care Facilities, 2003*, a compilation of recommendations for the prevention and control of infectious diseases that are associated with healthcare environments, and (3) the *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*. CDC and HICPAC also developed summary recommendations specifically for ambulatory care targeting basic infection control practices that should be used in all healthcare settings. CDC has worked with professional associations to reach out to healthcare professionals and is collaborating with CMS to incorporate CDC guidelines into CMS practice requirements.

#### *Tools To Improve Basic Infection Control*

CDC develops tools to translate CDC and HICPAC guidelines into practice. For example, CDC is improving basic infection control practices through collaborations with CMS to expand survey and oversight capacity of non-acute healthcare settings. CDC and CMS worked together to develop a new tool that state inspectors can use to better ensure the quality of care in ambulatory surgical centers (ASCs); use of the tool has been expanded nationwide. In a 2008 Federal survey of ASCs, 68 percent of 68 surveyed had noncompliance with the infection control requirements in the Medicare ASC health and safety standards. CMS has found infection control problems in ASCs to be both common and egregious, ranging from failure to clean equipment between patients and re-use of single-dose vials of medication for multiple patients. CDC is working with CMS to expand incorporation of basic infection control content into CMS interpretive guidance for their conditions of coverage. The tool has now been adapted for use in nursing homes and used to assess infection control practices in Nevada nursing homes. CDC continues to work with CMS to develop similar tools for use in acute care and other healthcare settings.

Breaches in basic infection control practices have put greater focus on the authorities and role of State and local health departments in ensuring patient safety. State licensure boards can promote ongoing training and certification as a part of licensure requirements for healthcare professionals. State health departments play critical public health roles in preventing harm due to incorrect practices, including issuance of cease and desist notices when necessary.

#### *Identifying and Responding To New and Emerging Threats*

CDC serves as a national and global leader in the investigation and control of HAI outbreaks. Through its investigations, CDC identifies problems, develops new prevention strategies, and works with partner agencies such as the Food and Drug Administration (FDA) to implement policy changes. Investigation of single suspect cases has in many instances led to the detection of sizable outbreaks, highlighting the point that recognized outbreaks are usually only the tip of the iceberg. Outbreaks often reveal unsafe practices and can require large scale patient notifications (as described below). Countless infections were prevented because of interventions that were implemented in collaboration with FDA and other partners to stop these outbreaks, including the identification and recall of contaminated or defective products, changes in device construction, revised recommendations for device use, closure of non-compliant facilities, and recommendation of new practices to prevent additional infections.

CDC deploys experts including healthcare epidemiologists, infectious disease physicians, and laboratory scientists to assess healthcare settings, collect and analyze data, evaluate practices, and perform microbiologic testing in response to a recognized outbreak or problem. CDC has assisted with laboratory testing of patients put at risk for hepatitis. Information from these investigations not only serves to control the immediate problem, but also has a direct impact on future HAI prevention nationwide. Experience from outbreak investigations also contributes to refinement of infection control guidelines and improvements in HAI tracking.

Viral hepatitis is a reportable condition in all States, but our ability to detect transmission in healthcare settings through this routine surveillance is limited because the system relies on passive reporting and in many cases we cannot evaluate how patients became infected. Therefore, CDC provides funding to several States to conduct enhanced viral hepatitis surveillance through the Emerging Infections Program (EIP). A case control study was conducted as part of the EIP activity to examine the role of healthcare exposures among older adults with acute hepatitis B and C. Results of this study indicate that viral hepatitis infections transmitted to individual patients in healthcare settings represent a significant but under-recognized problem.

#### *Promotion of Infection Control Through Education*

CDC is working with partners through the Safe Injection Practices Coalition (SIPC), a partnership of healthcare-related organizations, professional organizations, and patient advocacy groups, that promote safe injection practices in healthcare settings. Through CDC funding, the SIPC developed the *One & Only Campaign*—a public health education and awareness campaign—aimed at both healthcare providers and patients to advance and promote safe injection practices and implemented the campaign in Nevada, New York, and New Jersey. In addition, CDC has disseminated almost 5,000 DVDs and logged over 20,000 online views of a 10-minute educational video for healthcare providers on safe injection practices launched in collaboration with the SIPC.

### *Promoting Development of Safer Medical Devices*

CDC is working to promote innovation and development of product and marketing improvements to protect patients. For example after the identification of several outbreaks of viral hepatitis resulting from shared use of fingerstick (lancing) devices and point of care blood testing devices for glucose monitoring, in August 2010, the FDA, CDC, and CMS issued clinical reminders and public health notifications highlighting the risk of transmission of disease from these devices. FDA is working with manufacturers to ensure that adequate labeling and instructions for use are provided to healthcare personnel so that they can adhere to recommended practices.

### **CDC's Collaborations With the VA To Prevent Infections**

CDC's efforts to eliminate HAIs are amplified through close collaborations with a range of Federal agencies, including the VA. The VA has been directly involved with CDC in many of the efforts outlined above. A senior representative from the VA serves as an ex-officio member of HICPAC, and as such is engaged in the ongoing development of infection prevention guidelines and strategies for surveillance and prevention of HAIs. The VA is also engaged in HHS inter-agency initiatives to improve and expand HAI prevention efforts, including the HHS Steering Committee for the Prevention of Healthcare-Associated Infections, of which the VA is an active member. CDC has worked with the VA in the investigation and response to lapses in basic infection control at VA medical facilities.

The VA hospital system has been a leader in implementing CDC and HICPAC infection prevention recommendations. CDC has directly partnered with the VA to implement prevention initiatives resulting in a 60 percent reduction of MRSA in VA facilities over a 32 month period, initially as a pilot project at the local level and ultimately translated into regional and national programs. CDC is working with several groups to assess the effectiveness of several other successful implementation strategies. These and other prevention implementation examples demonstrate the savings in lives and healthcare costs that can result from national implementation of evidence-based HAI prevention programs.

### **When Infections Occur**

The ultimate goal is to ensure that all healthcare is delivered safely across the spectrum of healthcare delivery; however, when an infection control failure is identified, there is a need to notify patients who might have been exposed and to protect other patients from harm. During the past decade, over 120,000 patients had to be notified of the need to seek testing in the context of two dozen incidents and outbreaks involving unsafe injections; additional patients have been notified of risks associated with other errors, such as improper sterilization of equipment. In addition to Federal oversight and payment policies to drive prevention of unsafe practices, local and State authorities are necessary to temporarily or permanently halt unsafe medical practices. Once halted, strategies for identifying exposed individuals are needed so that those put at risk by incorrect practices can be notified and provided care.

### *Patient Notifications*

When failures of infection control result in a need to notify patients who were put at risk, such notifications and the accompanying diagnostic testing can be resource and labor intensive and are not without potential harm to patients notified. Decisions regarding notification of exposed patients when there is no evident disease transmission are challenging. CDC has engaged diverse partners that include State and local health departments, patient advocates, public health professionals, ethicists, healthcare industry representatives, and the Safe Injection Practices Coalition to discuss and obtain input on the ethical and communication issues related to such patient notification. CDC also hosted six focus groups in New York and Atlanta to identify best practices for notification. CDC's Public Health Ethics Committee also informed the process.

Based on the process described, CDC has developed recommendations for determining whether patient notification should be initiated and how best to do so. This includes evaluation of the problem in order to classify it as Category A: a gross error or demonstrated high-risk practice (e.g., reuse of needles or syringes between patients or use of contaminated syringes to access shared medication vials), or Category B: an error with lower likelihood of blood exposure (e.g., endoscope reprocessing errors). Patient notifications are indicated for Category A. When an error is classified as Category B and there is no known transmission of blood borne or other pathogens, decisions should be based on several factors, including the risk of infection, the duty to warn versus the potential harm to patients from the notification, and addressing public concerns.

CDC is currently developing a patient notification communications toolkit based on the information gathered through the process above. The toolkit will contain resources for developing documents for patient notification (e.g., sample notification letters, sample patient test results letter, resources for risk communication); establishing communication resources (e.g., setting up a call center); planning media and communication strategies (e.g., sample press release); and best practices for patient notification (e.g. planning the release of media and notification letters, communicating with key stakeholders and partners).

CDC has met with and continues to work with the VA to share CDC's recommended practices for patient notifications.

### **Conclusion**

Ensuring that appropriate infection control practices are adhered to in all healthcare settings is a priority for CDC. Public health plays an important role in ensuring a unified approach through systematic implementation of prevention practices, monitoring to detect problems, outbreak investigation and control, oversight, education, and research. As healthcare continues to grow in complexity and is increasingly provided in outpatient settings such as ambulatory surgical centers, dialysis centers, and nursing homes, where infection control programs and oversight are generally less rigorous, outbreaks from transmission of pathogens through lapses in basic infection control practices have grown. As a result, CDC has undertaken a number of efforts to evaluate the problem and develop prevention strategies so that these errors do not recur. Many of these efforts are in collaboration with diverse partners, including the VA, allowing for broad implementation of recommended practices.

As we continue to work toward elimination of HAIs, new healthcare settings and changing technology will create new challenges and will require continued vigilance. CDC continues to strive to address those challenges and ensure that patients are safe in every healthcare setting. Infections caused by lapses in basic infection control are unacceptable. We know how to protect patients from these events; they can and must be prevented.

Thank you for the opportunity to testify today; I am happy to take any questions you may have.

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**Prepared Statement of Anthony D. Watson, BS, MS, MBA, Director,  
Division of Anesthesiology, General, Hospital, Infection Control, and  
Dental Devices, Office of Device Evaluation, Center For Devices and  
Radiological Health, Food and Drug Administration,  
U.S. Department of Health and Human Services**

### **Introduction**

Mr. Chairman, Ranking Member Filner, and Members of the Committee, I am Anthony D. Watson, Director, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices, Office of Device Evaluation, Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to discuss reprocessing of reusable medical devices and the importance of adequate reprocessing to protect patient safety. FDA is committed to working with our partners in industry, government and care settings to ensure patients are not at risk from unacceptable lapses in patient safety practices related to the reprocessing of medical devices. Today, I will provide you with an overview of medical device regulation, discuss the background on reprocessed medical devices, and describe actions FDA is taking to address safety concerns related to reprocessing of reusable medical devices.

### **Overview of Device Regulation**

A medical device, as defined by Federal law, encompasses several thousand health products, from simple articles such as tongue depressors and heating pads to cutting-edge and complex devices such as implantable defibrillators and robotic equipment for minimally invasive surgery.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) gave FDA specific authority to regulate the safety and effectiveness of medical devices. Medical devices are assigned to one of three regulatory classes based on risk.

Class I, General Controls, is the lowest risk category of devices and includes items such as adhesive bandages. These devices are subject to the General Controls of the Act, which include establishment registration and device listing, compliance with current Good Manufacturing Practice (cGMP) and labeling, recordkeeping, and reporting requirements.

Class II, Special Controls, is the next category of risk and includes devices such as intravenous catheters and powered wheelchairs. They are subject to the General Controls of the Act as well as Special Controls, which may include special labeling requirements, mandatory performance standards, and post-market surveillance, in order to provide reasonable assurance of the safety and effectiveness of the device.

Class III is the highest risk category of device and includes devices such as heart valves and coronary stents. These devices are subject to the General Controls of the Act, plus approval prior to marketing of a premarket approval application containing scientific evidence of the device's safety and effectiveness.

#### ***Adverse Event Reporting***

Once a medical device is marketed, FDA monitors reports of adverse events and alerts health professionals and the public when needed to ensure proper use of devices and the health and safety of patients. FDA uses two principal systems to capture device-related adverse event and product problem reports: the Medical Device Reporting regulation (MDR) and the Medical Product Safety Network (MedSun).

MDR is the mechanism by which FDA receives over 300,000 significant medical device adverse events annually from manufacturers, importers, and user facilities, including hospitals. FDA carefully evaluates the reports received to identify safety concerns of public health importance, such as product problems that could potentially cause injury. User facilities are required to report deaths to the manufacturer and FDA and serious injuries to the manufacturer. Manufacturers must report to FDA within 30 days deaths, serious injuries, and malfunctions that could contribute to a death or serious injury. FDA also receives voluntary reports from many different sources including consumers and healthcare professionals.

The limitations inherent in passive reporting systems such as MDR, include underreporting of adverse events, the submission of incomplete or difficult-to-understand reports, and insufficient information to accurately identify the product in question. Recognizing the limitations of passive reporting systems, FDA launched MedSun in 2002. MedSun is an "active" adverse event reporting program that allows FDA to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices. Over 350 healthcare facilities, primarily hospitals, participate in the MedSun Network.

Facilities participating in the MedSun Network use an Internet-based system to report adverse medical device events to FDA. MedSun facility reporting differs from the other (mandatory) user facility reporting because MedSun participants not only report medical device problems that result in serious injury or death, but they also are encouraged to voluntarily report problems with devices, such as "close-calls," potential for harm, and other safety concerns.

In general, FDA may become aware of device-related or associated adverse events that occur in hospitals through the following mechanisms:

1. the hospital submits an MDR directly to FDA (as described above);
2. a voluntary report from a clinician or patient associated with the hospital and/or the event;
3. a report to the MedSun program (if the hospital is in the program, as described above);
4. the hospital submits information regarding the event to the manufacturer, who then reports an MDR to FDA as part of their MDR reporting obligation; and
5. through the Centers for Disease Control and Prevention (CDC) when it undertakes a possible outbreak investigation at the request of a State health department.

#### ***Reprocessing of Reusable Medical Equipment***

Reusable medical devices are devices that are designed and labeled for use on multiple patients and are made of materials that can withstand repeated reprocessing, including manual brushing and the use of chemicals. Some examples of reusable medical devices are surgical instruments, such as clamps and forceps; endoscopes, used to visualize areas inside the body; and accessories to endoscopes, such as arthroscopic shavers; and laparoscopic surgery accessories, such as graspers and scissors.

All reusable medical devices can be grouped into one of three categories according to the degree of risk of infection associated with their use:

- Critical devices, such as surgical forceps that come in contact with the bloodstream or normally sterile tissue.
- Semi-critical devices, such as certain endoscopes that come in contact with mucus membranes.
- Non-critical devices, such as stethoscopes that come in contact with intact skin.

### ***Description of Reprocessing Process***

Adequate reprocessing of reusable medical devices is a critically important step in protecting patient safety. Reprocessing is intended to remove blood, tissue, and other debris and to inactivate infectious microbes to ensure that devices are safe for the next patient use. Reprocessing can be both labor-intensive and time-consuming, because most reusable medical devices require a specific reprocessing regimen.

In general, reprocessing reusable medical devices involves three steps: initial decontamination and cleaning at the point of use; transfer to the reprocessing work area where the device is thoroughly cleaned; and, either low/intermediate disinfection, high-level disinfection, or sterilization, depending on the intended use of the device, its risk of infection transmission, and the materials from which it is made. The device is then stored or routed back into use.

Many factors contribute to reprocessing difficulties, including device complexity, absence of best practices, user error, and poor instructions on how to reprocess. Manufacturers, healthcare facilities, healthcare professionals, and FDA share responsibility for reducing the risk of healthcare-associated infections (HAIs) from inadequately reprocessed reusable medical devices. HAIs are infections caused by a wide variety of common and unusual bacteria, fungi, and viruses during the course of receiving medical care.

### ***FDA Authority/Role***

Under FDA labeling regulations, 21 CFR Part 801, a device must have adequate directions for use. This includes instructions on how to reprocess (i.e., clean and disinfect or sterilize) a reusable device to ensure that it is effectively prepared for its clinical use. FDA applies its unique position and expertise to reduce the risk of infection from reusable medical devices by evaluating devices prior to marketing, identifying device designs that facilitate proper reprocessing, assuring that manufacturer instructions are clear, and promoting collaboration among all stakeholders. FDA also works with manufacturers to correct product problems associated with reprocessed medical devices.

### ***Manufacturer Role***

Manufacturers should design their devices to minimize debris retention, so they can be easily and effectively cleaned. Instructions for reprocessing, included in product labeling, should be complete, detailed, practical, and easy to understand. FDA expects manufacturers to validate their reprocessing protocols using clinically relevant soil, considering the internal components of the device, and using an actual marker(s) (a measured component of the soil, such as protein, inorganic carbon, etc.) for clean under-simulated use conditions and worst-case scenarios.

### ***Healthcare Facility and Provider Roles***

Healthcare institutions and staff and medical personnel share responsibility for preventing problems associated with reprocessing. Facilities should periodically assess infection control practices in clinical areas using audit tools. Facilities should also ensure that those responsible for reprocessing understand the importance of the job, are given the necessary training to perform it properly, and maintain proficiency in performing reprocessing for each type of device they reprocess. Reprocessing staff should understand that pre-cleaning, cleaning, high-level disinfection, and/or sterilization are distinct and separate steps of reprocessing and that they should follow reprocessing instructions provided by device manufacturers.

Physicians and nurses should consider that reprocessing plays a role in device performance and follow-up with the appropriate chain of accountability. They can do this by reporting adverse events that may be related to inadequate reprocessing, following guidelines established by professional societies, and communicating with manufacturers regarding labeling issues and ease of reprocessing.

### ***Challenges***

Based on adverse event reports received, FDA has identified several safety concerns with reprocessed medical equipment. For example, in a review of adverse event reports on endoscopes filed with the Agency from January 1, 2007, to May 11, 2010, FDA identified 80 reports of inadequate reprocessing and 28 reports of infection that may have occurred from inadequate reprocessing. Endoscopes are long thin tubes with a camera or a light that are threaded into the lungs, the blood vessels, or other cavities to visualize areas within the body. The designs of endoscopes are intricate and complex, making optimal cleaning, high-level disinfection, or sterilization difficult. It is important to note, however, that endoscopes are used in over 10 million medical procedures per year. While it appears that the risk of acquiring such an infection is relatively low and that the benefits of these important devices outweigh their risks, we continue to work with industry, provider and government partners to further reduce risks to patients.

Additional challenges to adequate reprocessing of reusable devices include the detailed, labor-intensive, and time-consuming nature of the necessary processes and the fact that each reusable medical device requires specific reprocessing steps or techniques appropriate for that device. While manufacturers are required to validate their reprocessing instructions by documenting that the recommended cleaning, disinfection, or sterilization process consistently results in an adequately reprocessed device, many manufacturers do not use a clinically relevant test soil in the validation testing of their cleaning instructions for use, nor do they use an adequate marker for the removal of soil. Finally, facility reprocessing challenges, such as inadequate staff training and failure to consistently follow reprocessing procedures, have been noted.

#### ***FDA's Work With the VA and CDC***

The VA and FDA have a Memorandum of Understanding in place which allows for timely information sharing to enhance knowledge and efficiency between the Federal partners. Within FDA, CDRH has designated a liaison that the VA may contact at any time regarding questions or concerns on any topic. With regard to reprocessing, beginning in 2008, the VA and FDA have collaborated to address concerns regarding reprocessing of reusable medical devices and cross-contamination of endoscopes during reprocessing. The Agency has provided labeling and general information on FDA regulations and participated in the VA conference entitled "Reprocessing of Reusable Medical Equipment: Using a Team Approach Towards a Strategic Plan," December 9–11, 2009.

Further, on November 19, 2009, the VA, CDC, and FDA issued a joint safety communication regarding endoscope reprocessing, cautioning healthcare facilities, including hospitals, ambulatory care facilities, and private practices, about the risks to patients of improperly processed flexible endoscopes and their accessories and recommended steps to reduce these risks.

The VA has developed and shares with FDA information from its national electronic Cardiovascular Assessment Reporting and Tracking System (CART-CL), a network of approximately 70 cardiac catheterization labs. FDA staff reviews this information with VA on a monthly basis, and triages for appropriate further actions. Ongoing communication benefits both parties, with FDA learning of unexpected lab-based experiences, and CART-CL learning about FDA recalls and public health communications.

CDC and FDA communicate quite frequently on matters related to general infection control and to coordinate on the approval of some respiratory devices. FDA has an ex-officio member on CDC's Healthcare Infection Control Practices Advisory Committee. CDC has an official liaison stationed at FDA, and there are regular interagency teleconferences with CDC, FDA and EPA to discuss liquid chemical germicides, high-level disinfectants and various aspects of reprocessing of mutual interest to all three agencies.

#### ***Actions FDA is Taking***

Adequately reprocessing reusable medical devices is a critically important step in protecting patient safety. FDA is taking a collaborative approach toward improving the reprocessing of reusable medical devices. On April 29, 2011, FDA launched the Reusable Medical Devices Improvement Initiative to reduce the risk of HAIs from inadequately reprocessed medical devices. FDA's approach to addressing reprocessing problems focuses on collaborating with other government agencies, manufacturers, healthcare facilities, and healthcare professionals to strengthen all steps in reusable device reprocessing by fostering improved, innovative device designs to reduce debris retention, strengthening the science of cleaning and high-level disinfection or sterilization of medical devices, and ensuring that healthcare facilities properly perform cleaning, disinfecting, and sterilization.

Specifically, FDA has issued revised draft guidance that updates and clarifies the recommended content of, and review procedures for, medical device applications concerning the labeling instructions for reprocessing reusable medical devices. In addition, this draft document provides more detail about FDA's recommendations for the validation of processes intended to support reprocessing. We have also announced a public meeting to be held on June 8–9, 2011, to discuss factors affecting the reprocessing of reusable medical devices and FDA's plans to address the identified issues. Finally, FDA has developed a webpage that provides general outreach about reprocessing of reusable medical devices, the challenges of reprocessing, actions FDA is taking to improve safety and effectiveness, and steps consumers and healthcare professionals can take to learn more about reprocessing reusable medical devices and reporting problems to FDA.

***Goals of These Actions***

The Reusable Medical Devices Improvement Initiative focuses on improvements in device design, reprocessing procedures and protocols, and healthcare facility quality assurance practices. This initiative will promote innovation in next-generation reusable medical device design that will make medical devices easier to clean, disinfect, and sterilize, advance the science of cleaning and cleaning validation methods, foster healthcare facility reprocessing quality assurance programs, and share best practices.

The Public Meeting will bring together key stakeholders including industry, user facilities, standards organizations, healthcare accreditation organizations, government agencies, and professional societies the first in a series of conversations between FDA and reusable medical device stakeholders.

**Conclusion**

Reducing the risk of infection from reusable medical devices is a shared responsibility, and one that the FDA takes very seriously. By using its unique vantage point, FDA is helping address unacceptable patient safety problems with reprocessed devices while facilitating improvements in innovative design of the next generation of these devices. Mr. Chairman, this concludes my formal statement. I will be happy to address any questions you may have.

**MATERIAL SUBMITTED FOR THE RECORD**

Committee on Veterans' Affairs  
 Washington, DC.  
 May 12, 2011

The Honorable Eric K. Shinseki  
 The Secretary  
 U.S. Department of Veterans Affairs  
 Washington, DC 20420

Dear Secretary Shinseki:

In reference to our Full Committee hearing entitled "Sacred Obligation: Restoring Veteran Trust and Patient Safety," that took place on May 3, 2011, I would appreciate it if you could answer the enclosed hearing questions by the close of business on June 24, 2011.

In an effort to reduce printing costs, the Committee on Veterans' Affairs, in cooperation with the Joint Committee on Printing, is implementing some formatting changes for materials for all full Committee and Subcommittee hearings. Therefore, it would be appreciated if you could provide your answers consecutively and single-spaced. In addition, please restate the question in its entirety before the answer.

Due to the delay in receiving mail, please provide your response to Debbie Smith by fax at 202-225-2034. If you have any questions, please call 202-225-9756.

Sincerely,

BOB FILNER  
*Ranking Democratic Member*

CW:ds

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**The Honorable Bob Filner**  
**Ranking Democratic Member**  
**House Committee on Veterans' Affairs**

**Hearing on Sacred Obligation: Restoring Veteran Trust and Patient Safety**  
**May 3, 2011**

**Question 1:** Dr. Petzel, would you agree that there is a problem within the Veterans Health Administration with compliance of established protocols, policies and procedures? If so, what are you doing about it?

**Response:** Yes, there are challenges in ensuring 100 percent compliance with established policies across 152 medical centers, 798 community based outpatient clinics, and 313,539 employees. Because this is such an important issue, I, as Under Secretary for Health, have undertaken a realignment of the Veterans Health Administration (VHA). Clinical elements previously focused only policy development have been moved into the Deputy Under Secretary for Health for Operations and Management (DUSHOM) Operations and Management section. This realignment provides clinical leaders who will: better ensure compliance with existing policies; improve compliance mechanisms in future policies; and improve accountability, with a direct link to the Veterans Integrated Service Network operational structure and the ability to directly influence practices and clinical outcomes.

These clinical leads will develop a dashboard, or set of metrics, in the areas of homelessness, primary care, mental health, dental, surgical services, geriatrics and extended care, sterile processing department (SPD), disability management, and rural health operations. These dashboards allow the DUSHOM to better monitor the quality of care provided at the field level. For example, we are aggressively inspecting SPDs (a total of 9 per year per facility), and are consolidating inspection data to track policy compliance in several key areas. Facilities with problems identified through inspections must submit remediation plans that are tracked through completion by VA's national SPD office.

Additionally, VHA oversight functions have been consolidated under the Principal Deputy Under Secretary for Health (PDUSH). This will serve to align and reconcile results of internal and external reviews, with VHA performance metrics and performance results within a single entity allowing for clear identification of outliers and improvements. Under the leadership of the PDUSH and DUSHOM, operations and management leaders will work closely with a new VHA Quality, Safety, and

Value (QSV) program office to ensure policy compliance and oversight is improved. QSV will increase senior leader accountability for the quality of clinical programs as well as the quality of VHA oversight of those clinical programs. The Clinical Consultation and Compliance program within QSV is tasked with implementing an International Organization for Standardization (ISO) 9001-consistent Quality Management System (QMS) in VHA, beginning with SPD.

ISO 9001 is the internationally recognized standard for the quality management of businesses. It applies to the processes that create and control the products and services an organization supplies. This approach prescribes systematic control of activities to ensure that the needs and expectations of customers are met. This method is designed and intended to apply to virtually any product or service, made by any process anywhere in the world. The ISO 9001 tools are widely recognized as a best practice approach to hardwire continuous quality improvement into organizational structures. I believe this approach will move VHA forward in reaching our shared goals for improvements in the VA healthcare system.

**Question 2:** It is clear to me that more attention needs to be brought upon managers within the system who are accountable for ensuring that policies are in place, enforced and reinforced and that the management of personnel who are entrusted with carrying out the policies needs to be bolstered. People need to be held accountable at every level for not doing the right thing. When you have a Service Chief who does not do ANYTHING about the behavior of practicing dentist, even though he had been informed that infectious control protocols were being completely ignored, indicates to me a glaring weakness in leadership principles.

**Question 2(a):** How can behavior such as that [of the dentist in question in Dayton] go unnoticed for as long as it did when multiple staff members knew what was going on?

**Response:** This error was one of leadership—a failure on the part of the service chief to act in response to employee complaints. Inadequate leadership by the dental service chief created an atmosphere in the dental clinic that discouraged individual employee responsibility and accountability. The employees failed to go above the service chief to make the medical center director or others aware of the issue. Given the number and frequency of physical reviews and inspections of the dental clinic by individuals from other departments at the Dayton VAMC, employees from other VHA facilities, and organizations external to VHA, I, as Under Secretary for Health, was greatly disappointed to learn that the dental clinic issues were not reported earlier. As a side note, a large number of VHA employees are also veterans who receive care at their place of employment. These employees represent the full range of healthcare professional and support occupations, and are trained in VHA's expectations for infection control and customer service. VHA did not receive complaints from our non-dental service employees who received dental services.

During the week of May 2–5, 2011 a Management Review Team conducted an on-site Management Program Review at the dental clinic as requested by the DUSHOM. This team was comprised of seasoned current and former VHA executives. Among many issues reviewed in detail were the length of time the unacceptable practices continued and the failure to correct those practices. The team report offered 11 recommendations for improvement across many program areas. These recommendations are under final review and action plans have been developed to implement them. Again, while this situation occurred primarily due to a failure of leadership by the former service chief, it was determined that improvement actions were needed in other program areas such as quality management, organizational development, and patient safety.

**Question 2(b):** Why do you think other staff members did not come forward when nothing was done about the dentist's behavior?

**Response:** Cultural and other environmental factors may have contributed to staff members not reporting. However, despite concerns regarding the impact of making such a complaint on their career, or about retaliation from the dentist in question or the former service chief, VHA employees have various means of reporting complaints or concerns. These include reporting through the Office of the Inspector General (OIG), Office of the Medical Inspector, or to Infection Control or Patient Safety. Additionally, the System-wide Ongoing Assessment and Review Strategy (SOARS) program, The Joint Commission, and OIG had visited the facility on multiple occasions before discovery of this unacceptable practice. Dental employees could have approached those individuals at any time to make them aware of these issues.

The VHA National Center for Organizational Development (NCOD) offers organizational assessment and consultation services to VHA organizations nationwide. NCOD assists with the design, administration, and feedback provision of the VHA All Employee Survey. NCOD also maintains an active research arm focused on organizational outcomes. Approximately 1 year prior to discovery of the practices of the dentist-in-question, NCOD had been engaged by Dayton VAMC to review and assess outlier employee satisfaction scores identified at the dental clinic via the nationally administered All Employee Survey. Since the discovery of issues at the dental clinic, NCOD has conducted onsite programs in the dental clinic to help clarify organizational climate and environmental issues. NCOD is available to provide training, coaching, and other assistance to individual leaders, managers, and supervisors in all programs and departments at the Dayton VAMC.

Although this report is still being reviewed, of the recommendations in the Management Review Team Report, three encompass organizational climate and development issues: specifically executive team building; development of soft skills across the organization; and executive leadership transition. NCOD will provide additional consultation in these areas and actions are underway to identify seasoned VHA leaders to provide additional coaching and consultation as action plans are developed to move forward to address the recommendations made by the review team.

Additionally, the situation in the dental clinic has been used as a teachable moment in a variety of meetings with Dayton VAMC staff, in particular the obligation and requirement to report instances of improper infection control and substandard patient care, to pursue those reports further if action is not taken to address identified issues, and to identify methods such reporting can be accomplished either anonymously or by self identification. This was specifically addressed during the stand-down period held in the dental clinic, where the dental clinic was temporarily closed to allow for staff retraining.

**Question 2(c):** Is the leadership team not accessible to the front-line worker?

**Response:** We have no evidence that any employee from the dental clinic ever attempted to bring their concerns to the leadership team and were turned away, or prevented from doing so. No member of the dental clinic staff interviewed stated that they had made any effort to contact the leadership team.

The senior leadership team at any VA Medical Center is accessible to staff by several means, including scheduled committee meetings, special hospital wide programs and celebrations, visits to various work areas, and facility assessment walk throughs. In addition, all senior leadership team members are accessible by email, as they are included in the e-mail directory at each location.

A number of reviews of the dental clinic were conducted prior to the discovery of practices of the dentist in question. Among these were semi-annual physical environmental inspections conducted by a large multi disciplinary team from other Dayton VAMC departments and led by the Associate Medical Center Director. During these environmental rounds, extensive discussions take place between team members and employees in the area undergoing inspection. These discussions take place simultaneously in the various work areas under review. It would not have been possible for the former service chief to monitor or control in any way all related interactions or discussions. The practices of the dentist in question were not identified during these physical inspections of the dental clinic.

At the Dayton VAMC, suggestion boxes are placed at multiple locations across the Dayton campus to allow for employees, patients and visitors to communicate directly with the senior leadership team. This approach allows for anonymous participation. The former Medical Center Director conducted quarterly all employee town hall meetings where any employee had the opportunity to raise issues and/or ask him questions directly.

Presently, the Acting Medical Center Director has a well-publicized open door policy allowing for any employee to drop by unscheduled, to discuss any issue. He is frequently out in the medical center on unannounced "walkabouts" to seek out and engage employees. A formal ambassador program has been created for senior leaders where senior leaders all are scheduled for well-publicized informal engagement sessions in the main hospital lobby and accessible to employees, veterans, and visitors. A new working group has been established that includes Veteran Service Organization (VSO) and elected officials representatives, to share information collaboratively and specifically identify stakeholder issues and concerns. Finally, the Acting Medical Center Director is making personal visits to individual VSO posts across the Dayton VAMC service area.

**Question 3:** Please explain to the Committee how long the external peer review program has been in place and how often they look at cases for each facility to assess the care provided?

**Question 3(a):** What, as a manager, do you do with those reports?

**Question 3(b):** The Veterans Integrated Service Network Directors are very senior employees, how do these reports affect them?

**Response:** The national external peer review contract was awarded on September 30, 2009 and was implemented during FY 10. The external reviews consist of audit reviews and facility requested peer reviews. The audit reviews serve to assess inter-rater reliability on peer reviews completed by facility staff as well as validate our local process. Facility requested peer reviews are conducted when there is not enough clinical depth in a particular specialty to obtain a peer review, when a senior level provider, such as a service chief, is under review, or when facility leadership determines an independent outside review is warranted.

All VA facilities are required to submit cases once per quarter for audit review. The large tertiary care facilities (complexity 1a and 1b) submit 15 cases/quarter; the smaller facilities (complexity 1c, 2, and 3) submit 10 cases/quarter. As of May 20, 2011, 281 facilities requested reviews and 1,785 audit reviews have been completed. The completed external peer reviews have a secondary review by clinical staff in the Office of Quality and Safety (OQS). Any clinical concerns are brought to the attention of the VISN Chief Medical Officer, VISN Quality Management Officer, facility Chief of Staff, and the facility Quality Manager or Risk Manager. Teleconference calls are scheduled with OQS staff, medical experts from the contractor, VISN, and medical staff to discuss cases when an opportunity for performance improvement is identified. The external peer review program is contributing to our ongoing mission to provide high quality care to our veteran population.

**Question 4:** What qualities and skills does VHA look at when considering a selection for a VA Medical Center Director?

**Response:** Any Medical Center Director candidate must have a broad and in-depth knowledge of healthcare systems. They must be able to analyze complex issues, identify steps to resolve problems or implement policy, evaluate outcomes and take corrective action where indicated. They must have strong leadership skills to responsibly and effectively triage clinical and management issues as they arise. Sound judgment is paramount and must foster an environment of professionalism, optimism, honesty, integrity, commitment to quality, continuous learning and candor. The candidate must have a strong sense of duty, honor and commitment to provide the highest quality of healthcare to those who have served our country. Potential candidates are required to have demonstrated hands-on healthcare operations experience, professional board certification and continuing education are used to ascertain an individual's commitment to maintaining and advancing one's personal skill set, and a proven record of significant prior accomplishments is required.

**Question 5:** What are the actions taken with facility management and leadership when the VA Inspector General repeatedly finds problems at a facility?

**Response:** VA leadership assesses each case and takes appropriate personnel actions when indicated. A broad range of actions may be considered ranging from the development of remediation plans to disciplinary action depending on the nature and severity of the issue. Issue-specific action plans may also be developed by the facility to address identified issues. These are approved by the VISN and the OIG and implementation is then monitored at the facility and VISN level.

**Question 6:** Both the Inspector General and the Government Accountability Office have stated in separate reports that patient safety is at risk due to leadership failures and weaknesses in policies and oversight.

**Question 6(a):** What are you doing to improve leadership quality and management training?

**Response:** As stated previously, a VHA reorganization is being implemented at the highest levels of VHA to ensure appropriate resources are aligned to accomplish the improvements needed. NCOD as described previously, is a nationwide resource, that is actively engaged across the VHA system to help identify improvement opportunities and provides the tools and support necessary to achieve improvements.

Additional actions have been taken by the National Center for Patient Safety (NCPS). NCPS provides patient safety training programs geared toward improving communication and hand-offs for facility staff and leadership including: Medical Team Training (MTT), and Clinical Crew Resource Management (CCRM). Specifically in regards to infection control and re-useable medical equipment, training mod-

ules and tools related to supply/equipment reprocessing resulting from joint work have been shared with facilities, Networks and VHA Central Office leadership and staff. These include: a series of core lessons learned from reprocessing investigations completed in late 2010 (Attachment A); a nationwide Healthcare Failure Mode and Effects Analysis (HFMEA) project completed in 2007 (Attachment B); and, a presentation at the national Network and Facility leadership meeting “Preventing Infection is Everyone’s Job” in early 2011.

### **NCPS Lessons Learned—Reusable Medical Equipment in VHA**

*Lori A. King, Biomedical Engineer, NCPS*

The National Center for Patient Safety (NCPS) has been involved in many investigations involving set-up, use, and reprocessing of reusable medical equipment (RME) over the last few years. We have issued Patient Safety Alerts and Advisories on some of these topics. The two most well-known VHA Patient Safety Alerts on the subject are the following:

- Patient Safety Alert AL06–11, issued on April 3, 2006, dealt with transrectal ultrasound transducers used for prostate biopsies (<http://www.patientsafety.gov/alerts/B-KMedicalTransducerAlert06-011.pdf>). The facility reported soiled needle guides and later learned that brushes had not been used to clean the lumens of the needle guides. Patients from several medical centers required notification and follow up testing (for HIV, Hep C, and Hep B), resulting in the largest look back/notification in VHA’s history.
- Patient Safety Alert AL09–07, issued on December 22, 2008, discussed improper setup and reprocessing of endoscopic irrigation accessories (<http://www.patientsafety.gov/alerts/OlympusScopesAlertAL09-07-WWW.pdf>). This Alert also required patient notification for some facilities and prompted VHA to look at all of the reprocessing of RME in VHA facilities.

With all of the additional attention provided nationally to reprocessing since December 2008, numerous issues with set-up, use, and reprocessing of RME have been reported from VHA facilities via Issue Briefs up through their VISN Offices to Central Office. Additional issues have been identified in Office of the Inspector General Combined Assessment Program (OIG–CAP) reports, System-wide Ongoing Assessment and Review Strategy (SOARS) reports, and other investigations.

From involvement in many of these investigations we have identified causative factors that have contributed to the potential for risk to patients. The risk factors are outlined below along with suggestions that facilities can put in place to mitigate the risks. The risk factors and suggestions are listed in no particular order; all are important to protect our veterans from potential harm.

By providing an environment where staff feel protected to report discrepancies, without fear of retribution or discipline, we encourage such issues to come to light and they (along with suggestions for mitigating the risks) can be shared nationally to ensure we are providing the best care for our veterans.

#### **Attachment A**

<b>Risk Factor</b>	<b>Suggestion to Mitigate Risk</b>
<p>Reprocessing devices and device accessories in a manner inconsistent with manufacturer’s instructions (i.e., not following the manufacturer’s instructions step by step or omitting steps).</p> <p><i>Some examples:</i></p> <ul style="list-style-type: none"> <li>• Devices and device accessories not fully disassembled before reprocessing</li> <li>• Devices not sufficiently cleaned prior to disinfection or sterilization (e.g., neglecting to brush lumens or channels; failing to fully submerge a device that requires full submersion into the cleaning solution)</li> </ul>	<p>Follow the manufacturer’s instructions for reprocessing—exactly, step by step.</p> <p>Don’t use an item if you don’t have manufacturer instructions and an SOP that matches the manufacturer’s instructions.</p> <p>At least annually, verify that SOPs match the most current manufacturer’s instructions. A new model of device can mean new reprocessing instructions and manufacturers reserve the right to change reprocessing instructions. While suppliers will likely notify facilities of changes, often that information doesn’t make it to the end users of the devices.</p>

Risk Factor	Suggestion to Mitigate Risk
<ul style="list-style-type: none"> <li>• Use of reprocessing agents not approved by the manufacturer (e.g., use of hand soap instead of an enzymatic cleaner; use of alcohol or sterilizing wipes instead of high level disinfection or sterilization)</li> <li>• Devices not high level disinfected or sterilized (e.g., not using the sterilization parameters set forth by the manufacturer's instructions; cleaning but not high level disinfecting or sterilizing)</li> </ul>	<p>Do not rely on verbal or emailed instructions from manufacturers. Follow official guidance from the manufacturer (e.g., information obtained from the Instructions for Use, Reprocessing Guides, Company Brochures, Memorandum on company letter head, etc.).</p> <p>Do not adapt/modify manufacturer's instructions to fit your needs. If you don't have enough devices to properly reprocess them—order more devices.</p> <p>Establish and follow QC procedures in SPD and other areas reprocessing devices (e.g., commercially available quality testing for equipment in the decontamination area as well as endoscopy instruments). Technical quality controls such as mechanical, chemical and biological indicators must be used in all areas that perform sterile processing.</p> <p>Implement a QA program, to include <i>at minimum</i> random audits to observe actual reprocessing practices and annual review of SOPs.</p> <p>Initial cleaning of instruments (at the point of use after the procedure) should be completed as soon as possible after the procedure so that bioburden does not dry on them or in their lumens/channels.</p> <p>Reprocess every channel of a device, whether or not the channel has been used during the procedure.</p> <p>Provide magnification tools and proper lighting for SPD (and other areas reprocessing RME) to conduct visual inspection of devices. Any devices that manage to emerge from reprocessing still dirty should be identified in SPD (or other areas reprocessing RME), not where the devices are ready to be used (e.g., in the OR, Dental Clinic, etc.).</p>
<p>Manufacturer's set up and/or use instructions not followed</p> <p><i>Some examples:</i></p> <ul style="list-style-type: none"> <li>• Not priming endoscope irrigation systems prior to insertion into patient</li> <li>• Staff "rigging" or "making do" with defective devices or devices missing parts such that procedures don't get canceled</li> <li>• Multiple patient use of single use devices</li> </ul>	<p>Follow the manufacturer's instructions for set-up and use—exactly, step by step.</p> <p>Do not modify, create, or enhance devices, tubing or accessories. If parts are missing, obtain the proper part that is missing. If this is not possible, cancel the procedure. "Rigging" or "making do" may seem like a good idea at the time, but it could and often does more harm than good.</p> <p>Do not reprocess or reuse single use devices.</p> <p>Conduct audits to observe set up and use of RME.</p>

Risk Factor	Suggestion to Mitigate Risk
	<p>Purchase devices and systems with built-in fault tolerance, where possible, making it harder for users to make mistakes in set up or operation.</p> <p>Encourage staff to report discrepancies without fear of discipline or retribution.</p>
Inappropriately trained staff	<p>Ensure that there are an adequate number of trained staff and supervisors at all times in SPD to meet their mission and responsibilities.</p> <p>Ensure staff who reprocess devices understand the implications of improperly reprocessed devices (e.g., the risk of disease transmission to our veterans). Staff should be reprocessing these devices as if the next person they were to be used on—were themselves.</p> <p>Initially and then annually, assess competency of those setting up, using, and reprocessing RME.</p> <p>Assure SOPs are available to staff, in the location where they reprocess the devices.</p> <p>Ensure that reprocessing staff (those in SPD and those who may reprocess in peripheral areas) have completed the appropriate SPD training.</p>
Use of reusable devices that are difficult to clean properly, by design, even when the manufacturer's instructions are followed (e.g., certain graspers, Kerrison Rongeurs, suction tips, dental burrs)	Where possible, purchase and use disposable or "take apart devices" for hard to reprocess items.
Staff not wanting to surrender instruments to SPD for reprocessing for fear of loss or damage to devices	Have the department work closely with SPD and ensure SPD staff is properly trained to handle and reprocess the department's delicate devices.
Not reprocessing a reusable device according to the original equipment manufacturer's instructions once a protective sheath has been removed (e.g., removing the sheath and then using sterilizing wipes followed by application of another sheath)	Reprocess the device according to the original equipment manufacturer's instructions after each use—even if a protective sheath was used on the device during the procedure.
Unclear terminology and/or lack of clear reprocessing instructions from the manufacturer and subsequent assumptions made by staff	Don't make assumptions if a manufacturer's instructions are unclear or non-existent. Get clarification <i>in writing</i> (in a manner more official than email) from the supplier. If this proves impossible, contact the National SPD Office at 513-487-6030.

Risk Factor	Suggestion to Mitigate Risk
Lack of communication/acceptable hand off between staff in SPD (and other areas reprocessing RME) and subsequent assumptions made (e.g., a staff member hands off the process to another staff member, without indicating where they are in the process)	Ensure staff communicate what step they are at in the reprocessing process when they hand off the process to another staff member. If the staff member receiving the hand off is unsure of any details after the hand off, they should err on the side of caution (i.e., assume that nothing has been done on the device and start from the beginning).
Use of inappropriate storage containers for dirty devices (e.g., using sterilization bags to store and transport dirty items) and use of inappropriate storage containers for reprocessed devices (e.g., using reprocessing cassettes, use of foam-backed transport containers)	Use appropriate storage containers for dirty and clean devices. Label storage containers appropriately and keep them in separate areas from one another. Ensure containers physically look different—both in shape and color—to clearly differentiate between containers for clean and dirty devices.
Reprocessing occurring in peripheral locations (e.g., Dental, Eye Clinic, GI, Urology, Radiology, etc) and oversight staff not knowing that reprocessing was going on in the peripheral areas	Consolidate reprocessing to SPD if at all possible. If not possible, include audits of all areas outside of SPD (e.g., Dental, GI, Eye Clinic, GI, Urology, Radiology, etc). Assure that staff working in these peripheral areas are held to the same training/certification standards as the staff in SPD.
Not being cognizant of different reprocessing steps done on the same device used in different areas of the facility (e.g., laryngoscope blades sterilized for the OR but high level disinfected for other areas of the facility—when the manufacturer instructions indicate to sterilize)	Finding different reprocessing processes existing with the same model of device should raise a red flag to be investigated. Note however that sometimes it is perfectly acceptable that the same device can be reprocessed differently depending on area used in the facility—that is, provided the manufacturer’s instructions indicate it can be reprocessed in these manners and the areas where the devices will be used can accept the level of reprocessing. Encourage staff to speak up, without fear of discipline or retribution, when they notice inconsistencies in reprocessing of devices throughout the medical center.
Human factors/systems issues with devices and automatic reprocessors  <i>Some examples:</i> <ul style="list-style-type: none"> <li>• Not using the appropriate automatic reprocessor</li> <li>• Not using appropriate connections with the automated reprocessor</li> </ul>	Ensure staff has been properly trained on the use and function of any automatic reprocessor they use. Verify compatibility of devices when using automated reprocessors and that the appropriate connections are made to devices and reprocessing agents. Purchase automated reprocessors with fail safe features designed into them to mitigate human error. Ensure the device is approved for processing in the automatic reprocessor and that the approval information is reflected in the SOP.

Risk Factor	Suggestion to Mitigate Risk
<p>Staff not following facility policy/protocol or lack of policy/protocol</p> <p><i>Some examples:</i></p> <ul style="list-style-type: none"> <li>• Use of equipment prior to having the approval to use it</li> <li>• Physician bringing in his/her own device (e.g., intubation device) and reprocessing it (often inappropriately)</li> <li>• Damaged scope (to be sent for repair) used on patient</li> <li>• Loaner instruments cleaned but not sterilized</li> <li>• Loaner instruments not being reprocessed prior to use (e.g., delivered from the vendor to the OR instead of SPD)</li> </ul>	<p>Put in place the proper policies/protocols to ensure the examples shown to the left will not occur at your facility.</p> <p><i>For example:</i></p> <p>Ensure there is a protocol to prevent damaged devices from being used on patients. The protocol should include clear labeling on damaged devices and authority to hold onto the device if it is being requested for use on a patient.</p> <p>Assure a policy is written and followed to indicate direction for all OR staff, SPD staff, and vendors, such that they understand what is expected (and not expected) of them regarding loaner instruments.</p>

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## Attachment B

### 2007 Healthcare Failure Mode and Effect Analysis (HFMEA) on Supply Processing and Distribution (SPD) Topics

#### Topics/Processes

1. The process of reprocessing a flexible cystoscope between patients including transportation, decontamination, high level disinfection, sterilization and storage.
2. The process of reprocessing a flexible colonoscope between patients including transportation, decontamination, high level disinfection, sterilization and storage.
3. The process of reprocessing a flexible bronchoscope between patients including transportation, decontamination, high level disinfection, sterilization and storage.
4. The process of reprocessing a flexible esophagogastroduodenoscope (EGD) between patients including transportation, decontamination, high level disinfection, sterilization and storage.
5. The process of reprocessing a rigid endoscope used in urology between patients including transportation, decontamination, high level disinfection, sterilization and storage.
6. The process of reprocessing a rigid endoscope used in ENT between patients including transportation, decontamination, high level disinfection, sterilization and storage.
7. The process of reprocessing reusable items used to perform a transrectal prostate biopsy between patients including transportation, decontamination, high level disinfection, sterilization and storage.
8. The process of assuring sterility of orthopedic implantable devices that come in orthopedic loaner instrument trays.
9. The process of communicating positive biological test results from steam, EtO, and plasma sterilizers to the Chief of Staff, Chief of Surgical Service, Operating Room Supervisor and Infection Control.
10. The process of disinfecting an infusion pump after patient use including transportation and storage.

11. The process of using a pre-vacuum steam sterilizer in SPD including verifying testing (e.g. Bowie-Dick, biological), reviewing printouts (to determine sterilization parameters were met, signature of reviewer, content list (detailed enough to enable item[s] retrieval if necessary) and documentation of all required aspects of sterilization process.
12. The process of using the ethylene oxide (EtO) sterilizer within SPD including verifying testing (biological), reviewing printouts (parameters were met, content list, list of items), content list (detailed enough to enable item(s) retrieval if necessary) and documenting the results.
13. The process of using the plasma sterilizer within SPD including verifying biological testing, reviewing printouts (to determine sterilization parameters were met, signature of reviewer), content list (detailed enough to enable item(s) retrieval, if necessary) and documentation of all required aspects of the sterilization process.
14. The process of using steam sterilization in Dental including verifying biological testing (Bowie-Dick type test if using a pre-vacuum sterilizer), reviewing printouts (to determine if sterilization parameters were met, signature of reviewer), content list (detailed enough to enable item(s) retrieval, if necessary), and documentation of all required aspects of the sterilization process.
15. The process of decontaminating surgical instruments prior to sterilization.
16. The process of preparing surgical instruments for sterilization including preparing the surgical instrument trays (e.g. inspecting for bioburden, checking for instrument usability, correct instruments in correct trays) and packaging instruments.
17. The process of coordinating and communicating the availability of needed equipment and supplies between the OR and SPD.
18. The process of maintaining the primary storage environment including: monitoring room temperature, humidity, the number of air exchanges per hour, pest control; maintaining the storage arrangement (e.g. stock rotation, avoiding outdates); and maintaining cleanliness for sterilized instrumentation, equipment and supplies in SPD.
19. The process of maintaining the secondary storage environment in the operating room including: monitoring room temperature, humidity, the number of air exchanges; pest control; storage arrangement, and cleanliness for sterilized instrumentation, equipment and supplies.
20. The processes of using sterilizers for flash sterilization in the operating room including monitoring the frequency of use, biological testing, identification of the date and patient and the item(s) flash sterilized, and reviewing printouts to verify sterilization parameters are being met.

**Topic 1**

**The process of reprocessing a flexible cystoscope between patients including transportation, decontamination, high level disinfection, sterilization and storage.**

Number of reporting facilities: 8

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Untrained Personnel</i></p> <ul style="list-style-type: none"> <li>• Scope not cleaned properly</li> <li>• Scope not cleaned as per manufacturer's instructions</li> <li>• Lack of standardized staff training</li> </ul>	<ul style="list-style-type: none"> <li>• Provide all staff with a thorough education</li> <li>• Implement a mentoring program that matches new employees with seasoned employees</li> <li>• Provide specific training on procedures that are more difficult to perform or remember</li> <li>• Provide cognitive aids to reduce the amount of information that SPD staff must recall from memory</li> <li>• Provide training on manufacturer's procedure for cleaning</li> <li>• Repeat training annually as necessary</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Scope not placed in distinguishable container for transport</i></p> <ul style="list-style-type: none"> <li>• May result in damage to the scope</li> <li>• Red containers not easily accessible</li> <li>• Difficult to find</li> </ul>	<ul style="list-style-type: none"> <li>• Place distinguishable containers in easy access areas and areas where they are used often</li> </ul>
<p><i>Unable to notify SPD or bring scope to SPD when needed</i></p> <ul style="list-style-type: none"> <li>• SPD not available</li> <li>• Off hours</li> <li>• Not enough staff</li> </ul>	<ul style="list-style-type: none"> <li>• Designate other staff to transport as per policy for off hours scope use</li> <li>• Hire more staff</li> </ul>
<p><i>Frequent use of brush tends to damage bristles</i></p> <ul style="list-style-type: none"> <li>• Result in bioburden build up</li> <li>• Single use brushes used more than once</li> </ul>	<ul style="list-style-type: none"> <li>• Use single use brushes once and throw away when done</li> <li>• Purchase only single use brushes</li> <li>• Indicate to staff how important it is to only use the brush one time</li> </ul>
<p><i>Personal Protective Equipment (PPE) is not donned for cleaning procedure</i></p> <ul style="list-style-type: none"> <li>• PPE is not available</li> </ul>	<ul style="list-style-type: none"> <li>• Place PPE in easy to access</li> <li>• Make sure PPE is available in all clinic rooms</li> </ul> <p><b>ID/SPD Note: PPE cannot be placed inside a room where cleaning takes place, the PPE must be put on before entering this area.</b></p> <ul style="list-style-type: none"> <li>• Create step by step protocol that includes donning PPE</li> <li>• Use cognitive aids that illustrate the step by step protocol</li> </ul>
<p><i>Scopes dry in a horizontal position that causes pooling</i></p>	<ul style="list-style-type: none"> <li>• Purchase a drying cabinet with a fan within which scopes can be hung vertically</li> </ul> <p><b>ID/SPD Note: Scopes must be flushed with alcohol and blown out with air and never stored wet.</b></p>
<p><i>Proper protocol not followed due to lack of adequate equipment</i></p> <ul style="list-style-type: none"> <li>• Not enough equipment</li> <li>• Not the right equipment (e.g. wrong sized brush can cause damage to the scope)</li> </ul>	<ul style="list-style-type: none"> <li>• Purchase more equipment</li> <li>• Be sure to get the proper equipment for cleaning the scopes</li> </ul>
<p><i>Scopes are not being processed at the highest level of sterilization because there are not enough scopes to meet the caseload of the clinic</i></p>	<ul style="list-style-type: none"> <li>• Purchase more scopes to allow proper sterilization between patients</li> </ul>
<p><i>Using different sized sinks or wash basins can alter the cleaner to water ratio</i></p>	<ul style="list-style-type: none"> <li>• Limit process to use of a standard basin only. Ensure all staff use the correct basin</li> </ul>

**Topic 2****The process of reprocessing a flexible colonoscope between patients including transportation, decontamination, high level disinfection, sterilization and storage.**

Number of reporting facilities: 8

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Failure to disassemble endoscope before cleaning</i>	<ul style="list-style-type: none"> <li>• Use the endoscope manufacturer provided cognitive aids showing the cleaning process will be posted where clearly visible during the cleaning of the endoscope</li> <li>• If none are available, construct cognitive aids to provide to staff</li> </ul>
<i>Surgical residents performing endoscopic procedures after hours and on weekends do not wipe down the scope with a detergent soaked sponge/cloth immediately post procedure</i>	<ul style="list-style-type: none"> <li>• Use signage to remind residents of post-operational cleaning</li> <li>• Annual staff education on proper maintenance</li> <li>• Purchase a cleaning kit to be kept bedside for the surgeon to do initial cleaning of the endoscope</li> <li>• Develop a checklist/instruction for the immediate pre and post procedure care of the endoscope and associated equipment and post it in the appropriate areas</li> </ul>
<i>Personal Protective Equipment (PPE) not used regularly</i>	<ul style="list-style-type: none"> <li>• Provide PPE in locations near where reprocessing takes place</li> <li>• Use signage to indicate where and when to use PPE</li> <li>• Be sure to educate staff on proper use of PPE</li> </ul>
<i>Endoscope does not dry properly, water pools in the endoscope</i> <ul style="list-style-type: none"> <li>• Clean endoscope cabinet located in same area as contaminated endoscopes</li> </ul>	<ul style="list-style-type: none"> <li>• Provide a storage cabinet that has adequate ventilation and is equipped to store the endoscopes vertically</li> <li>• Flush lumens with alcohol and/or air prior to storage to promote drying</li> <li>• Move clean endoscope cabinet to an area without contaminated endoscopes</li> </ul>
<i>Steps skipped when going through procedures of cleaning and disinfecting (i.e. forgetting to flush lumens with alcohol)</i>	<ul style="list-style-type: none"> <li>• Post signage of steps for cleaning to jog memory</li> <li>• Set up room to promote the proper cleaning and disinfecting procedures</li> </ul>
<i>Appropriate containers not used to transport contaminated endoscopes</i> <ul style="list-style-type: none"> <li>• Choose not to use container because it is only a short distance to decontamination area</li> <li>• Appropriate containers not available (i.e. only open top containers available)</li> </ul>	<ul style="list-style-type: none"> <li>• See topic 4 “Transportation”</li> <li>• Post signage indicating that contaminated endoscopes must always be transported in a closed top container</li> <li>• Provide more appropriate (i.e. closed top) containers for transport of contaminated endoscopes</li> <li>• Be sure to place an adequate amount of the containers in areas they are needed</li> </ul>
<i>Water temperature not adequate for activating enzymatic solution</i>	<ul style="list-style-type: none"> <li>• Install thermometers to verify water temperature before using the enzymatic solution</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Not using adequate amount of solution when flushing lumens with alcohol or other cleaning steps</i>	<ul style="list-style-type: none"> <li>• Purchase measuring containers that will measure and/or dispense the exact amount of solution needed when flushing lumens or otherwise cleaning the endoscopes</li> </ul>
<i>Timing is not adequate for steps in the reprocessing of endoscopes (i.e. soak time)</i>	<ul style="list-style-type: none"> <li>• Purchase and install a timer in the appropriate areas to use when timing reprocessing steps</li> </ul> <p><b>ID/SPD Note: Make sure there are enough scopes to allow them to be properly cleaned and disinfected/sterilized between use.</b></p>
<i>Endoscope not picked up from Operating Room (OR) in a timely manner</i>	<ul style="list-style-type: none"> <li>• Provide SPD staff with a means of communication (i.e. pagers)</li> </ul>
<i>Results for each scope are not traceable to specific patients on whom a procedure was performed</i>	<ul style="list-style-type: none"> <li>• Staff will record the scope number in the procedure log</li> <li>• Create a column in the procedure log that is used to record the endoscope number for each procedure on each patient</li> <li>• Implement a barcode system, coding both the patient's wristband and the endoscope</li> </ul>
<i>Scopes which fail leak test may be re-processed and used again on a patient</i>	<ul style="list-style-type: none"> <li>• Add to the procedure the process to follow if a leak test fails</li> <li>• All scopes which fail the leak test either before or after the procedure should have a work order placed and be taken out of service until repaired</li> </ul>
<i>Patient specific tracking not done</i>	<ul style="list-style-type: none"> <li>• Develop and implement patient specific tracking log for all scopes</li> </ul>

### Topic 3

**The process of reprocessing a flexible bronchoscope between patients including transportation, decontamination, high level disinfection, sterilization and storage.**

Number of reporting facilities: 10

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Transportation</i></p> <ul style="list-style-type: none"> <li>• Lack of appropriate space to separate clean from dirty instruments/equipment</li> <li>• Adequate container not available for transport</li> </ul>	<ul style="list-style-type: none"> <li>• Set up separate rooms for dirty and clean instruments/equipment</li> <li>• Set up the dirty room so that it is a negative air flow room with monitor checked daily</li> <li>• See Topic 4 "Transportation"</li> <li>• Provide an appropriate transport container that is rigid and properly labeled (i.e. biohazard)</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Decontamination</i></p> <ul style="list-style-type: none"> <li>• Not performed correctly</li> <li>• Lack of training</li> <li>• Process not standardized</li> </ul>	<ul style="list-style-type: none"> <li>• Post the cleaning checklist, use as a cognitive aid</li> <li>• Make employees accountable by including the employee's identification tag to determine who processed the instruments</li> <li>• Maintain record log to reflect serial number of each scope reprocessed and name of the staff doing the procedure</li> <li>• Require annual training for all staff</li> <li>• Develop SOP for all processes and educate staff</li> </ul>
<p><i>Cannot properly complete procedure because of lack of supplies</i></p>	<ul style="list-style-type: none"> <li>• Purchase adequate supplies</li> <li>• Create and utilize a system to report and purchase needed items</li> <li>• Bar code area for items needed</li> </ul> <p><b>ID/SPD Note: Set levels to make sure that an adequate stock is in place and orders are placed in time for supplies to come in before items are out of stock.</b></p>
<p><i>Staff unaware of correct brush to use to remove bioburden</i></p>	<ul style="list-style-type: none"> <li>• Purchase only disposable brushes</li> <li>• Educate staff on which brushes to use to adequately remove bioburden</li> </ul>
<p><i>Staff too busy to properly perform process</i></p>	<ul style="list-style-type: none"> <li>• Re-write position descriptions to adequately reflect the need of the hospital and fill all vacant positions</li> </ul>
<p><i>Lack of appropriate pre-cleaning/Decontamination room and potential for contamination</i></p>	<ul style="list-style-type: none"> <li>• Provide appropriate space to separate clean from dirty instruments/equipment that meets VA directive 7176 requirements</li> <li>• Provide a technician to perform all decontamination procedures</li> </ul>
<p><i>Disinfection of bronchoscope is performed in various areas making it difficult to monitor and ensure compliance with proper procedure</i></p>	<ul style="list-style-type: none"> <li>• Designate one area where the whole process of disinfecting the bronchoscope occurs</li> <li>• Require disinfection of bronchoscopes to occur in SPD</li> </ul> <p><b>ID/SPD Note: Recommend if at all possible all bronchoscopes be packaged and sterilized for each use.</b></p>
<p><i>Proper concentration of enzymatic solution not used</i></p>	<ul style="list-style-type: none"> <li>• Place a waterproof label in the sink to indicate water level needed</li> <li>• Purchase a container that will dispense the amount of enzymatic solution needed for that amount of water (pump bottle)</li> <li>• Or purchase a measuring device for obtaining the correct amount of enzymatic solution (measuring cup/scoop)</li> </ul>
<p><i>Improper sterilization</i></p>	<ul style="list-style-type: none"> <li>• Develop a checklist using manufacturer's recommendations</li> <li>• Direct observation by supervisor to assure compliance with manufacturer's checklist</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Scope not aspirated with alcohol, substituted with another solution</i>	<ul style="list-style-type: none"> <li>• Educate staff on alcohol use</li> <li>• Implement an initialed log to identify scope and process steps</li> </ul>
<i>Inappropriate storage</i> <ul style="list-style-type: none"> <li>• Clean scopes left lying flat in clean containers in dirty areas</li> </ul>	<ul style="list-style-type: none"> <li>• Provide separate areas to accommodate patient procedure decontamination and storage of instruments and equipment in a cabinet</li> <li>• Change the procedure to ensure that scopes are hung to dry after reprocessing</li> </ul>
<i>Failure to link scope and patient to processing cycle</i>	<ul style="list-style-type: none"> <li>• Use a bar coding system</li> <li>• Develop a system that tracks trays and scopes to patient and process used</li> <li>• Number the scopes and keep a log that links scope number to patient and process</li> </ul>

#### Topic 4

#### The process of reprocessing a flexible esophagogastroduodenoscope (EGD) between patients including transportation, decontamination, high level disinfection, sterilization and storage.

Number of reporting facilities: 6

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Transportation</i> <ul style="list-style-type: none"> <li>• Uncertain which bin to use</li> <li>• Potential for mixing the rinsed soiled scope with the clean scope</li> <li>• Potential for wrong container to transport from manual cleaner to Steris</li> <li>• Potential for using wrong bin for delivery of scope to end user <ul style="list-style-type: none"> <li>• Scope could be transported incorrectly (e.g. on its knobs, coiled, twisted or double stacked)</li> </ul> </li> </ul>	Develop a system using different colored bins to differentiate dirty and clean scopes <ul style="list-style-type: none"> <li>• Purchase different colored bins, example: <ul style="list-style-type: none"> <li>• Red bins: Biohazard and dirty scopes</li> <li>• White bins: Transport from manual cleaning to Steris</li> <li>• Gray bins: Clean scope delivery to end user</li> </ul> </li> <li>• Educate staff on the need for proper transportation of these scopes and the need to transport all equipment correctly</li> </ul>
<i>Improper decontamination</i>	<ul style="list-style-type: none"> <li>• Have reprocessing manual available for GI and SPD staff for immediate reference during reprocessing</li> </ul>
<i>Potential for using the wrong sized brush or not having the appropriate brushes available</i>	<ul style="list-style-type: none"> <li>• Keep an ample supply of appropriately sized, disposable brushes</li> </ul>
<i>Potential for attaching the wrong cover to the channels (i.e. different type of scope or different manufacturer)</i>	<ul style="list-style-type: none"> <li>• Implement plastic identifier card using sturdy chains installed to each connector that identifies type of scope and manufacturer</li> <li>• Implement bar coding system if possible</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Scope is not wiped down immediately following procedure</i>	<ul style="list-style-type: none"> <li>• Develop procedure for nursing supervisor and ICU staff on pre-cleaning and handling scopes immediately after a procedure</li> </ul>
<i>Dried bioburden is not removed</i>	<ul style="list-style-type: none"> <li>• Competency for GI nurses will include details on aspirating detergent and flushing air through channel</li> <li>• Ensure appropriate brushes are available for removing bioburden</li> <li>• Post instructions as to proper removal of bioburden emphasizing proper technique</li> </ul>
<i>Failure to accomplish leak testing</i> <ul style="list-style-type: none"> <li>• Failure to deflect distal tip to check for leakage</li> </ul>	<ul style="list-style-type: none"> <li>• Monitor number of wet tests related to number of scope procedures completed</li> <li>• Post a detailed sequence of steps in view of key staff assigned to reprocessing of scopes with demonstrated competency assessed annually and as changes occur</li> <li>• Monitor number of tip deflections performed related to number of scope procedures performed</li> </ul>
<i>High level disinfection</i>	<ul style="list-style-type: none"> <li>• Write SOP to provide a standard of practice on processing scopes using high level disinfection to clean scopes on clinical days</li> <li>• SOP needs to be in place to provide communication with end users on processing of scopes to use during high level disinfection</li> </ul>
<i>Biological results are positive, but are not communicated as such</i>	<ul style="list-style-type: none"> <li>• Alter the process to include running biological indicator at the end of the shift</li> <li>• Results will be available to ensure next morning's workload begins with an operational unit</li> <li>• Develop means of communicating test status between microbiology and endoscopy</li> </ul>
<i>Staff may not be aware to test the Steris system each day</i>	<ul style="list-style-type: none"> <li>• Quality control book should be maintained to ensure each Steris machine is checked for diagnostics and biologicals daily during regular tours</li> <li>• Educate staff and post signage near the Steris indicating daily procedures</li> </ul>
<i>All staff may not be aware of the minute details that should be completed for each cleaning of scopes</i>	<ul style="list-style-type: none"> <li>• Assign key staff to endoscope cleaning trained with a detailed step by step process, annually or as changes occur</li> <li>• Create a specialty team for the scope cleaning process</li> </ul>
<i>Storage</i>	<ul style="list-style-type: none"> <li>• Provide a cabinet that will allow scopes to hang to promote proper drying</li> </ul>

## Topic 5

**The process of reprocessing a rigid endoscope used in urology between patients including transportation, decontamination, high level disinfection, sterilization and storage.**

Number of reporting facilities: 8

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Transportation</i></p> <ul style="list-style-type: none"> <li>• Containers used for storage and sterilization do not protect the scopes during transportation</li> <li>• Sterile instruments are transported on a dirty wire cart</li> <li>• Scope transported without a solid lid</li> </ul>	<ul style="list-style-type: none"> <li>• Purchase and implement appropriate containers to protect the scopes during transportation</li> <li>• Permanently label wire transport cart as “clean” and “dirty”</li> </ul> <p><b>ID/SPD Note: These carts must be closed carts, or solid bottom shelves and impervious covers, (closed is better, metal).</b></p> <ul style="list-style-type: none"> <li>• All scopes will be placed in a covered container with a solid lid for transporting to SPD</li> </ul>
<p><i>Variation in the concentration of the enzymatic cleaner</i></p>	<ul style="list-style-type: none"> <li>• Purchase a measuring device to select the correct amount of enzymatic solution</li> <li>• Purchase a container that will dispense the correct amount of solution</li> <li>• Make a waterproof mark on the sink indicating the adequate water level to achieve the correct concentration of enzymatic cleaner solution</li> </ul>
<p><i>Brushes being re-used</i></p>	<ul style="list-style-type: none"> <li>• Decontaminate the brushes daily</li> <li>• Purchase disposable brushes only</li> <li>• Decontaminate the brushes after every use</li> </ul>
<p><i>Scopes arrive at SPD with dried debris on them</i></p>	<ul style="list-style-type: none"> <li>• Implement use of enzymatic cleaner in a spray bottle to spray scopes with after procedures to prevent dried debris</li> </ul> <p><b>ID/SPD Note: Simply spraying the scopes will not correct the problem, the scopes must be wiped by the user and the suction and biopsy ports suction/irrigated.</b></p>
<p><i>Staff unaware that ultrasonic cleaner needs to be changed often and needs enzymatic solution</i></p>	<ul style="list-style-type: none"> <li>• Place signage above the ultrasonic cleaner regarding the use of the enzymatic cleaning solution and the amount to be used</li> <li>• Change the process to state that the ultrasonic cleaner must be drained after each case cart</li> <li>• Post manufacturer cleaning instructions and review cleaning techniques for all scopes</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Variation in the scope cleaning process by SPD staff</i>	<ul style="list-style-type: none"> <li>• Standardize the process by implementing a SOP</li> <li>• Educate staff in SOP</li> <li>• Install cognitive aids indicating appropriate steps to take during process of cleaning</li> <li>• Be sure to purchase adequate numbers of scopes to allow reprocessing in SPD between uses</li> <li>• Purchase adequate amounts of cleaning supplies to allow appropriate reprocessing procedures</li> <li>• Create a system such as bar coding to track the scope to the person who cleaned it</li> </ul>
<i>Washer/Disinfector machine's dry cycle does not dry instruments</i>	<ul style="list-style-type: none"> <li>• Ensure that the biomedical engineer's periodic maintenance includes drying cycle checks</li> <li>• Ensure SPD staff know how to report malfunctions</li> <li>• Add malfunction reports to annual staff training and new employee orientation</li> </ul>
<i>Variations in scope cleaning process by SPD staff</i>	<ul style="list-style-type: none"> <li>• Establish SOP and include it in new employee orientation, and annual staff training</li> </ul>
<i>Storage</i> <ul style="list-style-type: none"> <li>• Inadvertently placed soiled items on the top of the cart where clean items are being stored</li> <li>• There are environmental hazards such as cleaning materials or dust in the storage area</li> </ul>	<ul style="list-style-type: none"> <li>• Store all sterile supplies in a sterile supply room only</li> <li>• Evaluate for the availability of storage space for clean items in the OR rooms so clean items are not stored on the top of the case cart during procedures</li> <li>• Purchase closed shelving units for quarantined items</li> <li>• Relocate current shelving to minimize the contamination of packages due to environmental hazard</li> </ul>

**Topic 6**

**The process of reprocessing a rigid endoscope used in ENT between patients including transportation, decontamination, high level disinfection, sterilization and storage.**

Number of reporting facilities: 2

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Transportation</i> <ul style="list-style-type: none"> <li>• While transporting the scope to be cleaned, it is broken</li> <li>• Endoscope may not be used in an area where biohazard bags are present, resulting in endoscopes not placed in biohazard bags</li> </ul>	<ul style="list-style-type: none"> <li>• Obtain larger containers to transport scopes out of room to the area where they are processed</li> <li>• Provide biohazard bags inside transport case to cover contaminated endoscope from inpatient units after use</li> <li>• Post in the exam rooms and outside of the endoscope transportation case, signage indicating that used endoscopes must be placed in biohazard bags</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Timing for disinfecting and cleaning steps is not consistent</i>	<ul style="list-style-type: none"> <li>• Purchase and install a clock with a second hand in the work room</li> <li>• Purchase timers to time endoscope exposure to enzymatic detergent and Cidex OPA</li> </ul>
<i>Crucial steps in the cleaning process are omitted or incomplete</i>	<ul style="list-style-type: none"> <li>• Sterile processing of endoscopes should be done by SPD staff who have completed required training and certification as per VHA directive 7176</li> <li>• Ensure manual is updated and available</li> <li>• Provide in-service by vendor to all who are responsible for cleaning the endoscopes</li> <li>• Due to tedious process, rotate SPD staff through different duties during the day</li> <li>• Implement a system for accountability using identifying tags, or a bar coding system</li> </ul>
<i>Personnel without validated VAMC competency initiate the high level disinfection process</i>	<ul style="list-style-type: none"> <li>• ENT clinic staff, ENT medical staff and rotating ENT resident rosters should be reviewed for competency</li> <li>• If not competent, schedule in-service training for staff who need it</li> <li>• Schedule in-service training for physicians and residents as well</li> </ul>
<i>Storage cabinets are not labeled potentially causing clean and dirty instruments to be mixed up</i>	<ul style="list-style-type: none"> <li>• Label clean storage cabinets “clean endoscope”</li> <li>• Label any container that holds dirty instruments “dirty endoscope”</li> </ul>

### Topic 7

**The process of reprocessing reusable items used to perform a transrectal prostate biopsy between patients including transportation, decontamination, high level disinfection, sterilization and storage.**

Number of reporting facilities: 7

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Power goes out: weather, earthquake, fire</i>	<ul style="list-style-type: none"> <li>• Reschedule cases</li> <li>• Obtain backup power sources</li> <li>• Develop a backup plan to use other facilities</li> </ul>
<i>Nobody in SPD available to receive items (i.e. lumens)</i> <ul style="list-style-type: none"> <li>• Staffing issues</li> <li>• Lack of communication process</li> </ul>	<ul style="list-style-type: none"> <li>• Hire more staff or backup staff</li> <li>• Use an end of shift report, morning and afternoon reports and a communication board in a prominent location</li> </ul>
<i>Items missing/left in urology procedure area or in the OR</i> <ul style="list-style-type: none"> <li>• Items picked up by SPD staff inadvertently from the OR area</li> <li>• Items are thrown away after the case</li> </ul>	<ul style="list-style-type: none"> <li>• Urology should assume the responsibility for items used during OR (operating room) procedures and should perform initial cleaning prior to delivering items to SPD decontamination area</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Incorrect solution or ratio of enzymatic cleaning agent and water used for cleaning</i>	<ul style="list-style-type: none"> <li>• Identify correct amount of enzymatic cleaning agent purchasing container that dispense correct amount of cleaning agent or using other measuring device (i.e. cup)</li> <li>• Post this information at the decontamination sink to avoid re-labeling each new bottle and to identify the correct solution</li> <li>• Add measurement markers at 1 gallon intervals to act as a visual aid for staff when they fill the sink with water</li> </ul>
<i>Failure to follow the correct protocol when cleaning the instruments</i>	<ul style="list-style-type: none"> <li>• Educate the staff in the standardized processes available for instrument maintenance</li> <li>• Review this information annually</li> <li>• Post visual aids and/or memory joggers to assist staff</li> </ul>
<i>Contamination occurs during handling</i>	<ul style="list-style-type: none"> <li>• Establish strict standardized procedure for handling and sterilization of the prostate needle guide device. SPD manual H90.1 guideline (<b>ID/SPD Note: this should be the VA Directive/Handbook 7176</b>) will be followed to prevent contamination (e.g. end user rinses the dirty device with tap SPD picks up the device the device is submerged in cleaning solution external and internal)</li> </ul>
<i>Instruction not complete /correct</i>	<ul style="list-style-type: none"> <li>• For new equipment/devices procedures/instructions are developed using the manufacturer's guidelines. Guidelines are attached to the new procedure</li> </ul>
<i>Failure to follow manufacturer's instructions</i> <ul style="list-style-type: none"> <li>• Staff is hurried and/or distracted</li> <li>• Staff was never informed of the instructions</li> </ul>	<ul style="list-style-type: none"> <li>• Reduce distractions in the work area</li> <li>• Hire more staff to spread out the responsibility</li> <li>• Educate staff on the Manufacturer's instructions</li> <li>• Use cognitive aids (posters) to help staff remember the cleaning steps</li> </ul>
<i>Brush Issues</i> <ul style="list-style-type: none"> <li>• Correct sized brushes not available</li> <li>• Staff not aware of need to brush channels</li> <li>• Brushes are dirty or worn</li> <li>• Reusable brushes are not sterilized at the end of the day following use</li> </ul>	<ul style="list-style-type: none"> <li>• Establish par levels for the required sizes of brushes</li> <li>• Use only <b>NON</b> reusable brushes</li> <li>• Use cognitive aids displaying step by step cleaning of instruments</li> <li>• Educate staff of the need to brush channels</li> <li>• Inspect brushes prior to use and dispose of if dirty or worn</li> <li>• Use signage to remind staff of sterilizing brushes at the end of the day</li> </ul>

**Topic 8****The process of assuring sterility of orthopedic implantable devices that come in orthopedic loaner instrument trays.**

Number of reporting facilities: 9

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Manufacturers recommendations for cleaning instruments not sent with tray and not on file with SPD</i></p>	<ul style="list-style-type: none"> <li>• SPD staff to keep files of manufacturers recommendations for cleaning instruments on all instruments received on loaner trays for staff's future reference</li> <li>• Provide staff with manufacturer's instructions for cleaning instruments for all instruments staff is unfamiliar with</li> </ul>
<p><i>Breakdown in communication between SPD, OR and/or vendor</i></p> <ul style="list-style-type: none"> <li>• SPD releases case cart to OR without communication of critical information as part of this handoff</li> <li>• May not properly deliver orthopedic loaner instrument sets/non-biological implants on time</li> <li>• No adherence to 48 hour hold time for implants ordered for elective procedures</li> <li>• Loaner implantable device/instrumentation needs are not communicated to OR staff</li> <li>• Possible case conflicts related to types and numbers of similar cases resulting in the unavailability of vendor or loaner implant sets (multiple cases of same type scheduled on same day)</li> </ul>	<ul style="list-style-type: none"> <li>• Create a handoff form to communicate critical information between SPD and OR for all trays</li> <li>• OR charge RN initiates a spreadsheet showing future surgical cases with information including but not limited to procedure name, dates of surgery provider, and specific instrument/implant request</li> <li>• Vendors are notified in advance as cases are requested. Due to a variety of factors some vendors are not able to meet 48 hour deliver per VHA directives. If implants are incorporated in loaner sets waivers may be initiated only if necessary</li> <li>• Education of surgical service residents to utilize OR scheduling comment box to enhance verbal communication</li> <li>• Development of cognitive aid with vendor and OR contact information to be included in training</li> <li>• Use a spreadsheet to coordinate scheduling between SPD and OR. Arrange daily/weekly meetings to discuss scheduling for SPD and OR</li> </ul>
<p><i>Not enough in house implantable devices to accommodate emergent cases</i></p>	<ul style="list-style-type: none"> <li>• Purchase additional implantable devices commonly needed in emergent cases</li> </ul>
<p><i>Defect in instrument or cleaning of the instrument overlooked</i></p> <ul style="list-style-type: none"> <li>• Tech may be distracted or overworked</li> </ul>	<ul style="list-style-type: none"> <li>• Hold an educational in-service</li> <li>• Hire more employees, or create an additional shift</li> </ul>
<p><i>Equipment malfunction (e.g. ultrasonic cleaner, washer/sterilizer)</i></p>	<ul style="list-style-type: none"> <li>• Perform periodic maintenance checks on such equipment to ensure proper performance</li> <li>• Update older machinery</li> </ul>

Potential failure modes, causes and vulnerabilities identified:	Proposed solutions:
<i>Delays in getting the releases signed by the approving official</i>	<ul style="list-style-type: none"> <li>• If release can only be signed by one person, consider finding a backup such as a charge nurse to ensure the process is not delayed</li> </ul> <p><b>ID/SPD Note: if a release is required by a person in a position such as the Chief of Staff, and that person is not present, the person acting in that position is to be the one who signs the release.</b></p>
<i>Implant arrives late from vendor</i>	<ul style="list-style-type: none"> <li>• Department of surgery and Prosthetics to develop a process to ensure timely arrival of implants to allow full biological testing verification (72 hours prior to surgery)</li> </ul>

### Topic 9

**The process of communicating positive biological test results from steam, EtO, and plasma sterilizers to the Chief of Staff, Chief of Surgical Service, Operating Room Supervisor and Infection Control.**

Number of reporting facilities: 7

Potential failure modes, causes and vulnerabilities identified:	Proposed solutions:
<i>Positive biological indicator results might not be detected and communicated in a timely way due to limitations of current equipment</i>	<ul style="list-style-type: none"> <li>• Purchase and implement new biological indicator with capability of rapid biological testing</li> </ul> <p><b>ID/SPD Note: There is no Rapid Read biological monitoring for EtO or Plasma sterilization. Also, this does not completely take care of the issue, if the biological is not properly put in rapid read out false reading will be given. Rapid readout is not approved in VA per Policy (7176)</b></p> <ul style="list-style-type: none"> <li>• Purchase biological indicator with alarm function for positive results</li> </ul> <p><b>ID/SPD Note: This is not available for any except for Rapid readout and it can give false negatives. Training and quality assurance checks must be in place to monitor the Biological test</b></p>
<i>Positive biological indicator results might not be detected in a timely way due to coordination between SPD and Lab and workstation setup in Lab. Lab personnel could be unaware of the result</i>	<ul style="list-style-type: none"> <li>• Coordinate SPD and Lab functions to improve workflow and tracking</li> <li>• Revise workstation setup and implement shift change tracking sheet in Lab</li> <li>• Set timers to alarm during testing to prompt lab personnel to check for results</li> </ul> <p><b>ID/SPD Note: Biological monitoring is self contained and should be read and documented in SPD. They should be checked several times during the day.</b></p>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Lack of rapid communication of positive biological indicator results from Medical Supply Technician to Chief of Staff and Infection control Nurse because it must go through several administrative tiers before reaching them</i>	<ul style="list-style-type: none"> <li>Develop procedure for reporting positive biological indicator readings under current SPD configuration. Procedure should include an algorithm of responsibility and authority to report positive biological indicator results procedure posted in incubator/prep room</li> </ul>
<p><i>Indicator result is not detected due to:</i></p> <ul style="list-style-type: none"> <li>Lack of proper equipment</li> <li>Positive biological indicator not perceived as needing immediate action</li> <li>Change shift unaware of pending tests or available results</li> </ul>	<ul style="list-style-type: none"> <li>Select, purchase, and implement new incubator systems that include alarms and with capability of rapid incubation</li> </ul> <p><b>ID/SPD Note: Rapid Readout is not approved in the VA due to false readings. If ampoules are not placed in the incubator correctly a false reading will be indicated by the reader.</b></p> <ul style="list-style-type: none"> <li>Purchase and implement new incubator with alarm function for positive biological indicator results biological testing</li> </ul> <p><b>ID/SPD Note: Rapid Readout is not approved in the VA due to false readings. If ampoules are not placed in the incubator correctly a false reading will be indicated by the reader.</b></p> <ul style="list-style-type: none"> <li>Periodic education of staff members</li> <li>Coordinate SPD and Lab functions to improve workflow and tracking process</li> <li>lab checks samples several times each day</li> <li>tracking systems for negative and positive test results (record log)</li> <li>Implement change of shift hand off tool for lab</li> </ul>
<i>Supervisor not available when reporting positive biological indicator</i>	<ul style="list-style-type: none"> <li>Designate a back up person</li> <li>SPD will develop a call tree of critical and emergency numbers of key personnel. Distribute call tree to all major services and a copy provided to the patient safety office</li> </ul>
<i>Biologics being read in more than one area of the facility increased likelihood of errors occurring</i>	<ul style="list-style-type: none"> <li>Read all biological results in lab</li> </ul> <p><b>ID/SPD Note: SPD is the better place for self contained biological monitoring as it cuts down on transportation and the test not getting into the incubator in a timely manner.</b></p>
<i>Sterilization log not accurate or illegible</i>	<ul style="list-style-type: none"> <li>Double check sterilized items with list</li> <li>Educate staff to identify instruments individually or by specific name</li> <li>minimize distractions through controlling work flow</li> <li>Create a computer spreadsheet to replace handwritten log</li> </ul>
<i>Reading of biological indicators on weekends or holidays</i>	<ul style="list-style-type: none"> <li>Establish a 24/7 reading of biological indicators</li> </ul>

Potential failure modes, causes and vulnerabilities identified:	Proposed solutions:
<i>Lack of clear understanding on reporting process of positive biological indicators</i>	<ul style="list-style-type: none"> <li>• Increase education on biological indicators</li> <li>• Develop procedure for reporting positive biological indicator readings under current SPD configuration. Procedure should include an algorithm of responsibility and authority to report positive biological indicator results procedure posted in incubator/prep room</li> </ul>
<i>Unclear process for follow up on load that is positive after used on the patient</i>	<ul style="list-style-type: none"> <li>• Implement a team for recall process</li> <li>• Write charter for team</li> <li>• Follow up on (<i>used instruments affected by a recall</i>) instruments reported to Infection control coordinator</li> </ul>

**Topic 10****The process of disinfecting an infusion pump after patient use including transportation and storage.**

Number of reporting facilities: 8

Potential failure modes, causes and vulnerabilities identified:	Proposed solutions:
<i>When staff is on leave, disinfection activity is delayed</i>	<ul style="list-style-type: none"> <li>• Hire more SPD technicians to ensure full service during planned and unplanned leave</li> <li>• Implement change in infusion pump flow where the pump travels with the patient when transferred to another unit to reduce the frequency at which the pump and pole must be disinfected</li> </ul>
<p><i>Infusion pumps and poles are placed back into use without a thorough disinfection</i></p> <ul style="list-style-type: none"> <li>• Unable to discern if pump is clean or dirty</li> <li>• Pump is not considered a gross contamination and is only 'wiped down'</li> </ul>	<p><b>ID/SPD Note: Any infusion pumps or their associated equipment that are not covered with a bag labeled with the date cleaned is to be considered dirty and must be cleaned before being used on a patient, There is no need to bag used pumps, they are a class 1 medical device and are not considered grossly soiled. They are transported throughout the medical centers attached to tubing and the patient.</b></p> <ul style="list-style-type: none"> <li>• 'Red Bag' discontinued infusion pumps and poles prior to removal from patient's room to prevent accidental re-use before disinfection</li> <li>• Send all infusion pumps and poles to SPD for a thorough disinfecting process after discontinued from use</li> <li>• All infusion pumps and poles should be picked up by SPD and receive complete SPD cleaning prior to reuse</li> <li>• Cover and label clean poles and infusion pumps and store them in the SPD clean room</li> <li>• Assign one staff member at every shift to ensure dirty infusion pumps are not being used and are being taken to the dirty room</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>SPD is not notified of soiled pumps</i>	<ul style="list-style-type: none"> <li>• Establish an SOP for routine exchange of pumps for disinfection</li> <li>• Provide a means of communication for SPD (e.g. pagers)</li> </ul>
<i>SPD is out of infusion pumps</i> <ul style="list-style-type: none"> <li>• It is an emergent situation</li> <li>• It is the weekend when SPD is off duty</li> <li>• Shortage due to missing infusion pumps</li> </ul>	<ul style="list-style-type: none"> <li>• Identify a method for cleaning infusion pumps and poles appropriate for emergent situations</li> <li>• Provide education for nursing staff on appropriate circumstances and techniques for cleaning infusion pumps</li> <li>• Extend operating hours of SPD</li> <li>• Recommend that SPD deliver multiple (e.g. four or more) clean pumps to acute areas late Friday afternoon to ensure clean pumps are available in each area for use on the weekend</li> <li>• Establish and utilize systems tracking method for infusion pumps</li> </ul>
<i>Staff unaware of proper cleaning procedure or cleaning solutions to use when cleaning infusion pumps and poles</i>	<ul style="list-style-type: none"> <li>• Develop SOP for cleaning infusion pumps and poles</li> <li>• Educate staff periodically on proper methods for cleaning infusion pumps</li> <li>• Provide cognitive aids near the cleaning areas</li> </ul>
<i>SPD staff not available on weekends to clean pump</i>	<ul style="list-style-type: none"> <li>• Have enough pumps on hand to carry the staff through the weekend</li> <li>• Hire a weekend SPD shift</li> </ul>

**Topic 11**

**The process of using a pre-vacuum steam sterilizer in SPD including verifying testing (e.g. Bowie-Dick, biological), reviewing printouts (to determine sterilization parameters were met, signature of reviewer, content list (detailed enough to enable item[s] retrieval if necessary) and documentation of all required aspects of sterilization process.**

Number of reporting facilities: 7

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Power outage</i>	<ul style="list-style-type: none"> <li>• Have backup power to run at least one sterilizer on the supply allocated</li> <li>• Have an adequate supply of sterile supplies on site for a short term power outage</li> <li>• Have a backup plan that includes notifying another facility to provide needed supplies until process is up and running again</li> </ul>
<i>No water/steam for sterilizer</i> <ul style="list-style-type: none"> <li>• Steam generator may not be working</li> <li>• Connectivity between generator and water may not be working</li> </ul>	<ul style="list-style-type: none"> <li>• Approach other facilities for assistance</li> <li>• Develop a specific contingency plan that is posed as an attachment to service disaster emergency plan</li> <li>• Teach staff trouble shooting to check connectivity and correct the problem</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Operator failure due to frequent distractions/interruptions</i>	<ul style="list-style-type: none"> <li>• Limit phone calls to SPD to Nursing Unit emergency needs</li> <li>• Implementation of a warning mechanism (i.e. red light) that engages when the sterilizing process starts warning staff that SPD personnel should not be disturbed</li> <li>• Employ more operators</li> </ul>
<i>No process for tracking the minimum amount of time needed for complete sterilization</i>	<ul style="list-style-type: none"> <li>• Purchase and implement the use of timers that will start when the sterilization process begins</li> </ul> <p><b>ID/SPD Note: All sterilizers used in the VA must have recording devices (mechanical printout/recorders).</b></p>
<i>Operator chooses wrong cycle</i>	<ul style="list-style-type: none"> <li>• Existing cycles have processes with newer sterilizers that minimizes the likelihood of the wrong cycle being chosen</li> <li>• If the sterilizer is older, or does not have such a process developed, create and implement a process that will ensure the correct cycle will be chosen. Then train all staff to use it.</li> </ul>
<i>Document wrong load number or date due to misreading of calendar, forgetting to read label, or misreading label</i> <ul style="list-style-type: none"> <li>• Could be due to rushed or distracted staff</li> </ul>	<ul style="list-style-type: none"> <li>• Write sterilization policies and procedures to include daily crossing out of the Julian date for improved accuracy when logging dates</li> <li>• Research the feasibility of using new date guns that change the date automatically</li> <li>• Write sterilization policies and procedures to include another staff member double checking date, log number and signature before the process begins and after it is finished</li> <li>• Implement an electronic instrument tracking system for the entire sterilization process</li> </ul>
<i>Biological results are not checked over the weekend</i>	<ul style="list-style-type: none"> <li>• Hold the delivery of operating room(OR) instruments until Monday morning when biological tests can be read and confirmed</li> </ul> <p><b>ID/SPD Note: Only implants are held until the results of the biological are know. Biological are read at 48 hours, but can be read up to 7 days, Biologicals processed on Thursday or Friday (when SPD is closed on the weekends) may be read on Monday morning.</b></p> <ul style="list-style-type: none"> <li>• Train OR staff on how to read and confirm that biological tests are negative</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Information in Load Record is missing or wrong</i>	<ul style="list-style-type: none"> <li>• Write contents on paper or external tape prior to wrapping to ensure consistent recording of pack contents during preparation and packing</li> <li>• Add a post check of load record, with signature, after sterilization</li> <li>• Have team leader monitor post-check signature</li> <li>• Compare load record to name of item on external tape</li> </ul>
<i>Insufficient cooling time can lead to condensation</i>	<ul style="list-style-type: none"> <li>• Cool the cart at least 1 hour to minimize condensation</li> <li>• Purchase timers and label them according to what cart they will be on to ensure proper timing</li> </ul>
<i>Training of OR and SPD staff not adequate</i>	<ul style="list-style-type: none"> <li>• Ask manufacturer's technical representative to observe the process and make suggestions for improvement</li> </ul>

**Topic 12**

**The process of using the ethylene oxide (EtO) sterilizer within SPD including verifying testing (biological), reviewing printouts (parameters were met, content list, list of items), content list (detailed enough to enable item(s) retrieval if necessary) and documenting the results.**

Number of reporting facilities: 7

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Item does not have specified place for storage after removal from chamber (e.g. equipment or supplies not placed in correct area)</i>	<ul style="list-style-type: none"> <li>• Specify storage areas and specific places for each item sterilized</li> <li>• Barcode storage areas and check daily by scanning bar code and visual inspection of items</li> <li>• Educate and train staff on correct storage of items in SPD</li> </ul>
<i>No biological indicator placed in load</i> <ul style="list-style-type: none"> <li>• Biological placed in wrong position</li> </ul>	<ul style="list-style-type: none"> <li>• Require two signatures for load sheet verification and biological positioning</li> </ul>
<i>Exposure time for biological indicator not monitored</i>	<ul style="list-style-type: none"> <li>• Recheck load when removed from sterilizer that parameters have been met for sterilization if exposure time has not been monitored</li> </ul>
<i>Indicator not checked before items removed</i> <ul style="list-style-type: none"> <li>• No check of printout after cycle</li> </ul>	<ul style="list-style-type: none"> <li>• Implement double check system by assigning specific SPD staff</li> </ul>
<i>Staff work load too high</i>	<ul style="list-style-type: none"> <li>• Keep staff numbers at an adequate level for the facility</li> </ul>
<i>Staff turnover too high</i>	<ul style="list-style-type: none"> <li>• Create memory joggers (posters, visual aids) to help new staff remember quickly</li> </ul>

**Topic 13**

**The process of using the plasma sterilizer within SPD including verifying biological testing, reviewing printouts (to determine sterilization parameters were met, signature of reviewer), content list (detailed enough to enable item(s) retrieval, if necessary) and documentation of all required aspects of the sterilization process.**

Number of reporting facilities: 4

Potential failure modes, causes and vulnerabilities identified:	Proposed solutions:
<p><i>Issues with biological indicators</i></p> <ul style="list-style-type: none"> <li>• Daily control indicators not placed in correct location or not used</li> <li>• Verifying color change</li> </ul> <p>NCPS Note: This is applicable for all sterilization monitoring not just for Plasma sterilizers.</p>	<ul style="list-style-type: none"> <li>• Pull random trays and check for (chemical) indicators and submit findings to infection control committee</li> <li>• Biological would run in next load and first load reprocessed</li> </ul> <p><b>ID/SPD Note: Biological is to be run in each gas load.</b></p> <ul style="list-style-type: none"> <li>• Post signage/memory joggers to remind staff of indicator</li> <li>• Post written directions</li> <li>• Have case cart tech perform a second check prior to delivering to the designated area, and a third check by the end user</li> </ul>
<p><i>List of instruments that cannot be plasma sterilized not up to date</i></p>	<ul style="list-style-type: none"> <li>• Develop a list of items approved for plasma sterilization using manufacturer's recommendations</li> <li>• Post list near sterilizers</li> </ul>
<p><i>Staff lacks training</i></p> <ul style="list-style-type: none"> <li>• Loads incorrectly packed</li> <li>• Regarding items processed</li> <li>• Limitations of the plasma sterilizer</li> <li>• Information misinterpreted by Technician</li> </ul>	<ul style="list-style-type: none"> <li>• Place each new SPD employee with a preceptor for the first few weeks</li> <li>• Use signage and other cognitive aids and memory joggers to help staff</li> <li>• Conduct periodic training reviews</li> </ul>
<p><i>Facility SOP is not present or not adequate</i></p> <ul style="list-style-type: none"> <li>• Does not include manufacturer and VHA guidelines</li> </ul>	<ul style="list-style-type: none"> <li>• Develop and implement SOP for all areas</li> <li>• Ensure SOP contains manufacturer and VHA guidelines</li> </ul>

**Topic 14**

**The process of using steam sterilization in Dental including verifying biological testing (Bowie-Dick type test if using a pre-vacuum sterilizer), reviewing printouts (to determine if sterilization parameters were met, signature of reviewer), content list (detailed enough to enable item(s) retrieval, if necessary), and documentation of all required aspects of the sterilization process.**

Number of reporting facilities: 1

Potential failure modes, causes and vulnerabilities identified:	Proposed solutions:
<p><i>Ineffective ultrasonic cleaning of instruments</i></p>	<ul style="list-style-type: none"> <li>• Increase time instruments are left in ultrasonic cleaner</li> <li>• Educate staff regarding extended time in ultrasonic cleaning machine</li> <li>• Create a visual aid with step by step instruction delineating the entire instrument process</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Recontamination</i></p> <ul style="list-style-type: none"> <li>• Compromised packaging</li> <li>• Wet packs and tears in bags due to sterilizer not functioning properly</li> </ul>	<ul style="list-style-type: none"> <li>• Redesign instrument processing areas to create separate areas to handle dirty and clean instruments</li> <li>• Educate staff regarding appropriately wrapping, bagging and sealing of instruments</li> <li>• Create a visual aid with step by step instructions for packaging instruments</li> <li>• Repair sterilizer and perform periodic maintenance checks</li> </ul>

**Topic 15****The process of decontaminating surgical instruments prior to sterilization.**

Number of reporting facilities: 7

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Unable to visualize bioburden</i></p> <ul style="list-style-type: none"> <li>• Tiny spaces</li> <li>• Poor vision</li> <li>• Poor lighting</li> <li>• Lack of staff knowledge</li> </ul>	<ul style="list-style-type: none"> <li>• Purchase magnifying glass with light</li> <li>• Implement mandatory eye exam to identify staff with vision troubles</li> <li>• Install more light</li> <li>• Increase lighting wattage</li> <li>• Clearly define bioburden</li> <li>• Increase in-servicing, training</li> <li>• Install cognitive aids to help identify bioburden</li> </ul>
<p><i>Staff rushed</i></p> <ul style="list-style-type: none"> <li>• Increased demand for equipment</li> <li>• Staff shortage</li> </ul>	<ul style="list-style-type: none"> <li>• Increase staff to ensure backup</li> <li>• Use a temp agency as needed</li> <li>• Increase inventory of surgical instruments to have enough instruments to support surgical scheduling peaks and emergency cases</li> <li>• Increase availability of instruments through better coordination with surgery department</li> </ul>
<p><i>Vendors bring grossly contaminated instruments</i></p>	<ul style="list-style-type: none"> <li>• Develop a Memorandum of Understanding with vendor and SPD</li> <li>• Support addition to National Contract for having vendor supplied instruments in house 48 hours prior to case</li> </ul> <p><b>ID/SPD Note: Require that the instruments remain at the VA as required by the national contract, and do not allow them to be taken back and forth.</b></p> <ul style="list-style-type: none"> <li>• Vendor accountability in having instruments cleaned properly before bringing them in for cases</li> <li>• Consider purchase of one-of-a-kind, high use instruments to decrease dependence on vendors</li> <li>• Standardization of inventory used for cases</li> <li>• Flexibility of SPD to increase staffing the day prior to cases with numerous instruments to assure thorough decontamination and processing</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Inappropriate use of the flash sterilizer</i></p> <ul style="list-style-type: none"> <li>• hurry to get instrument to sterile field</li> <li>• instrument not meant to be flashed</li> </ul>	<ul style="list-style-type: none"> <li>• See Topic 20</li> <li>• Post AAMI standards and VA Policy in OR for flash sterilization</li> <li>• Evaluate need for additional instrument/sets to meet case demand and project future demand in interdisciplinary meetings between surgeons, material coordinators and SPD</li> <li>• Evaluate SPD process to streamline and get instruments returned to OR rather than have to flash sterilize</li> <li>• Develop policy/guideline for flash sterilization use</li> </ul>
<p><i>Gross contamination present inside hollow instruments, difficult to remove</i></p>	<ul style="list-style-type: none"> <li>• Provide adequate number and size of receptacles to submerge all hollow instruments in water in OR</li> <li>• Purchase ultrasonic cleaner to provide proper decontamination of lumens</li> </ul>
<p><i>Covering for transport of contaminated instruments does not meet infection control standards</i></p>	<ul style="list-style-type: none"> <li>• Purchase containers with fitted lids that will fit securely into c-lockers and avoid spills</li> <li>• Purchase stainless steel case carts with doors to provide a barrier to prevent spills</li> <li>• Use dumbwaiter elevator between OR and SPD</li> </ul>
<p><i>Next day schedule not always accurate or subject to late changes due to bed availability and SPD not prepared for first morning cases</i></p>	<ul style="list-style-type: none"> <li>• Add a night shift in addition to call person to cover routine processing from late cases including a communication process for what sets are needed for next day cases</li> </ul> <p><b>ID/SPD Note: all instruments are to be put up and ready for use, as soon after use as possible and should never be down overnight</b></p> <ul style="list-style-type: none"> <li>• Keep communication open between OR and SPD</li> </ul>
<p><i>Errors occur due to repetitive and tedious nature of role</i></p>	<ul style="list-style-type: none"> <li>• Create rewards and incentives for job well done</li> <li>• Recognize SPD staff who perform well at staff meetings</li> <li>• Pay market rate and give a higher level pay for staff with experience</li> <li>• Hire people who clearly understand the importance of this role and take pride in performing exceptional work each day</li> <li>• Implement a mandatory rotation of SPD staff through different duties throughout the day</li> </ul> <p><b>ID/SPD Note: While cross training is encouraged permanently scheduled rotations are not recommended.</b></p>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Inconsistent process of using manufacturer recommended guidelines for instrument cleaning</i>	<ul style="list-style-type: none"> <li>• Create a file for manufacturer recommended guidelines</li> <li>• Assign a staff member to maintain file of manufacturer recommended guidelines</li> </ul>

**Topic 16****The process of preparing surgical instruments for sterilization including preparing the surgical instrument trays (e.g. inspecting for bioburden, checking for instrument usability, correct instruments in correct trays) and packaging instruments.**

Number of reporting facilities: 11

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Lack of staff with knowledge necessary to meet the demands of the hospital</i></p> <ul style="list-style-type: none"> <li>• Non-standardized procedures</li> <li>• Manufacturer or vendor did not provide protocol</li> <li>• Incomplete training of staff</li> <li>• Lack of knowledge of instrument use</li> <li>• Staff unfamiliar with seldom used instruments</li> <li>• All inclusive education not provided prior to use of equipment</li> </ul>	<ul style="list-style-type: none"> <li>• Develop SOPs to reflect the requirements of each scope</li> <li>• Visual aid posters hung close to where trays are assembled to assist in disassembly/assembly, cleaning and identification of tools</li> <li>• Equipment/Instrumentation will not be implemented without published guidelines for SPD and surgery staff regarding proper maintenance of instruments and equipment</li> <li>• Keep file on protocol for instruments that are borrowed</li> <li>• Designate preceptor for new employees for entire period of mandatory training</li> <li>• SPD staff rotate to OR and observe cases to see how instruments are used during procedures</li> <li>• Both SPD staff and OR staff rotate through services to observe the systems</li> <li>• OR provides in-service periodically (i.e. monthly) on complex trays</li> <li>• Implement preceptor program for new employees</li> <li>• Provide each staff member with a thorough education during new employee orientation</li> <li>• Implement mandatory rotation of staff through different SPD positions to increase knowledge of different areas and to prevent boredom</li> </ul>
<p><i>Water and enzymatic cleaner is not measured but 'eyeballed' due to lack of measurable containers and portion dispensing enzymatic pumps</i></p>	<ul style="list-style-type: none"> <li>• Mark sink to reflect the correct amount of water for scope cleaning</li> <li>• Provide a measuring cup to allow for correct measurement of enzymatic cleaner</li> <li>• Or provide a container that will dispense the appropriate amount of enzymatic cleaner</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Incorrect instruments placed in container</i></p> <ul style="list-style-type: none"> <li>• Non-standardized nomenclature for instruments</li> <li>• Incorrect label</li> <li>• Inconsistent measurement of instruments</li> <li>• Similar/look-alike instruments</li> </ul>	<p>Random tray monitoring by SPD and OR staff to ensure sterilization, completeness of instruments, and functionality of instruments</p> <ul style="list-style-type: none"> <li>• Write SOP for nomenclature and labeling</li> <li>• Affix a permanent measurement tool to area where trays are assembled</li> <li>• Obtain detailed visual aid poster and hang closer to where trays are assembled</li> </ul>
<p><i>Washer/Sterilizer breaks down</i></p>	<ul style="list-style-type: none"> <li>• Purchase another washer/sterilizer</li> </ul>
<p><i>Malfunctioning instrument is identified by doctor and disposed of and not reported to SPD</i></p> <ul style="list-style-type: none"> <li>• Incorrect count sheets</li> <li>• Instrument is not replaced in inventory</li> <li>• Loss of instrument not known until it is needed</li> </ul>	<ul style="list-style-type: none"> <li>• Adequate documentation of number and types of instruments coming in and going out of the OR</li> <li>• Locate any missing instruments/equipment</li> <li>• Replace/repair malfunctioning instruments/equipment</li> <li>• Increase inventory of instruments</li> </ul>
<p><i>Malfunctioning instrument is not identified</i></p> <ul style="list-style-type: none"> <li>• Broken instruments or instruments needing repair are recycled into service without repair</li> </ul>	<ul style="list-style-type: none"> <li>• Random tray monitoring by SPD and OR staff to ensure sterilization, completeness of instruments, and functionality of instruments</li> <li>• Write SOP for visual inspection when cleaning instruments to check for bioburden or malfunctioning instruments</li> </ul>
<p><i>Instruments not available</i></p> <ul style="list-style-type: none"> <li>• Vendor/Loaner tray not received 48 hours in advance</li> </ul>	<ul style="list-style-type: none"> <li>• Construct a Memorandum of Understanding (MOU) between SPD staff and the vendor that discusses appropriate time periods for receiving instruments and equipment</li> </ul> <p><b>(ID/SPD comment: and make sure the MOU is agreed to by all parties and is followed.)</b></p>
<p><i>Failed to visually inspect for bioburden</i></p> <ul style="list-style-type: none"> <li>• Blood, bone, fecal matter left on instrument</li> <li>• Inadequate lighting</li> </ul>	<ul style="list-style-type: none"> <li>• Write SOP for visual inspection when cleaning instruments to check for bioburden or malfunctioning instruments</li> <li>• Increase lighting in areas where visual inspection occurs</li> </ul>
<p><i>Failure to document counts on the original count sheet</i></p>	<ul style="list-style-type: none"> <li>• Revise policy to include the instructions that upon return of the surgical trays sent from the OR the original count sheet is returned to SPD with the surgical set</li> <li>• Communicate this revision with the OR staff and implement the requirement to complete the instrument count on the original count sheet</li> <li>• Have SPD revise the count sheet using the count sheet format approved by the VISN, SPD and nurse managers</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>The serial number of the scope is not written on the sterilizer logs to allow for tracking scope to sterilizer</i>	<ul style="list-style-type: none"> <li>Place patient identification and scope on sterilizer record to allow for tracking of scope to patient</li> </ul>
<i>Failure to visually inspect for bioburden</i> <ul style="list-style-type: none"> <li>Bioburden not recognized</li> <li>Light/Magnification not used</li> </ul>	<ul style="list-style-type: none"> <li>Designate an educator for SPD to show examples of bioburden</li> <li>Seek better magnifying options</li> <li>Post visual aids identifying bioburden</li> <li>Implement mandatory eye exam to identify any staff in need of vision correction</li> </ul>
<i>Failure to replace instrument</i> <ul style="list-style-type: none"> <li>Instrument not available due to being repaired</li> <li>Instrument not in inventory</li> <li>Instrument not returned from repair</li> </ul>	<ul style="list-style-type: none"> <li>Have an additional contract for repairs</li> <li>Place an order for loaner instruments</li> </ul> <p><b>ID/SPD Note: Loaner instruments are not recommended, instruments are to be at the medical center, loaner instruments must be kept to a minimum.</b></p> <ul style="list-style-type: none"> <li>Have SPD supervisor review inventory and complete needs assessment and collaborate with OR manager</li> <li>Purchase more instruments as necessary</li> <li>Create tracking for instruments out for repair</li> <li>SPD communicate with OR regarding availability of instrument and to report missing ones</li> </ul>
<i>Lack of staff training and process education (e.g. material incorrectly wrapped, or damaged wrapping, incorrect load alignment, cart packed too tightly)</i>	<ul style="list-style-type: none"> <li>Implementation of a structured educational program consisting of annual competency, supervisor observation and certification testing</li> <li>Include a preceptor program for new employees</li> <li>Implement mandatory daily rotation through different duties in SPD</li> </ul> <p><b>ID/SPD Note: While cross training is encouraged permanently scheduled rotations are not recommended.</b></p> <ul style="list-style-type: none"> <li>Post visual aids and memory joggers</li> </ul>

**Topic 17****The process of coordinating and communicating the availability of needed equipment and supplies between the OR and SPD.**

Number of reporting facilities: 9

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<i>Difficult to find where Operating Room (OR) supplies are stored</i>	<ul style="list-style-type: none"> <li>Create a table of the inventory of the supplies and their locations</li> <li>Standardize locations of supplies</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Scheduling issues</i></p> <ul style="list-style-type: none"> <li>• Scheduling changes made over weekend</li> <li>• Elective surgery scheduled between already scheduled cases</li> <li>• Patient scheduled for first case does not show up</li> <li>• No standardized means of communication for scheduling changes</li> </ul>	<ul style="list-style-type: none"> <li>• Create an OR scheduling protocol that will outline the proper procedure for changing OR cases</li> <li>• Also, look into feasibility of purchasing an OR scheduling package</li> <li>• Assign each service a designated surgery scheduler who is aware of patient's travel constraints and takes these constraints into account when making the surgery schedule</li> <li>• Identify a point of contact so that if the OR/scheduler have questions regarding the surgery it can be clear who should be contacted</li> </ul>
<p><i>Lack of communication and/or miscommunication</i></p>	<ul style="list-style-type: none"> <li>• OR and SPD staff must share info across departmental lines as well as throughout all levels of management</li> <li>• Provide clear upfront directions to the staff that will enable them to carry out tasks more timely and avoid unnecessary delays</li> <li>• Have up-to-date information available</li> <li>• Periodic review of equipment/supply lists is a feasible way to monitor inventory and enhance the coordination of quality care</li> <li>• SPD staff must have sufficient knowledge of policies and procedures related to order control and inventory management</li> <li>• Procedure verification. Utilize a write down, "read back" procedure to ensure total understanding by both staff members</li> </ul>
<p><i>Communication Issues between SPD and OR</i></p> <ul style="list-style-type: none"> <li>• No communication with OR regarding being out of supplies</li> <li>• Miscommunication between provider (requestor) staff and OR/SPD (ordering) staff for new or changed equipment request</li> <li>• Miscommunication between OR staff, nursing, SPD and Medical/Surgical department secretary when order is placed resulting in incorrect equipment order</li> <li>• OR not fully aware of SPD process</li> <li>• Lack of communication between SPD and OR due to limited phones and contact information</li> </ul>	<ul style="list-style-type: none"> <li>• Establish a process for communication of missing items between OR and SPD liaison to communicate with SPD night supervisor on a daily basis prior to setup of cases in OR</li> <li>• Collect data on number of OR delays/cancellations related to missing instruments</li> <li>• Explore feasibility of employing an OR/SPD trainer ensure on going consistent training of staff particularly focusing on communication</li> <li>• Utilize a write down, "read back" procedures</li> <li>• Requestor to use written standard request (including date, subject-specifics). Request form is put on shared drive, all parties will use a voting button for department review and check off</li> <li>• Before completing the purchasing request, medical/surgical program secretary sends to SPD/OR/Nursing mail group the list of ordered equipment and supplies</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
	<ul style="list-style-type: none"> <li>• Each department reviews for errors and sends back a confirming email</li> <li>• During OR orientation, have new OR staff rotate in SPD to reinforce the importance of timely communication between the OR and SPD</li> <li>• OR room extensions posted in SPD telephones with multiple phone lines will be installed in SPD</li> </ul>
<p><i>Issues with vendors</i></p> <ul style="list-style-type: none"> <li>• Vendor drops off borrowed instrument kits but it is unknown if all kits have been delivered</li> <li>• Loaner trays not received in a timely fashion from vendor or sales representative resulting in late arrival in instruments and possible delays in procedures</li> <li>• Vendor contact info is unavailable or inaccurate which causes barriers for communication</li> <li>• Mixing of vendor and facility instruments resulting in lost instruments</li> </ul>	<ul style="list-style-type: none"> <li>• Require vendors to provide a list of items in instrument kits as well as the number of trays, weight of trays, type of tray and contents of each tray. SPD will be informed of the number of trays to inspect and verify that this is accurate upon delivery from vendor</li> <li>• Arrange for a company consignment of commonly used trays so loaner trays are not needed</li> <li>• Establish a policy requiring vendor to drop tray off by a certain time at least 48 hours prior to the surgical procedure</li> <li>• Make available a complete up to date list of vendor contact information via computer access and hard copy posed in key areas of SPD and OR</li> <li>• Denote area for vendor trays coming in and those going to</li> <li>• Purchase and implement an instrument locator system</li> <li>• Implement a log system of loaner instruments</li> </ul>
<p><i>Instruments not available delivered to wrong dept, mislabeled, unable to locate</i></p>	<ul style="list-style-type: none"> <li>• Establish a process for communication of missing items between OR and SPD (OR/SPD liaison to communicate with SPD night supervisor on a daily basis prior to setup of cases in OR</li> <li>• Take a picture of instruments in loaner trays</li> </ul>
<p><i>Case carts inaccurate</i></p> <ul style="list-style-type: none"> <li>• Wrong Cart</li> <li>• Missing supplies</li> </ul>	<ul style="list-style-type: none"> <li>• Standardize procedure names and case cart codes needed for those procedures</li> <li>• Establish a process for communication of missing items between OR and SPD</li> <li>• Implement a system that can track individual instruments on each cart</li> </ul>

**Topic 18**

**The process of maintaining the primary storage environment including: monitoring room temperature, humidity, the number of air exchanges per hour, pest control; maintaining the storage arrangement (e.g. stock rotation, avoiding outdates); and maintaining cleanliness for sterilized instrumentation, equipment and supplies in SPD.**

Number of reporting facilities: 7

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Monitoring room temperature, humidity, and number of air exchanges per hour</i></p> <ul style="list-style-type: none"> <li>• Temperature and humidity are not controlled or tracked</li> <li>• No assessment of temperature and humidity if staff not physically present</li> <li>• Records of temperature and humidity are not maintained</li> <li>• No monitoring of air exchanges</li> <li>• Negative and positive pressure is not monitored</li> <li>• Potential to tamper with thermostat</li> </ul>	<ul style="list-style-type: none"> <li>• Develop and implement a Standard Operating Procedure for the environmental controls of the storage areas</li> <li>• Purchase and implement temperature and humidity loggers to continuously monitor the area</li> <li>• Install an alarm that will sound if the area's temperature or humidity goes out of range and will alert the physical plant</li> <li>• Download and print data periodically (e.g. weekly) from the logger</li> <li>• Print data for out of range deficiencies and report to facilities engineering, Patient Safety Manager, and Infection Control Coordinator</li> <li>• Put in to effect a system of maintaining the records</li> <li>• Educate all SPD staff that will be responsible for temperature and humidity control</li> <li>• The air conditioning department needs to verify and log the number of air exchanges as well as the positive and negative pressures in SPD on a monthly basis</li> <li>• In the SOP require that air exchange data be kept for 3 years</li> <li>• Monitor with a vanometer</li> <li>• Place a secure cover over the thermostat</li> </ul>
<p><i>Current temperature and humidity recorders require annual calibration resulting in downtime in use; due to the nature of work schedules, there is a potential for failures to go undetected for an unacceptable amount of time</i></p>	<ul style="list-style-type: none"> <li>• Develop a rotation schedule for current recorders to allow annual calibration</li> <li>• Try to obtain temperature and humidity monitors with centralized monitoring which will wire into current system in use in engineering to provide computerized alarming when temperature and humidity are out of range and 24/7 monitoring</li> </ul>
<p><i>Pest control could be an issue if food items are present</i></p> <ul style="list-style-type: none"> <li>• Corrugated boxes for shipping could also bring in pests</li> <li>• SPD tech does not check for insects daily, including in light fixtures</li> <li>• No schedule for performing pest control</li> </ul>	<ul style="list-style-type: none"> <li>• Do not allow food or drink in any area except the break room</li> <li>• Post signage indicating areas that should be clear of food</li> <li>• No shipping containers (or any corrugated material) should be allowed in SPD</li> <li>• All areas should be cleaned daily</li> <li>• Garbage should be removed daily</li> </ul>

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
	<ul style="list-style-type: none"> <li>• Develop an SOP for maintenance that includes checking for pests daily in all areas</li> <li>• In this SOP, include periodic pest control in all areas</li> </ul>
<p><i>Maintaining storage arrangement</i></p> <ul style="list-style-type: none"> <li>• Supplies on shelves do not get rotated and checked for outdates</li> </ul>	<ul style="list-style-type: none"> <li>• Supplies should be obtained, monitored, and distributed by SPD rather than individual services to allow better control of stock, outdates, recalls, etc.</li> <li>• Develop a schedule for inventory rotation to prevent outdates of supplies</li> <li>• Rotate stock so that first in is first out</li> <li>• Periodically (<b>ID/SPD Comment: weekly, shelves must be cleaned, stocked checked for rotation, and supplies that will expire in the next seven days, or until the next scheduled cleaning and checking, will be pulled</b>) a technician should print out a log sheet showing which supplies will outdate in the next year and do a walk through of SPD to determine what supplies will need to be added to the list ensuring that items are pulled before outdate</li> <li>• Put SPD staff in charge of all inventory for disposable and reusable supplies</li> </ul>
<p><i>Lack of duplicate instruments for OR and clinic procedures may cause delay and postponement of procedures</i></p>	<ul style="list-style-type: none"> <li>• Make additional instruments available through contract or purchase to ensure availability for OR and clinic areas</li> </ul>
<p><i>Maintaining cleanliness for sterilized instrumentation, equipment and supplies</i></p> <ul style="list-style-type: none"> <li>• No schedule for cleaning the shelving to maintain the cleanliness for sterilized instrumentation, equipment and supplies</li> <li>• Items stored in closed cabinets may have compromised sterility</li> <li>• Carts are not cleaned on a regular basis</li> </ul>	<ul style="list-style-type: none"> <li>• Physically separate clean and sterilized instruments, equipment and supplies from the dirty ones</li> <li>• To ensure cleanliness in the clean room, construct the floors, walls, and ceiling with moisture proof material</li> <li>• Periodically (i.e. weekly) wipe down all shelving and storage bins that are used to store clean and sterile supplies</li> <li>• Include this in the SOP for this area</li> <li>• Check items stored in closed cabinets for punctures, tears, outdates, or anything that may compromise the sterility of the item prior to issue</li> <li>• Develop and implement SOP for cleaning distribution carts on a regular basis as per VA Central Office for cleaning of SPD cleaning logs to be kept in Business service as per policy</li> <li>• Educate all SPD staff that will be responsible for cleaning carts on new SOP</li> </ul>
<p><i>SPD staff assigned to decontamination area are not showering at end of the shift</i></p>	<ul style="list-style-type: none"> <li>• Educate staff on need to use shower</li> </ul> <p>Post signage indicating need/requirement to use shower</p>

**Topic 19**

**The process of maintaining the secondary storage environment in the operating room including: monitoring room temperature, humidity, the number of air exchanges; pest control; storage arrangement, and cleanliness for sterilized instrumentation, equipment and supplies.**

Number of reporting facilities: 8

<b>Potential failure modes, causes and vulnerabilities identified:</b>	<b>Proposed solutions:</b>
<p><i>Monitoring temperature, humidity, and the number of air exchanges</i></p> <ul style="list-style-type: none"> <li>• Infrequent cleaning of the filters on air conditioning units</li> <li>• No controls in place for monitoring humidity, temperature and the number of air exchanges in the procedure rooms and supply storage areas</li> <li>• Current air exchanges for secondary storage areas do not meet 10 air exchanges per hour as recommended by SPD handbook</li> </ul>	<ul style="list-style-type: none"> <li>• Increase the frequency of filter cleaning to monthly</li> <li>• Implement a continuous (24/7), automated monitor for humidity, temperature and air exchanges</li> <li>• Ensure the monitor has an alarm system to alert SPD (or other appropriate people) in case the temperature, humidity or air exchange rate is out of range</li> </ul>
<p><i>Pest control</i></p> <ul style="list-style-type: none"> <li>• Food present in inappropriate areas and it is attracting pests</li> <li>• Cardboard boxes, open windows, and other penetrations in the building could be allowing pests to enter</li> </ul>	<ul style="list-style-type: none"> <li>• Implement weekly pest control rounds in the surgical suite</li> <li>• Once insects or other pests are detected, initiate means to eliminate them from the area such as fly paper or other traps</li> <li>• Enforce a “no eating” policy in patient care and reception areas</li> <li>• Ensure staff food is properly stored in break room and trash is removed timely</li> <li>• Identify staff to monitor the general cleaning of the surgical suite</li> <li>• Add “no corrugated boxes” to the environmental survey checklist</li> <li>• Pin close windows in OR area and educate staff on pest control barriers</li> <li>• Inspect building near areas where pest concentration is the highest to find any penetrations that could allow pests in</li> </ul>
<p><i>Storage arrangement</i></p> <ul style="list-style-type: none"> <li>• Bar code component of generic inventory computer package not utilized</li> <li>• Instruments not available (out for repair, broken, worn out)</li> <li>• Instrument kits incomplete</li> <li>• Expiration dates not monitored</li> </ul>	<ul style="list-style-type: none"> <li>• SPD storage should meet the same standard as OR storage</li> <li>• Utilize bar coding system and organize inventory using this system to identify instruments</li> <li>• Establish a contract for instrument refurbishing services, a pro-active approach to keeping instruments in shape</li> <li>• Use a count sheet to verify instrument counts before reprocessing</li> <li>• Designate two people to independently check the instruments</li> <li>• Purchase a scale to use to weigh the kits to determine if anything is missing</li> </ul>

Potential failure modes, causes and vulnerabilities identified:	Proposed solutions:
	<ul style="list-style-type: none"> <li>Periodically (i.e. monthly) a technician should print out a log sheet showing which supplies will outdate in the next year and do a walk through of SPD to determine what supplies will need to be added to the list ensuring that items are pulled before outdate</li> </ul>
<p><i>Cleanliness for sterilized instrumentation, equipment and supplies</i></p> <ul style="list-style-type: none"> <li>Lack of a SOP which is tailored to the facility for cleaning the surgical procedure room</li> <li>Wood shelving is used for SPD supplies</li> <li>Breaches in traffic control in OR (i.e. non OR staff with inadequate coverings and doors that allow access)</li> <li>Sterile supplies are transported to OR covered with a drape or left uncovered in hallways</li> </ul>	<ul style="list-style-type: none"> <li>Develop and implement a SOP that is tailored to the facility</li> <li>Increase cleaning frequency to include cleaning rooms regardless of use on all working days</li> <li>Include in that SOP, designation of a housekeeper to the surgical procedure room during administrative hours to promote consistent cleanliness of the procedure room</li> <li>Replace with metal shelving</li> <li>Post signage indicating personnel approved for entry</li> <li>Educate non-OR staff who need access to OR</li> <li>Purchase closed carts for these purposes</li> <li>Post signage in prominent areas indicating importance of using closed carts</li> </ul>

### Topic 20

**The processes of using sterilizers for flash sterilization in the operating room including monitoring the frequency of use, biological testing, identification of the date and patient and the item(s) flash sterilized, and reviewing printouts to verify sterilization parameters are being met.**

Number of reporting facilities: 10

Potential failure modes, causes and vulnerabilities identified:	Proposed solutions:
<p><i>Flash sterilization is used too frequently</i></p> <ul style="list-style-type: none"> <li>Issues with instruments</li> <li>inadequate supply of instrumentation (i.e., demand for instruments exceeds instrument supply)</li> <li>debris on instruments</li> <li>wet instruments</li> <li>integrity of packaging</li> <li>instrument was not sterilized</li> <li>missing an instrument</li> </ul>	<ul style="list-style-type: none"> <li>Ensure instrument supply is greater than demand (e.g., purchase more of the frequently used instruments and those that are most frequently flash sterilized)</li> <li>Maintain a running list of those instruments that require replacing</li> <li>Keep additional instruments stocked and ready to go</li> <li>SPD to use magnifying lens/lamp consistently, particularly with problem instruments</li> <li>Operating room (OR) to use enzymatic cleaner and flush any instrument with a lumen in the OR before sending it to SPD</li> <li>Revise tracking log in SPD to detect wet instruments before sending them to the OR</li> <li>Allow more SPD personnel to attend annually training to be certified with "SPD level one certification"</li> </ul>

Potential failure modes, causes and vulnerabilities identified:	Proposed solutions:
<p><i>SPD Issues</i></p> <ul style="list-style-type: none"> <li>• SPD understaffed at critical times</li> <li>• Turn around time in SPD viewed to be too long</li> <li>• No time for SPD to reprocess doctor supplied instruments and loaner instruments delivered later than anticipated</li> </ul>	<ul style="list-style-type: none"> <li>• Staff SPD appropriately (e.g., hire more SPD staff, consider 24 hour operation, schedule SPD staff to meet needs of reprocessing.)</li> <li>• Purchase better reprocessing technologies to decrease sterilization times to decrease SPD turn-around</li> <li>• Develop a Memorandum of Understanding (MOU) between SPD and OR staff, which will discuss, but is not limited to: Scheduling, expected turn-around times within SPD, expectations of OR for initial decontamination, etc.)</li> <li>• Do not allow doctors to have their own instruments flash sterilized—they must be brought in beforehand and reprocessed in SPD</li> <li>• Construct a MOU between vendors and SPD for loaner or other instruments (e.g., vendor agrees to get instruments or products to the facility within a certain time period)</li> </ul>
<p><i>Improper documentation of use of flash sterilization (e.g., staff enters instrument sets in flash sterilization log, but doesn't identify the types of instruments; no reason specified for flash sterilization.)</i></p>	<ul style="list-style-type: none"> <li>• Write a SOP for flash sterilizers containing the most current AORN information and reflect the VHA directive 7176 and provide educate applicable staff members on the SOP</li> <li>• Implement a dual layer review of flash sterilizer documentation. Revise documentation form to include both (Supervisor and Center Core SPD tech) reviewer's initials</li> </ul>
<p><i>Improper procedure followed when using flash sterilization (e.g., not sterilized long enough, no biological indicators used)</i></p>	<ul style="list-style-type: none"> <li>• Write SOP for OR for flash sterilization</li> <li>• Increase cognitive aids/signage near flash sterilizers (e.g., stating what can or cannot be flash sterilized, indicating biological indicators must be used)</li> <li>• Staff training (e.g., so that they know to adhere to SOPs and MOUs)</li> </ul>